

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

**FORM 20-F**

(Mark One)

- REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934  
OR  
 ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  
For the fiscal year ended December 31, 2020  
OR  
 TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  
OR  
 SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  
Commission file number: 001-39081

**BioNTech SE**

(Exact name of Registrant as specified in its charter)

Federal Republic of Germany  
(Jurisdiction of incorporation or organization)

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(Name, Telephone, E-mail and/or Facsimile number and Address of Company Contact Person)

Securities registered or to be registered, pursuant to Section 12(b) of the Act

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
American Depositary Shares, each Representing one ordinary share	BNTX	The Nasdaq Stock Market LLC
Ordinary shares, no par value, with a notional amount attributable to each ordinary share of €1*	---	The Nasdaq Stock Market LLC*

Securities registered or to be registered pursuant to Section 12(g) of the Act: **None**

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act: **None**

Indicate the number of outstanding shares of each of the issuer's classes of capital stock or common stock as of the close of business covered by the annual report.

Ordinary shares, no par value, with a notional amount attributable to each share of €1 outstanding as of March 30, 2021, no par value: 241,521,065

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes  No

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934. Yes  No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer  Accelerated filer  Non-accelerated filer  Emerging growth company

If an emerging growth company that prepares its financial statements in accordance with U.S. GAAP, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards † provided pursuant to Section 13(a) of the Exchange Act.

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report.

Indicate by check mark which basis of accounting the registrant has used to prepare the financial statements included in this filing:

U.S. GAAP

International Financial Reporting Standards as issued  
by the International Accounting Standards Board

Other

If "Other" has been checked in response to the previous question indicate by check mark which financial statement item the registrant has elected to follow. Item 17  Item 18

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

\* Listed not for trading or quotation purposes, but only in connection with the registration of American Depositary Shares representing such ordinary shares pursuant to the requirements of the Securities and Exchange Commission. The American Depositary Shares are registered under the Securities Act of 1933, as amended, pursuant to a separate registration statement on Form F-6 (File No. 333-233898).

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## GENERAL INFORMATION

In this annual report on Form 20-F ("Annual Report"), "BioNTech," the "Group," the "Company," "we," "us," and "our" refer to BioNTech SE and its consolidated subsidiaries, except where the context otherwise requires.

In response to the fact that our consolidated financial statements are published in Euro, the selected consolidated financial data is presented in Euro as well. Amounts in U.S. dollar are translated into Euro using the exchange rates as per period end or average exchange rates for the periods indicated as published by the German Central Bank (*Deutsche Bundesbank*).

All references in this Annual Report to "\$" mean U.S. dollars and all references to "€" mean Euros.

## CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report contains forward-looking statements concerning our business, operations and financial performance and condition as well as our plans, objectives and expectations for our business operations and financial performance and condition. Any statements that are not of historical facts may be deemed to be forward-looking statements. Many of the forward-looking statements contained in this Annual Report can be identified by the use of forward-looking words such as “believes”, “estimates”, “anticipates”, “expects”, “plans”, “intends”, “may”, “could”, “might”, “will”, “should”, “aims” or other similar expressions that convey uncertainty of future events or outcomes.

These forward-looking statements are subject to known and unknown risks, uncertainties, assumptions and other factors that could cause our actual results of operations, financial condition, liquidity, performance, prospects, opportunities, achievements or industry results, as well as those of the markets we serve or intend to serve, to differ materially from those expressed in, or suggested by, these forward-looking statements. These forward-looking statements are based on assumptions regarding our present and future business strategies and the environment in which we expect to operate in the future. Important factors that could cause those differences include, but are not limited to:

- our expected revenues and net profit related to sales of our COVID-19 vaccine, referred to as COMIRNATY® in the European Union as authorized for use under conditional marketing approval, in territories controlled by our collaboration partners, particularly for those figures that are derived from preliminary estimates provided by our partners;
- our pricing and coverage negotiations with governmental authorities, private health insurers and other third-party payors after our initial sales to national governments;
- the extent to which a COVID-19 vaccine continues to be necessary in the future;
- competition from other COVID-19 vaccines or related to our other product candidates, including those with different mechanisms of action and different manufacturing and distribution constraints, on the basis of, among other things, efficacy, cost, convenience of storage and distribution, breadth of approved use, side-effect profile and durability of immune response;
- our ability and that of our collaborators to commercialize our COVID-19 vaccine and our product candidates, if approved;
- the pricing and reimbursement of our COVID-19 vaccine and our investigational medicines, if approved;
- the rate and degree of market acceptance of our COVID-19 vaccine and our investigational medicines, if approved;
- the initiation, timing, progress, results, and cost of our research and development programs and our current and future preclinical studies and clinical trials, including statements regarding the timing of initiation and completion of studies or trials and related preparatory work, the period during which the results of the trials will become available and our research and development programs;
- the timing of and our ability to obtain and maintain regulatory approval for our product candidates;
- our ability to identify research opportunities and discover and develop investigational medicines;
- the ability and willingness of our third-party collaborators to continue research and development activities relating to our development candidates and investigational medicines;
- our expectations regarding the size of the patient populations for our product candidates, if approved for commercial use;
- the impact of the COVID-19 pandemic on our development programs, supply chain, collaborators and financial performance;
- unforeseen safety issues and claims for personal injury or death arising from the use of our COVID-19 vaccine and other products and product candidates developed or manufactured by us;
- our estimates of our expenses, ongoing losses, future revenue and capital requirements and our needs for or ability to obtain additional financing;
- our ability to identify, recruit and retain key personnel;

- our and our collaborators' ability to protect and enforce our intellectual property protection for our proprietary and collaborative product candidates, and the scope of such protection;
- the development of and projections relating to our competitors or our industry;
- our ability and that of our collaborators to commercialize and market our product candidates, if approved, including our COVID-19 vaccine;
- the pricing and reimbursement of our investigational medicines, if approved, including our COVID-19 vaccine;
- the rate and degree of market acceptance of our investigational medicines, if approved, including our COVID-19 vaccine;
- the amount of and our ability to use net operating losses and research and development credits to offset future taxable income;
- our ability to manage our development and expansion;
- regulatory developments in the United States and foreign countries;
- our ability to effectively scale our production capabilities and manufacture our products, including our COVID-19 vaccine, and our product candidates;
- our ability to implement, maintain and improve effective internal controls; and
- other factors not known to us at this time.

The preceding list is not intended to be an exhaustive list of all of our forward-looking statements. The forward-looking statements contained in this Annual Report speak only as of the date of this report, and unless otherwise required by law, we do not undertake any obligation to update them in light of new information or future developments or to release publicly any revisions to these statements in order to reflect later events or circumstances or to reflect the occurrence of unanticipated events.

**PART I**

**Item 1. Identity of Directors, Senior Management and Advisers**

Not applicable.

**Item 2. Offer Statistics and Expected Timetable**

Not applicable.

**Item 3. Key Information**

**A. Selected Consolidated Financial Data**

Not applicable.

**B. Capitalization and Indebtedness**

Not applicable.

**C. Reasons for the Offer and Use of Proceeds**

Not applicable.

**D. Risk Factors**

*Our business is subject to various risks, including those described below. You should consider carefully the risks and uncertainties described below and in our future filings. If any of the following risks are realized, our business, financial condition, results of operations and prospects could be materially and adversely affected. Additionally, risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition, results of operations and/or prospects.*

**Risk Factors Summary**

*Investing in the ADSs involves various risks. You should carefully read and consider the matters discussed in this Annual Report under the heading "Risk Factors," which include the following risks:*

- Our revenue depends heavily on sales of our COVID-19 vaccine, and our future revenues from our COVID-19 vaccine are uncertain.
- Our commercial revenue is based on preliminary estimates of COVID-19 vaccine sales and costs from Pfizer Inc., or Pfizer, that are likely to change in future periods, which will impact our reported financial results.
- We may not be able to demonstrate sufficient efficacy or safety of our COVID-19 vaccine to obtain permanent regulatory approval in the United States, the United Kingdom, the European Union, or other countries where it has been authorized for emergency use or granted conditional marketing approval.
- We face significant competition with other makers of COVID-19 vaccines and may be unable to maintain a competitive market share for our COVID-19 vaccine.
- We have only recently built our marketing and sales organization. If we are unable to continue to increase our marketing and sales capabilities on our own or through third parties, we may not be able to market and sell our product candidates effectively in the United States and other jurisdictions, if approved, or generate product sales revenue.
- Even if we obtain regulatory approval for our product candidates, the products may not gain the market acceptance among physicians, patients, hospitals, cancer treatment centers and others in the medical community necessary for commercial success.
- Our operating results may fluctuate significantly, which makes our future operating results difficult to predict. If our operating results fall below expectations, the price of the ADSs representing our shares could decline.



- We may require substantial additional financing to achieve our goals, and a failure to obtain this capital on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our product development programs, commercialization efforts or other operations.
- We have in the past identified a material weakness in our internal control over financial reporting and may identify additional material weaknesses in the future that may cause us to fail to meet our reporting obligations or result in material misstatements in our financial statements. If we fail to remediate our material weakness, we may not be able to report our financial results accurately or to prevent fraud.
- As a “foreign private issuer,” we are exempt from a number of rules under the U.S. securities laws, as well as Nasdaq rules, and we are permitted to file less information with the SEC than U.S. companies. This may limit the information available to holders of the ADSs and may make our ordinary shares and the ADSs less attractive to investors.
- We face risks related to health epidemics and pandemics, such as COVID-19, that could adversely affect our operations.
- mRNA drug development has substantial clinical development and regulatory risks due to limited regulatory experience with mRNA immunotherapies.
- Clinical development involves a lengthy and expensive process with an uncertain outcome, and delays can occur for a variety of reasons outside of our control. Clinical trials of our product candidates may be delayed, and certain programs may never advance in the clinic or may be more costly to conduct than we anticipate, any of which can affect our ability to fund our company and would have a material adverse impact on our business.
- Results of earlier studies and trials of our product candidates may not be predictive of future trial results.
- Our mRNA product candidates are based on novel technologies and any product candidates we develop may be complex and difficult to manufacture. We may encounter difficulties in manufacturing, product release, shelf life, testing, storage, supply chain management or shipping. If we or any of the third-party manufacturers we work with encounter such difficulties, our ability to supply materials for clinical trials or any approved product could be delayed or stopped.
- If our efforts to obtain, maintain, protect, defend and/or enforce the intellectual property related to our COVID-19 vaccine or our product candidates and technologies are not adequate, we may not be able to compete effectively in our market.
- We have experienced and may continue to experience significant volatility in the market price of the ADSs representing our ordinary shares.
- Our principal shareholders and management own a significant percentage of our ordinary shares and will be able to exert significant control over matters subject to shareholder approval.

#### **Risk Factors**

*Our business is subject to various risks, including those described below. You should consider carefully the risks and uncertainties described below and in our future filings. If any of the following risks are realized, our business, financial condition, results of operations and prospects could be materially and adversely affected. Additionally, risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition, results of operations and/or prospects.*

#### **Risks Related to our COVID-19 vaccine and the Commercialization of our Pipeline**

***Our revenue depends heavily on sales of our COVID-19 vaccine, and our future revenues from our COVID-19 vaccine are uncertain.***

Our COVID-19 vaccine was granted emergency use authorization in the United States and the United Kingdom, and conditional marketing approval in the European Union, in December 2020, followed by emergency or limited use authorization in a number of other countries and approval for use in certain other countries. Prior to this, we had not sold or marketed any products in our pipeline. As a result, we expect that a majority of our total revenues, and all of our product revenues, in 2021 will be attributable to sales of our COVID-19 vaccine. There is intense competition in the field of COVID-19 vaccines, including with other vaccines that have been authorized for emergency use and those in late-stage clinical development. Our future revenues from sales of our COVID-19 vaccine depend on numerous factors, including:

- competition from other COVID-19 vaccines, including those with different mechanisms of action and different manufacturing and distribution constraints, on the basis of, among other things, efficacy, cost, convenience of storage and distribution, breadth of approved use, side-effect profile and durability of immune response;
- the extent of the spread of COVID-19 infection;
- the extent to which a COVID-19 vaccine continues to be necessary beyond the current pandemic;
- the durability of immune response generated by our COVID-19 vaccine, which has not yet been demonstrated in clinical trials;
- our ability to receive full regulatory approvals;
- our pricing and coverage negotiations with governmental authorities, private health insurers and other third-party payors after our initial sales to national governments;
- the extent to which SARS-CoV-2 mutates and the efficacy of our COVID-19 vaccine in preventing COVID-19 infection from mutated strains;
- the ability of countries and jurisdictions to store and distribute doses of our COVID-19 vaccine to end users at cold temperatures;
- the safety profile of our COVID-19 vaccine, including if previously unknown side effects or increased incidence or severity of known side effects as compared to those seen during clinical trials are identified with our COVID-19 vaccine with widespread global use after approval; and
- our manufacturing and distribution capabilities for our COVID-19 vaccine.

While our COVID-19 vaccine has established a competitive commercial profile, we cannot ensure it will maintain its competitive position as competing vaccines become approved, and we cannot accurately predict the revenues our COVID-19 vaccine will generate in future periods or for how long our COVID-19 vaccine will continue to generate material revenues. If our revenues, market share and/or other indicators of market acceptance of our COVID-19 vaccine do not meet the expectations of investors or securities analysts, the market price of the ADSs representing our ordinary shares may decline. In addition, if one or more of the factors above negatively affects our COVID-19 vaccine sales, our business and financial condition could be materially harmed.

***Our commercial revenue is based on preliminary estimates of COVID-19 vaccine sales and costs from Pfizer Inc., or Pfizer, that are likely to change in future periods, which may impact our reported financial results.***

Our reported commercial revenue is based on preliminary estimates from Pfizer, and other assumptions and judgments that we have made, which may be subject to significant uncertainties. Although our revenue recognition policy is based on facts and circumstances known to us and various other assumptions that we believe to be reasonable under the circumstances, our actual results may deviate from such reported revenue.

We depend on Pfizer to determine and provide estimates of the costs and profits to be shared with us in the countries where it is commercializing our COVID-19 vaccine under our collaboration agreement with Pfizer for our COVID-19 vaccine, which we refer to as the Pfizer Agreement. Because the information supplied by Pfizer is preliminary and is subject to change, the commercial revenue we report based on such information is also subject to finalization. This is particularly true for vaccine sales outside of the United States, where Pfizer has a different reporting cycle than ours. As a result, we may not have the complete sales results outside of the United States for any given period, but we are nonetheless required to report estimated figures.

For example, for the year ended December 31, 2020, Pfizer provided us profit figures for our COVID-19 vaccine sales in the United States using standard U.S. transfer prices and manufacturing and shipping cost variances (as far as those have been identified) that could be subject to adjustment (e.g., due to changes in manufacturing costs or the price of our COVID-19 vaccine). Pfizer also provided estimated profits for COVID-19 vaccine sales outside of the United States that were preliminary in nature, as Pfizer's subsidiaries outside of the United States do not have a fiscal year end of December 31. These estimated figures are likely to change as we receive final data from Pfizer for the year ended December 31, 2020 in accordance with the reporting cycle of its ex-U.S. subsidiaries and as actual costs become known. Further, to the extent that Pfizer does not provide such preliminary information in the future, our provisional sales figures for territories outside of the United States will be subject to an even greater level of estimates and judgments. Any changes to the preliminary data we report herein may have an impact on our reported revenues and expenses, profitability or financial position.

***Our COVID-19 vaccine is sensitive to temperature, shipping and storage conditions and could be subject to risk of loss or damage.***

Our COVID-19 is, and other product candidates we develop could be, sensitive to temperature, storage and handling conditions. In particular, our COVID-19 vaccine must be shipped and stored at very cold temperatures. Loss in supply of our COVID-19 vaccine and our product candidates could occur if the product or product intermediates are not stored or handled properly. Shelf life for our product candidates may vary by product, and it is possible that supply of our COVID-19 vaccine or our product candidates could be lost due to expiration prior to use. This has in the past led and could in the future lead to additional manufacturing costs and delays in our ability to supply required quantities for clinical trials or for commercial purposes. Such distribution challenges may make our COVID-19 vaccine a less attractive product than other COVID-19 vaccines that do not require extremely cold storage, and our COVID-19 vaccine may become increasingly less competitive as additional other vaccines become authorized for emergency use. If we, our partners and customers are unable to adequately manage these issues, the market opportunity for our COVID-19 vaccine may be reduced which could adversely affect our business prospects and our financial condition could be materially harmed.

***We may not be able to demonstrate sufficient efficacy or safety of our COVID-19 vaccine to obtain permanent regulatory approval in the United States, the United Kingdom, the European Union, or other countries where it has been authorized for emergency use or granted conditional marketing approval.***

Our COVID-19 vaccine was granted emergency use authorization in the United States and the United Kingdom, and conditional marketing approval in the European Union, in December 2020, followed by emergency or limited use authorization in a number of other countries and approval for use in certain other countries. Our COVID-19 vaccine has not yet been approved by the U.S Food and Drug Administration, or FDA, the European Medical Agency, or EMA, or other regulatory authorities in a number of countries. We and Pfizer Inc. or Pfizer, intend to continue to observe our COVID-19 vaccine and other variants of a COVID-19 vaccine candidate in global clinical trials. It is possible that subsequent data from these clinical trials may not be as favorable as data we submitted to the FDA, the EMA or other regulatory authorities to support our applications for emergency use authorization or conditional marketing approval or that concerns with the safety of our COVID-19 vaccine will arise from the widespread use of our COVID-19 vaccine outside of clinical trials. Our COVID-19 vaccine may not receive approval outside of the emergency use setting in the countries where it is not currently approved, which could adversely affect our business prospects.

***If we discover safety issues with our products, including our COVID-19 vaccine, that were not known at the time of approval or if we fail to comply with continuing regulatory requirements, commercialization efforts for our products could be negatively affected, approved products could lose their approval or sales could be suspended, and our business and reputation could be materially harmed.***

Our COVID-19 vaccine and any other product candidates for which we receive approval or emergency use authorization are subject to continuing regulatory oversight, including the review of additional safety information. Our COVID-19 vaccine will be more widely used by patients as an authorized product than it was used in clinical trials and therefore side effects and other problems may be observed after emergency use authorization that were not seen or anticipated, or were not as prevalent or severe, during clinical trials. We cannot provide assurance that newly discovered or developed safety issues will not arise. With the use of any vaccine by a wide patient population, serious adverse events may occur from time to time that did not arise in the clinical trials of the product or that initially appeared to be unrelated to the vaccine itself and only with the collection of subsequent information were found to be causally related to the product. Any such safety issues could cause us to suspend or cease marketing of our approved products, possibly subject us to substantial liabilities, and adversely affect our ability to generate revenue and our financial condition. The subsequent discovery of previously unknown problems with a product could negatively affect commercial sales of the product, result in restrictions on the product or lead to the withdrawal of the product from the market. The reporting of adverse safety events involving our products or public speculation about such events could cause the price of the ADSs representing our ordinary shares to decline or experience periods of volatility.

Unexpected safety issues, including any that we have not yet observed in our clinical trials for our COVID-19 vaccine, could lead to significant reputational damage for us and our product development platforms going forward and other issues, including delays in our other programs, the need for re-design of our clinical trials and the need for significant additional financial resources. We also may be restricted or prohibited from marketing or manufacturing our COVID-19 vaccine, even after obtaining product approval, if previously unknown problems with the product or its manufacture are subsequently discovered.

If we or our collaborators fail to comply with applicable continuing regulatory requirements, we or our collaborators may be subject to fines, suspension or withdrawal of regulatory approvals for specific drugs, product recalls and seizures, operating restrictions and/or criminal prosecutions. In addition, the manufacturers we engage to make our products and the manufacturing facilities in which our products are made are subject to periodic review and inspection by the FDA and foreign regulatory authorities. If problems are identified during the review or inspection of these manufacturers or manufacturing facilities, it could result in our inability to use the facility to make our product or a determination that inventories are not safe for commercial sale. Any of these factors could adversely affect our business prospects and our financial position could be materially harmed.

***The successful commercialization of our product candidates will depend in part on the extent to which governmental authorities, private health insurers and other third-party payors provide coverage and adequate reimbursement levels and implement pricing policies favorable for our product candidates. Failure to obtain or maintain coverage and adequate reimbursement for our product candidates, if approved, could limit our ability to market those products and decrease our ability to generate revenue.***

The availability and extent of reimbursement by governmental and private payors is essential for most patients to be able to afford certain treatments, including our COVID-19 vaccine and other product candidates we may develop and sell. In addition, because our mRNA product candidates represent an entirely new therapeutic modality, we cannot accurately estimate how future products we may develop and sell would be priced, whether reimbursement could be obtained, or any potential revenue. Sales of our product candidates will depend substantially, both domestically and abroad, on the extent to which the costs of our product candidates will be paid by health maintenance, managed care, pharmacy benefit, and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payors. If reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize an adequate return on our investment in any of our products.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products in particular in the United States, including genetic medicines. In the United States, the principal decisions about reimbursement for new medicines are typically made by the Centers for Medicare & Medicaid Services, or CMS, an agency within the U.S. Department of Health and Human Services, or HHS, as CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare. Private payors tend to follow CMS to a substantial degree. It is difficult to predict what CMS will decide with respect to reimbursement for novel products such as ours. Reimbursement agencies in Europe may be more conservative than CMS. For example, a number of cancer drugs have been approved for reimbursement in the United States but have not been approved for reimbursement in certain European countries.

Outside the United States, certain countries, including a number of member states of the European Union, set prices and reimbursement for pharmaceutical products, with limited participation from the marketing authorization holders. We cannot be sure that such prices and reimbursement will be acceptable to us or our collaborators. If the regulatory authorities in these jurisdictions set prices or reimbursement levels that are not commercially attractive for us or our collaborators, our revenues from sales by us or our collaborators, and the potential profitability of our drug products, in those countries would be negatively affected. An increasing number of countries are taking initiatives to attempt to reduce large budget deficits by focusing cost-cutting efforts on pharmaceuticals for their state-run health care systems. These international price control efforts have impacted all regions of the world but have been most drastic in the European Union. Additionally, some countries require approval of the sale price of a product before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then may experience delays in the reimbursement approval of our product or be subject to price regulations that would delay our commercial launch of the product, possibly for lengthy time periods, which could negatively impact the revenues we are able to generate from the sale of the product in that particular country.

Moreover, increasing efforts by governmental and third-party payors, in the United States and abroad, to cap or reduce healthcare costs may cause such organizations to limit both coverage and level of reimbursement for new products approved and, as a result, they may not cover or provide adequate payment for our product candidates. For example, the U.S. government recently released a "blueprint," which is a plan to reduce the cost of drugs. The blueprint contains certain measures that the HHS is already working to implement. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

We expect to experience pricing pressures in connection with the sale of any of our product candidates, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products in the marketplace.

***The imposition of export controls on our COVID-19 vaccine in the European Union or in other jurisdictions could severely and adversely impact our manufacturing activities, commercial activities and financial results.***

Governments of the jurisdictions in which we or our partners produce our COVID-19 vaccine may prohibit us from delivering orders of our COVID-19 vaccine to customers in other jurisdictions.

The European Union and other regions have imposed, or threatened to impose, export controls that would limit or block the delivery of COVID-19 vaccines manufactured in their territories in instances where manufacturers have been delayed or have not fully satisfied their delivery obligations to such governments. If the European Union enforces an export authorization scheme on COVID-19 vaccines, we may be prohibited from exporting commercial supply of the vaccine from our manufacturing site in Germany to non-EU countries (and Pfizer may likewise be prohibited from exporting out of its manufacturing site in Belgium). Such restrictions may have a material impact on our manufacturing or distribution activities, and the commercialization of our COVID-19 vaccine.

***Our ability to generate income from sales of our COVID-19 vaccine is uncertain, due to government interest and public perception regarding a vaccine.***

As a result of the emergency pandemic situations in many countries, there is a heightened risk that a COVID-19 vaccine may be subject to adverse governmental actions in certain countries, including intellectual property expropriation, compulsory licenses, strict price controls or other actions. Additionally, we may need to, or we may be required by governmental or non-governmental authorities to, set aside specific quantities of doses of our COVID-19 vaccine for designated purposes or geographic areas. We face challenges related to the allocation of supply of our COVID-19 vaccine, particularly with respect to geographic distribution.

Furthermore, public sentiment regarding commercialization of a COVID-19 vaccine may limit or negate our ability to generate income from sales of our COVID-19 vaccine. Given that COVID-19 has been designated as a pandemic and represents an urgent public health crisis, we have faced significant public attention and scrutiny over any current and any future business models and pricing decisions with respect to our COVID-19 vaccine. If we are unable to successfully manage these risks, we could face significant reputational harm, which could negatively affect the price of the ADSs representing our ordinary shares.

***We face significant competition with other makers of COVID-19 vaccines and may be unable to maintain a competitive market share for our COVID-19 vaccine.***

A large number of vaccine manufacturers, academic institutions and other organizations currently have programs to develop COVID-19 vaccine candidates and certain other vaccines have been authorized for emergency use or approved in various countries. For example, Moderna, Inc.'s vaccine candidate, mRNA-1273, has been approved for emergency use in the United States, United Kingdom, European Union and other countries. While we are not aware of all of our competitors' efforts, other vaccine candidates developed by the Gamaleya Research Institute of Epidemiology and Microbiology, the University of Oxford/AstraZeneca plc, CanSino Biologics Inc., Johnson & Johnson, the Vector Institute, Novavax, Inc., China National Pharmaceutical Group (Sinopharm)/Beijing Institute of Biological Products and Wuhan Institute of Biological Products, Sinovac Biotech Ltd., Bharat Biotech International Limited and other companies are in late stages of clinical development or have been authorized for emergency use or approved in certain countries. Our competitors pursuing vaccine candidates may have greater financial, product candidate development, manufacturing and marketing resources than we do. Larger pharmaceutical and biotechnology companies have extensive experience in clinical testing and obtaining regulatory approval for their products, and may have the resources to invest heavily to accelerate discovery and development of their vaccine candidates.

Our efforts to successfully commercialize our COVID-19 vaccine may fail if competitors develop and commercialize COVID-19 vaccines that are safer, more effective, produce longer immunity against COVID-19, require fewer administrations, have fewer or less severe side effects, have broader market acceptance, are more convenient to administer or distribute or are less expensive than any vaccine candidate that we have developed or we may develop.

*We are developing other product candidates in an environment of rapid technological and scientific change, and our failure to effectively compete would prevent us from achieving significant market penetration. Most of our competitors have significantly greater resources than we do and we may not be able to compete successfully.*

The pharmaceutical market is intensely competitive and rapidly changing. Many large pharmaceutical and biotechnology companies, academic institutions, governmental agencies, and other public and private research organizations are pursuing the development of novel drugs for the same diseases that we are targeting or expect to target. Many of our competitors have:

- greater financial, technical and human resources than we have at every stage of the discovery, development, manufacture and commercialization of products;
- more extensive experience in preclinical testing, conducting clinical trials, obtaining regulatory approvals, and in manufacturing, marketing and selling drug products;
- product candidates that are based on previously tested or accepted technologies;
- products that have been approved or are in late stages of development; and
- collaborative arrangements in our target markets with leading companies and research institutions.

We will face intense competition from drugs that have already been approved and accepted by the medical community for the treatment of the conditions for which we may develop drugs in the future. We also expect to face competition from new drugs that enter the market. There are a number of drugs currently under development, which may become commercially available in the future, for the treatment of conditions for which we are trying, or may in the future try, to develop drugs. These drugs may be more effective, safer, less expensive, or marketed and sold more effectively, than any products we develop.

We anticipate competing with the largest pharmaceutical companies in the world, many of which are all currently conducting research in the fields of infectious diseases, immuno-oncology, rare genetic diseases and cancer immunotherapies. Some of these companies have greater financial and human resources than we currently have. In addition to these large pharmaceutical companies, we may directly compete with fully-integrated biopharmaceutical companies and other immunotherapy-focused oncology companies, as well as a number of companies focused on immunotherapies or shared tumor antigen and neoantigen therapeutics, some of which have entered into collaboration and funding agreements with larger pharmaceutical or biotechnology companies.

If we successfully develop other product candidates, and obtain approval for them, we will face competition based on many different factors, including:

- the safety and effectiveness of our products relative to alternative therapies, if any;
- the ease with which our products can be administered and the extent to which patients accept relatively new routes of administration;
- the timing and scope of regulatory approvals for these products;
- the availability and cost of manufacturing, marketing and sales capabilities;
- the price of any approved immunotherapy;
- reimbursement coverage; and
- intellectual property position.

Our competitors may develop or commercialize products with significant advantages over any products we develop based on any of the factors listed above or on other factors. In addition, our competitors may develop collaborations with or receive funding from larger pharmaceutical or biotechnology companies, providing them with an advantage over us. Our competitors therefore may be more successful in commercializing their products than we are, which could adversely affect our competitive position and business. Competitive products may make any products we develop obsolete or noncompetitive before we can recover the expenses of developing and commercializing our products, if approved.

*The market opportunities for certain of our product candidates may be small due to the rarity of the disease, or limited to those patients who are ineligible for or have failed prior treatments. As the target patient populations for some*

*of our programs are small, we may never achieve or maintain profitability without obtaining regulatory approval for additional indication.*

The FDA often approves new cancer therapies initially only for use by patients with relapsed or refractory advanced cancer. We expect to seek approval initially of certain of our product candidates in this context. Subsequently, for those products that prove to be sufficiently beneficial, we would expect to seek approval in earlier lines of treatment and potentially as a first-line therapy but there is no guarantee that our product candidates, even if approved, would be approved for earlier lines of therapy, and, prior to any such approvals, we may have to conduct additional clinical trials. We are also developing product candidates for the treatment of rare diseases.

Our projections of the number of people who have or will have the diseases we may be targeting may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these diseases. The number of trial participants may turn out to be lower than expected. Additionally, the potentially addressable patient population for our product candidates may be limited or may not be amenable to treatment with our product candidates. Even if we obtain significant market share for our products, if approved, because the potential target populations may be small, we may never achieve or maintain profitability without obtaining regulatory approval for additional indications.

*We have only recently built our marketing and sales organization. If we are unable to continue to increase our marketing and sales capabilities on our own or through third parties, we may not be able to market and sell our product candidates effectively in the United States and other jurisdictions, if approved, or generate product sales revenue.*

We have only recently developed our sales, distribution or marketing capabilities, and, other than for our COVID-19 vaccine, we have not historically designed our preclinical studies and clinical trials with specific commercialization or marketing considerations in mind. To successfully commercialize our COVID-19 vaccine and any other products that may result from our development programs, we will need to continue developing sales and marketing capabilities in the United States, Europe and other regions, either on our own or with others. We may enter into collaborations with other entities to utilize their mature marketing and distribution capabilities, but we may be unable to enter into marketing agreements on favorable terms, if at all. If our current and future collaborators do not commit sufficient resources to commercialize our COVID-19 vaccine and our future products, if any, and we are unable to develop the necessary marketing capabilities on our own, we may be unable to generate sufficient product sales revenue to sustain our business. We will be competing with many companies that currently have extensive and well-funded marketing and sales operations. Without a significant internal team or the support of a third party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies.

*Our ability to achieve or maintain profitability depends in part on our and our collaborators' ability to penetrate global markets, where we would be subject to additional regulatory burdens and other risks and uncertainties associated with international operations that could materially adversely affect our business.*

Our ability to achieve or maintain profitability will depend in part on our ability and the ability of our collaborators to commercialize any products that we or our collaborators may develop in markets throughout the world. Commercialization of products in various markets could subject us to risks and uncertainties, including:

- obtaining, on a country-by-country basis, the applicable marketing authorization from the competent regulatory authority;
- the burden of complying with complex and changing regulatory, tax, accounting, labor and other legal requirements in each jurisdiction that we or our collaborators pursue;
- reduced protection for intellectual property rights;
- differing medical practices and customs affecting acceptance in the marketplace;
- import or export licensing requirements;
- governmental controls, trade restrictions or changes in tariffs;
- economic weakness, including inflation, or political instability in particular non-U.S. economies and markets;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad;
- longer accounts receivable collection times;
- longer lead times for shipping;

- language barriers;
- foreign currency exchange rate fluctuations;
- the impact of public health epidemics and pandemics, such as the COVID-19 pandemic, on employees and the global economy;
- reimbursement, pricing and insurance regimes; and
- the interpretation of contractual provisions governed by local laws in the event of a contract dispute.

We do not have prior experience in all of these areas, and the experience we do have in some of these areas is limited. Our collaborators may have limited experience in these areas as well. Failure to successfully navigate these risks and uncertainties may limit or prevent market penetration for any products that we or our collaborators may develop, which would limit their commercial potential and our revenues.

***Even if we obtain regulatory approval for our product candidates, the products may not gain the market acceptance among physicians, patients, hospitals, cancer treatment centers and others in the medical community necessary for commercial success.***

Even with the requisite approvals, the commercial success of our products will depend in part on the medical community, patients, and third-party or governmental payors accepting immunotherapies in general, and our products in particular, as medically useful, cost-effective and safe.

Any product that we bring to the market may not gain market acceptance by physicians, trial participants, third-party payors, and others in the medical community. Additionally, ethical, social and legal concerns about genetic research could result in additional regulations restricting or prohibiting the products and processes we may use. If these products do not achieve an adequate level of acceptance, we may not generate significant product sales revenue and may not be able to achieve or maintain profitability. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the potential efficacy and potential advantages over alternative treatments;
- the ability to offer our products, if approved, at competitive prices;
- the prevalence and severity of any side effects, including any limitations or warnings contained in a product's approved labeling;
- the prevalence and severity of any side effects resulting from checkpoint inhibitors or other drugs or therapies with which our products are administered;
- relative convenience and ease of transportation, storage and administration;
- any restrictions on the use of our products, if approved, together with other medications;
- the willingness of the target patient population to try new therapies, such as mRNA vaccines and therapies, and of physicians to prescribe these therapies;
- the strength of marketing and distribution support and timing of market introduction of competitive products;
- publicity concerning our products or competing products and treatments; and
- sufficient third-party insurance coverage or reimbursement, and patients' willingness to pay out-of-pocket in the absence of third-party coverage or adequate reimbursement.

Even if a potential product displays a favorable efficacy and safety profile in preclinical studies and clinical trials, market acceptance of the product will not be known until after it is launched. Our efforts to educate the medical community and third-party payors on the benefits of the products may require significant resources and may never be successful. Our efforts to educate the marketplace may require more resources than are required by the conventional technologies marketed by our competitors due to the complexity and uniqueness of our programs.

In addition, if any of our products are approved for marketing, we or a collaborator will be subject to significant regulatory obligations regarding the submission of safety and other post-marketing information and reports for such product, and will need to continue to comply (or ensure that our third-party providers comply) with current good manufacturing practices, or GMP, and current good clinical practices, or GCP, for any clinical trials that we or a



collaborator conduct post-approval. In addition, there is always the risk that we or a collaborator or regulatory authority might identify previously unknown problems with a product post-approval, such as adverse events of unanticipated severity or frequency. Compliance with these requirements is costly, and any such failure to comply or other issues with our product candidates identified post-approval could have a material adverse impact on our business, financial condition and results of operations.

***Coverage and reimbursement may be limited or unavailable in certain market segments for our product candidates, which could make it difficult for us to sell our product candidates, if approved, profitably.***

Successful sales of our product candidates, if approved, depend on the availability of coverage and adequate reimbursement from third-party payors including governmental healthcare programs, such as Medicare and Medicaid, managed care organizations and commercial payors, among others. Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we obtain regulatory approval. In addition, because our product candidates represent new approaches to the treatment of cancer, we cannot accurately estimate the potential revenue from our product candidates.

Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Obtaining coverage and adequate reimbursement from third-party payors is critical to new product acceptance.

Third-party payors decide which drugs and treatments they will cover and the amount of reimbursement. Reimbursement by a third-party payor may depend upon a number of factors, including, but not limited to, the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Obtaining coverage and reimbursement of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to the payor supporting scientific, clinical and cost-effectiveness data for the use of our products. Third-party payors could require us to conduct additional studies, including post-marketing studies related to the cost effectiveness of a product, to qualify for reimbursement, which could be costly and divert our resources. Even if we obtain coverage for a given product, if the resulting reimbursement rates are insufficient, hospitals may not approve our product for use in their facility or third-party payors may require co-payments that patients find unacceptably high. Patients are unlikely to use our product candidates unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our product candidates. Separate reimbursement for the product itself may or may not be available. Instead, the hospital or administering physician may be reimbursed only for providing the treatment or procedure in which our product is used. Further, from time to time, CMS revises the reimbursement systems used to reimburse health care providers, including the Medicare Physician Fee Schedule and Outpatient Prospective Payment System, which may result in reduced Medicare payments. In some cases, private third-party payors rely on all or portions of Medicare payment systems to determine payment rates. Changes to government healthcare programs that reduce payments under these programs may negatively impact payments from private third-party payors, and reduce the willingness of physicians to use our product candidates.

In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage for the product. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

We intend to seek approval to market our product candidates in the United States, the European Union and other selected jurisdictions. If we obtain approval for our product candidates in any particular jurisdiction, we will be subject to rules and regulations in that jurisdiction. In some countries, particularly those in Europe, the pricing of biologics is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time

after obtaining marketing approval of a product candidate. Some of these countries may require the completion of clinical trials that compare the cost-effectiveness of a particular product candidate to currently available therapies. Other member states allow companies to fix their own prices for medicines, but monitor and control company profits. The downward pressure on health care costs has become very intense. As a result, increasingly high barriers are being erected to the entry of new products into the marketplace. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country.

The marketability of any product candidates for which we receive regulatory approval for commercial sale may suffer if government and other third-party payors fail to provide coverage and adequate reimbursement. We expect downward pressure on pharmaceutical pricing to continue. Further, coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

***The advancement of healthcare reform legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize any product candidates we or our collaborators develop and may adversely affect the prices for such product candidates.***

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or the ACA, was passed, which substantially changes the way health care is financed by both governmental and private insurers, and significantly impacts the U.S. pharmaceutical industry. The ACA, among other things, increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations, established annual fees and taxes on manufacturers of certain branded prescription drugs, and promoted a new Medicare Part D coverage gap discount program. Considerable uncertainty remains regarding the implementation and impact of the ACA.

Some of the provisions of the ACA have yet to be fully implemented, while certain provisions have been subject to judicial and Congressional challenges. The Tax Cuts and Jobs Act of 2017, or the TCJA, includes a provision repealing the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." CMS has recently proposed regulations that would give states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces. Further, on October 13, 2017, an executive order was signed terminating the cost-sharing reduction, or CSR, subsidies that reimburse insurers under the ACA. The loss of the CSR payments is expected to increase premiums on certain policies issued by qualified health plans under the ACA. Several state Attorneys General filed suit to stop the administration from terminating the subsidies, but their request for a restraining order was denied by a federal judge in California on October 25, 2017. Another executive order was signed directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal burden on states or a cost, fee, tax, penalty or regulatory burden on individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. With the current presidential administration and Congress, there may be additional administrative or legislative changes, including modification, repeal or replacement of all, or certain provisions of, the ACA. However, it remains to be seen whether new legislation modifying the ACA will be enacted and, if so, precisely what the new legislation will provide, when it will be enacted and what impact it will have on the availability of healthcare and containing or lowering the cost of healthcare. The implications of a potential repeal or replacement of the ACA, for our and our collaborators' business and financial condition, if any, are not yet clear.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. The Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers up to 2% per fiscal year. These reductions will remain in effect through 2025 unless additional congressional action is taken.

The delivery of healthcare in the European Union, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than European Union, law and policy. National governments and health service providers have different priorities and approaches to the delivery of health care and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary

constraints in most EU member states have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with ever-increasing European Union and national regulatory burdens on those wishing to develop and market products, this could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities, and affect our ability to commercialize any products for which we obtain marketing approval.

We expect that additional healthcare reform measures or proposals will be adopted in the future, any of which could limit the amounts that governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures. In the event that the pricing structures for healthcare products, such as the product candidates we are developing, change materially and limit payments for such product candidates, our business will be adversely impacted as our products may no longer be commercially viable based on their expected net present value; we may have invested significant resources in products that cannot be commercially developed; or we may determine that assets that have reached an early phase of development cannot or will not be taken into further development, notwithstanding their clinical viability. In addition, development assets or clinical programs that are part of our collaborations may no longer be deemed commercially viable to pursue based on our collaborators' assessments of the impact of any proposed, announced, or legislated pricing reforms.

We cannot predict what healthcare reform initiatives may be adopted in the future. Further legislative and regulatory developments are likely, and we expect ongoing initiatives to increase pressure on drug pricing. Such reforms could have an adverse effect on anticipated revenues from product candidates that we may successfully develop and for which we may obtain regulatory approval, and may affect our overall financial condition and ability to develop product candidates.

***European Union drug marketing and reimbursement regulations may materially affect our ability to market and receive coverage for our products in the member states of the European Union.***

We intend to seek approval to market our product candidates in both the United States and in other selected jurisdictions. If we obtain approval for our product candidates in a particular jurisdiction, we will be subject to rules and regulations in that jurisdiction. In some countries, particularly those in the European Union, the pricing of biologics is subject to governmental control and other market regulations that could put pressure on the pricing and usage of our product candidates. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval of a product candidate. In addition, market acceptance and sales of our product candidates will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for our product candidates and may be affected by existing and future healthcare reform measures.

In addition, in most countries outside the United States, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing and reimbursement vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. Reference pricing used by various member states and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. In some countries, we may be required to conduct a clinical trial or other studies that compare the cost-effectiveness of any of our product candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the European Union do not follow price structures of the United States and, generally, prices tend to be significantly lower in the European Union. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If pricing is set at unsatisfactory levels or if reimbursement of our products is unavailable or limited in scope or amount, our revenues from sales by us or our collaborators and the potential profitability of any of our product candidates in those countries would be negatively affected.

**Risks Related to our Financial Condition and Capital Requirements**

***We have incurred significant losses since our inception and we may continue to incur significant losses in the foreseeable future, which makes it difficult to assess our future viability.***

In the past, we have incurred significant losses leading to accumulated losses of €409.6 million as of December 31, 2020. We have devoted most of our financial resources to research and development, including our clinical and preclinical

development activities and the development of our platforms. Prior to December 2020, we financed our operations primarily through the sale of equity securities and proceeds from collaborations and, to a lesser extent, through revenue from manufacturing operations and grants from governmental and private organizations. More recently, we have financed our operations from revenues from sales of our COVID-19 vaccine. Even for those products for which we have obtained regulatory approval or emergency use authorization our future revenues will depend upon the size of any markets in which our product candidates have received approval or authorization to market, our ability to achieve sufficient market acceptance, reimbursement from third-party payors, and adequate market share in those markets. If achieved, profitability is difficult to maintain over time and is highly dependent on various factors. Our future financial results will depend, in part, on the rate of our future expenditures, the extent to which we experience long-term success of our commercial products and our ability to obtain funding through equity or debt financings, sales of assets, collaborations or grants.

We expect to continue to incur significant and increasing operating expenses for the foreseeable future. We anticipate that our expenses will increase substantially if and as we and our collaborators:

- continue or expand our research or development of our programs in preclinical development;
- continue or expand the scope of our clinical trials for our product candidates;
- initiate additional preclinical, clinical, or other trials for our product candidates, including under our collaboration agreements;
- continue to invest in our immunotherapy platforms to conduct research to identify novel technologies;
- change or increase our manufacturing capacity or capability;
- change or add additional suppliers;
- add additional infrastructure to our quality control, quality assurance, legal, compliance and other groups to support our operations as a public company and our product development and commercialization efforts, including expansion of sites in Germany and new sites in the United States, and potentially others globally;
- attract and retain skilled personnel;
- seek marketing approvals and reimbursement for our product candidates;
- develop our sales, marketing, and distribution infrastructure for our COVID-19 vaccine and any other products for which we may obtain marketing approval or emergency use authorization;
- seek to identify and validate additional product candidates;
- acquire or in-license other product candidates and technologies;
- make milestone or other payments under any in-license agreements;
- maintain, protect, defend, enforce and expand our intellectual property portfolio; and
- experience any delays or encounter issues with any of the above.

***Our operating results may fluctuate significantly, which makes our future operating results difficult to predict. If our operating results fall below expectations, the price of the ADSs representing our shares could decline.***

Our financial condition and operating results have varied in the past and will continue to fluctuate from one financial period to the next due to a variety of factors, many of which are beyond our control.

Factors relating to our business that may contribute to these fluctuations include the following, as well as other factors described elsewhere in this report:

- the size and timing of orders for our COVID-19 vaccine;
- delays or failures in advancement of existing or future product candidates into the clinic or in clinical trials;
- our ability to develop and manufacture our product candidates and commercialize and manufacture our COVID-19 vaccine at commercial scale;
- our ability to manage our growth;

- the outcomes of research programs, clinical trials, or other product development or approval processes conducted by us and our collaborators;
- the ability of our collaborators to develop and successfully commercialize products developed from our suite of therapeutic classes;
- our relationships, and any associated exclusivity terms, with collaborators;
- our contractual or other obligations to provide resources to fund our product candidates, and to provide resources to our collaborators or to the collaborations themselves;
- risks associated with the international aspects of our business outside Germany, including the conduct of clinical trials in multiple locations and potential commercialization in such locations;
- our ability to minimize and manage product recalls or inventory losses caused by unforeseen events, cold chain interruption or testing difficulties;
- our ability to report our financial results accurately and in a timely manner;
- our dependence on, and the need to attract and retain, key management and other personnel;
- our ability to obtain, protect, maintain, defend and enforce our intellectual property rights;
- our ability to prevent the theft or infringement, misappropriation or other violation of our intellectual property, trade secrets, know-how or technologies;
- our and our collaborators' ability to defend against claims of infringement of the intellectual property rights of third parties;
- potential advantages that our competitors and potential competitors may have in securing funding, obtaining the rights to critical intellectual property or developing competing technologies or products;
- our ability to obtain additional capital that may be necessary to expand our business;
- our collaborators' ability to obtain and devote additional capital that may be necessary to develop and commercialize products under our collaboration agreements, including our COVID-19 vaccine;
- our ability to minimize and manage product liability claims arising from the use of our COVID-19 vaccine and our product candidates and other future products, if approved;
- business interruptions such as power outages, strikes, acts of terrorism or natural disasters; and
- our ability to use our net operating loss carryforwards to offset future taxable income.

Each of the factors listed above may be affected by the COVID-19 pandemic's or its impact on the global community and the global economy.

Due to the various factors mentioned above, and others, the results of any of our periods should not be relied upon as indications of our future operating performance. Our operating results may fluctuate significantly from one reporting period to the next, such that a period-to-period comparison of our results of operations may not be a good indication of our future performance.

In any particular period, our operating results could be below the expectations of securities analysts or investors, which could cause the price of the ADSs to decline. While as a general matter we intend to periodically report on the status of our product candidate pipeline, including articulating anticipated next steps in the form of development plans or potential data readouts, we may not always be able to provide forward-looking guidance on the timing of those next steps. In addition, we do not control the timing of disclosures of any milestones related to any of our programs that are managed by our collaborators. Any disclosure by a collaborator of data that are perceived as negative, whether or not such data are related to other data that we or others release, may have a material adverse impact on the price of the ADSs or overall valuation. The price of the ADSs may decline as a result of unexpected clinical trial results in one or more of our programs, including adverse safety events reported for any of our programs.

***Profitability is difficult to maintain over time and highly dependent on various factors.***

Our ability to generate revenue and achieve and maintain profitability depends on our ability, alone or with collaborators, to successfully complete the development of, and obtain the regulatory approvals necessary to commercialize, our product candidates. Although we generate revenue from sales of our COVID-19 vaccine and additional limited revenue from sales of products by our subsidiaries making other sales transactions, the amount of long-term revenue from such sales, including the sales of our COVID-19 vaccine, is uncertain at this time. Our ability to generate future revenues from other pharmaceutical product sales depends heavily on our success in:

- completing research and preclinical and clinical development of our product candidates;
- seeking and obtaining U.S. and non-U.S. marketing approvals for product candidates for which we complete clinical trials;
- furthering the development of our own manufacturing capabilities and manufacturing relationships with third parties in order to provide adequate (in amount and quality) products and services to support clinical development and the market demand for our product candidates, if approved;
- obtaining market acceptance of our product candidates as a treatment option;
- launching and commercializing product candidates for which we obtain marketing approval and reimbursement, either through collaborations or, if launched independently, by establishing a sales force, marketing and distribution infrastructure;
- addressing any competing technological and market developments;
- implementing additional internal systems and infrastructure;
- negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter;
- maintaining, defending, protecting, enforcing and expanding our portfolio of intellectual property rights, including patents, trade secrets and know-how; and
- attracting, hiring and retaining qualified personnel.

Additionally, we have incurred significant costs associated with the commercialization of our COVID-19 vaccine. Our expenses could increase beyond our expectations if we are required by the FDA, the EMA, or other regulatory agencies to perform clinical and other trials or make changes to our manufacturing or quality systems in addition to those that we currently anticipate. Accordingly, such costs could adversely affect our future profitability.

***The amount of and our ability to use, net operating losses and research and development credits to offset future taxable income may be subject to certain limitations and uncertainty. In addition, pending and future tax audits within our group, disputes with tax authorities and changes in tax law or fiscal regulations could lead to additional tax liabilities. We are subject to routine tax audits by the respective local tax authorities. Any additional tax liability could have an adverse effect on our business, financial conditions, results of operations or prospects.***

In Germany, we have unused tax loss carryforwards for corporate taxes, though we have not recognized deferred tax assets related to such loss carryforwards for International Financial Reporting Standards, or IFRS, reporting purposes in previous years. In general, net operating loss, or NOL, carryforwards in Germany do not expire. Even though we recognized deferred tax assets on a majority of German tax loss carry forwards in 2020, they are, however, subject to review and possible adjustment by the German tax authorities. Deferred tax assets are recognized for unused tax losses only to the extent that it is probable that taxable profit will be available against which the losses can be utilized. Furthermore, under current German tax laws, certain substantial changes in the Company's ownership and business may further limit the amount of NOL carryforwards that can be used annually to offset future taxable income. In addition, we have U.S. federal and state NOL carryforwards due to our subsidiaries in the United States, which may be subject to limitations on use after an ownership change.

We may not be able to utilize a material portion of our NOLs or credits in either Germany or the United States. In addition, the rules regarding the timing of revenue and expense recognition for tax purposes in connection with various transactions are complex and uncertain in many respects, and, if challenged, our recognition may be subject to a revised assessment. In the event any such challenge is sustained, our NOLs could be materially reduced or we could be determined to be a material cash taxpayer for one or more years which could have an adverse effect on our business, financial conditions, results of operations or prospects.

Furthermore, our ability to use our NOLs or credits is conditioned upon our attaining profitability and generating taxable income. Taxable income exceeding NOLs will be subject to taxation resulting tax liabilities. As described above, we have incurred significant net losses in every year since our inception other than 2018 and anticipate that in the future, we may incur significant losses for some of the group entities. Our ability to utilize our NOL or credit carryforwards in the United States and for some German group entities is uncertain.

***Under German tax laws, we are obligated to withhold a percentage of royalty payments we make to third party licensors of intellectual property rights and remit those withholdings to German tax authorities. Late withholding tax payments may subject us to penalties and fees.***

Under German tax laws, we are obligated to withhold a percentage of royalty payments we make to third parties in consideration of the grant of rights under their intellectual property, and remit those withholdings to German tax authorities. As a result of an internal review, we discovered that in the 11-year period before April 2019 we and certain of our subsidiaries did not withhold, report and remit certain withholding taxes in connection with the licensing of intellectual property as required to be withheld under German tax laws, and have not made the requisite recordings in our and their financial books and records in relation to such withholding taxes. We notified the tax authorities of the late payments and made the respective payments in 2019. No administrative offence or criminal proceeding were opened or are expected in the future.

It is possible to seek the refund of these withholding taxes from the German Federal Central Tax office after filing exemption and refund applications. We have filed such refund and exemption applications and the majority of the taxes paid have already been refunded. We expect further refunds to be paid out in the future. However, there is a possibility that the relevant claims against the licensors and/or the tax authorities, may in some instances, not be enforceable as a result of a licensor no longer existing, the lapse of time or any other facts preventing the enforcement of such claims.

***We may require substantial additional financing to achieve our goals, and a failure to obtain this capital on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our product development programs, commercialization efforts or other operations.***

As of December 31, 2020, we had cash and cash equivalents of €1,320.2 million. Our operating plans may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity or debt financings, government or other third-party funding, sales of assets, marketing and distribution arrangements, other collaborations and licensing arrangements, or a combination of these approaches. We will require additional capital to obtain regulatory approval for, and to commercialize, future product candidates. Even if we believe we have sufficient funds for our current or future operating plans, we may seek additional capital if market conditions are favorable or if we have specific strategic considerations. Our spending will vary based on new and ongoing development and corporate activities. Due to the high uncertainty of the length of time and activities associated with discovery and development of our product candidates, we are unable to estimate the actual funds we will require for development, marketing and commercialization activities.

Our future funding requirements, both near and long term, will depend on many factors, including, but not limited to:

- the initiation, progress, timing, costs, and results of preclinical or nonclinical studies and clinical trials for our product candidates;
- the amount and timing of revenues and associated costs from sales of our COVID-19 vaccine;
- the results of research and our other platform activities;
- the clinical development plans we establish for our product candidates;
- the terms of any agreements with our current or future collaborators, and the achievement of any milestone payments under such agreements to be paid to us or our collaborators;
- the number and characteristics of product candidates that we develop or may in-license;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA, the EMA and other comparable regulatory authorities;
- the cost of filing, prosecuting, obtaining, maintaining, protecting, defending and enforcing our patent claims and other intellectual property rights, including actions for patent and other intellectual property infringement,

- misappropriation and other violations brought by third parties against us regarding our product candidates or actions by us challenging the patent or intellectual property rights of others;
- the effect of competing technological and market developments, including other products that may compete with one or more of our product candidates;
- the cost and timing of completion and further expansion of clinical and commercial scale manufacturing activities sufficient to support all of our current and future programs; and
- the cost of establishing sales, marketing, and distribution capabilities for any product candidates for which we may receive marketing approval and reimbursement in regions where we choose to commercialize our products on our own.

To date, we have financed our operations primarily through the sale of equity securities, revenue from collaborations, and revenue from sales of our COVID-19 vaccine, and we cannot be certain that additional funding will be available on favorable terms, or at all. Until we can generate sufficient product sales or royalty revenue to finance our operations, which we may never do, we expect to finance our future cash needs through a combination of public or private equity offerings, debt financings, collaborations, licensing arrangements, and other marketing or distribution arrangements. Any fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts, at the right time, on favorable terms, or at all, including as a result of the impact that the COVID-19 pandemic may have on the capital markets.

Negative clinical trial data or setbacks, or perceived setbacks, in our programs or with respect to our technology could impair our ability to raise additional financing on favorable terms, or at all. Moreover, the terms of any financing may adversely affect the holdings or the rights of our shareholders, and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our shares to decline. If we raise additional funds through public or private equity offerings, the terms of these securities may include liquidation or other preferences that may adversely affect our shareholders' rights.

Further, to the extent that we raise additional capital through the sale of ADSs, ordinary shares or securities convertible or exchangeable into ordinary shares, share ownership interests will be diluted. We have entered into five credit facilities with an aggregate drawing capacity of €173.0million. As of December 31, 2020, three secured credit facilities with an aggregate drawing capacity of €23.0 million were drawn down, and the first scheduled repayments have occurred on three of the four credit facilities. In addition, during December 2020, we drew down €50.0 million (Credit A) from our European Investment Bank, or EIB, financing and may enter into additional credit facilities from time to time, which may be secured, to fund certain of our operations. If we raise additional capital through debt financing, we would be subject to fixed payment obligations and may be subject to security interests in our assets and covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional capital through marketing and distribution arrangements, sales of assets, collaborations, or licensing arrangements with third parties, we may have to relinquish certain valuable rights to our product candidates, technologies, future revenue streams or research programs. We also could be required to seek collaborators for one or more of our current or future product candidates at an earlier stage than otherwise would be desirable or relinquish our rights to product candidates or intellectual property that we otherwise would seek to develop or commercialize ourselves. If we are unable to raise additional capital in sufficient amounts, at the right time, on favorable terms, or at all, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our products or product candidates, or one or more of our other research and development initiatives. Any of the above events could significantly harm our business, prospects, financial condition and results of operations, cause the price of the ADSs to decline, and negatively impact our ability to fund operations.

***We will need to continue to develop and expand our company, and we may encounter difficulties in managing this development and expansion, which could disrupt our operations.***

To manage our anticipated development and expansion, we must continue to implement and improve our managerial, operational, legal, compliance and financial systems, expand our facilities, and continue to recruit and train additional qualified personnel. In addition, our management may need to divert a disproportionate amount of its attention away from its day-to-day activities and devote a substantial amount of time to managing these development activities.

As a growing biotechnology company, we are actively pursuing drug classes, platforms and product candidates in many therapeutic areas and across a wide range of diseases. Successfully developing products for, and fully understanding



the regulatory and manufacturing pathways to, all of these therapeutic areas and disease states requires a significant depth of talent, resources and corporate processes in order to allow simultaneous execution across multiple areas. Due to our limited resources, we may not be able to effectively manage this simultaneous execution and the expansion of our operations or recruit and train additional qualified personnel. This may result in weaknesses in our infrastructure, give rise to operational mistakes, legal or regulatory compliance failures, loss of business opportunities, loss of employees and reduced productivity among remaining employees. The physical expansion of our operations may lead to significant costs and may divert financial resources from other projects, such as the development of our product candidates. If our management is unable to effectively manage our expected development and expansion, our expenses may increase more than expected, our ability to generate or increase our revenue could be reduced and we may not be able to effectively implement our business strategy. Our future financial performance and our ability to compete effectively and commercialize our COVID-19 vaccine and our product candidates, if approved, will depend in part on our ability to effectively manage the current and future development and expansion of our company.

***We have incurred increased costs as a result of operating as a public company, and our management has been required to devote substantial time to new compliance initiatives. We are subject to financial reporting and other requirements for which our accounting and other management systems and resources may not be adequately prepared. We may fail to comply with the rules that apply to public companies, including Section 404 of the Sarbanes-Oxley Act of 2002, which could result in sanctions or other penalties that would harm the business.***

As a public company, we incur significant legal, accounting and other expenses. The federal securities laws, including the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, and rules subsequently implemented by the SEC and the Nasdaq Stock Market LLC, or Nasdaq, have imposed various requirements on public companies, including requirements to file annual and event-driven reports with respect to our business and financial condition, and to establish and maintain effective disclosure and financial controls and corporate governance practices. Our management and other personnel need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations have increased our legal and financial compliance costs and have made some activities more time-consuming and costly. We may not be able to produce reliable financial statements or file these financial statements as part of a periodic report in a timely manner with the SEC or comply with Nasdaq listing requirements. In addition, we could make errors in our financial statements that could require us to restate our financial statements.

Pursuant to Section 404 of the Sarbanes-Oxley Act, or Section 404, concurrent with this Annual Report on Form 20-F we are required to furnish a report by our management on our internal control over financial reporting, including the attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we have initiated the process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we have needed to continue to dedicate internal resources, have engaged outside consultants, and have adopted a detailed work plan to assess and document the adequacy of internal control over financial reporting. We will continue to implement steps to improve control processes as appropriate, validate through testing that controls are functioning as documented, and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that in the future neither we nor our independent registered public accounting firm will be able to conclude within the prescribed timeframe that our internal control over financial reporting is effective as required by Section 404. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

The Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act contains significant corporate governance and executive compensation related provisions that require the SEC to adopt additional rules and regulations in these areas such as “say on pay” and proxy access. Shareholder activism, the current political environment, and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate. Our management and other personnel need to devote a substantial amount of time to these compliance initiatives.

***In the past we have identified a material weakness in our internal control over financial reporting and may identify additional material weaknesses in the future that may cause us to fail to meet our reporting obligations or result in material misstatements in our financial statements. If we identify material weaknesses in the future and fail to remediate such material weaknesses, we may not be able to report our financial results accurately or to prevent fraud.***

Our management is responsible for establishing and maintaining internal control over financial reporting, disclosure controls, and compliance with the other requirements of the Sarbanes-Oxley Act and the rules promulgated by the SEC

thereunder. Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with international financial reporting standards. A material weakness is defined as a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of a company's annual or interim financial statements will not be prevented or detected by the company's internal controls on a timely basis.

Prior to our initial public offering, we operated as a private company that was not required to comply with the obligations of a public company with respect to internal control over financial reporting. We have historically operated with limited accounting personnel and other resources with which to address our internal control over financial reporting.

We and our auditors identified a material weakness in 2019 primarily related to (i) a lack of sufficient accounting and supervisory personnel who have the appropriate level of technical accounting experience and training, (ii) a lack of supervision over external consultants providing technical accounting services and (iii) a lack of consistent application of accounting processes and procedures by our accounting personnel. These deficiencies constitute a material weakness in our internal control over financial reporting in both design and operation. As a result of the material weakness, management failed to identify adjustments in various areas, including but not limited to revenue, capitalization of tangible and intangible assets, and share-based compensation.

If we identify material weaknesses in the future and are unable to successfully remediate such material weaknesses or successfully supervise and rely on outside advisors with expertise in these matters to assist us in the preparation of our financial statements, our financial statements could contain material misstatements that, when discovered in the future, could cause us to fail to meet our future reporting obligations and cause the price of the ADSs to decline.

***As a "foreign private issuer," we are exempt from a number of rules under the U.S. securities laws, as well as Nasdaq rules, and we are permitted to file less information with the SEC than U.S. companies. This may limit the information available to holders of the ADSs and may make our ordinary shares and the ADSs less attractive to investors.***

We are a "foreign private issuer," as defined in the rules and regulations of the SEC, and, consequently, we are not subject to all of the disclosure requirements applicable to companies organized within the United States. For example, we are exempt from certain rules under the U.S. Securities Exchange Act of 1934, as amended, or the Exchange Act, that regulate disclosure obligations and procedural requirements related to the solicitation of proxies, consents or authorizations applicable to a security registered under the Exchange Act. In addition, our officers and directors are exempt from the reporting and "short-swing" profit recovery provisions of Section 16 of the Exchange Act and related rules with respect to their purchases and sales of our securities. Moreover, we are not required to file periodic reports and financial statements with the SEC as frequently or as promptly as U.S. public companies. Accordingly, there may be less publicly available information concerning our company than there is for U.S. public companies.

As a foreign private issuer, we file an Annual Report on Form 20-F within four months of the close of each fiscal year ending December 31 and reports on Form 6-K relating to certain material events promptly after we publicly announce these events. Additionally, we rely on a provision in Nasdaq's Listed Company Manual that allows us to follow German company law and European law applicable to European stock corporations in general, the German Stock Corporation Act (*Aktiengesetz*), the Council Regulation (EC) No 2157/2001 of October 8, 2001 on the Statute for a European company (SE), or the SE Regulation, and the German Act on the Implementation of Council Regulation (EC) No 2157/2001 of October 8, 2001 on the Statute for a European company (SE) (*Gesetz zur Ausführung der Verordnung (EG) NR. 2157/2001 des Rates vom 8. Oktober 2001 über das Statut der Europäischen Gesellschaft (SE)*) (*SE-Ausführungsgesetz-SEAG*), in particular with regard to certain aspects of corporate governance. This allows us to follow certain corporate governance practices that differ in significant respects from the corporate governance requirements applicable to U.S. companies listed on Nasdaq.

For example, we are exempt from regulations of Nasdaq that require a listed U.S. company to:

- have a majority of the board of directors consist of independent directors;
- require non-management directors to meet on a regular basis without management present;
- adopt a code of conduct and promptly disclose any waivers of the code for directors or executive officers that should address certain specified items;
- have an independent compensation committee;

- have an independent nominating committee;
- solicit proxies and provide proxy statements for all shareholder meetings;
- review related party transactions; and
- seek shareholder approval for the implementation of certain equity compensation plans and issuances of ordinary shares.

As a foreign private issuer, we are permitted to follow home country practice in lieu of the above requirements. We therefore continue to follow German corporate governance practices in lieu of the corporate governance requirements of Nasdaq in certain respects. In particular, we follow German corporate governance practices in connection with the distribution of annual and interim reports to shareholders, the application of our code of conduct to our Supervisory Board, proxy solicitation in connection with shareholders' meetings, and obtaining shareholder approval in connection with the establishment of, or material amendment to, certain equity-based compensation plans.

In accordance with our Nasdaq listing, our audit committee is required to comply with the provisions of Section 301 of the Sarbanes-Oxley Act, and Rule 10A-3 of the Exchange Act, both of which are also applicable to U.S. companies listed on Nasdaq. As we are a foreign private issuer, however, our audit committee is not subject to additional requirements of Nasdaq applicable to listed U.S. companies, including an affirmative determination that all members of the audit committee are "independent," using more stringent criteria than those applicable to us as a foreign private issuer.

Due to the above exemptions for foreign private issuers, our shareholders will not be afforded the same protections or information generally available to investors holding shares in public companies organized in the United States, some investors may find the ADSs less attractive as a result, and there may be a less active trading market for the ADSs.

***We face risks related to health epidemics and pandemics, such as COVID-19, that could adversely affect our operations.***

Our business could be adversely impacted by the effects of COVID-19 or other epidemics or pandemics. The COVID-19 pandemic may negatively impact our operations in the future and could also affect our ability to enroll patients in clinical studies and complete clinical trials on the timelines we currently anticipate. Certain of our programs have experienced delays in the clinical development process as a result of the COVID-19 pandemic. In addition, we have modified our business practices, in response to the spread of COVID-19, including restricting employee travel, developing social distancing plans for employees and cancelling physical participation in meetings, events and conferences. This partial disruption, even temporary, may severely impact our operations and overall business by delaying the progress of our clinical trials and preclinical studies. Our operations, including research and manufacturing, could also be disrupted due to the potential impact of staff absences as a result of self-isolation procedures or extended illness.

Our suppliers, licensors or collaborators could also be disrupted by conditions related to COVID-19, or other epidemics, possibly resulting in disruption to our supply chain, clinical trials, partnerships or operations. If our suppliers, licensors, contract research organizations, or CROs, or collaborators are unable or fail to fulfill their obligations to us for any reason, our business could be adversely affected. Our customers could also be disrupted by conditions related to COVID-19 or other epidemics, possibly through deferring purchasing decisions or delaying research programs.

Although we have generated revenues from sales of our COVID-19 vaccine, there remains uncertainty regarding other potential effects of COVID-19 on our business. For example, if a new variant of COVID-19 emerges for which existing vaccines, including our COVID-19 vaccine, are ineffective, infections may become even more widespread or result in an economic downturn that could affect demand for our products and services or our ability to raise capital, which could have a material adverse effect on our business, operating results and financial condition.

***Our insurance policies are expensive and protect us only from some business risks, which leaves us exposed to significant uninsured liabilities.***

We do not carry insurance for all categories of risk that our business may encounter and insurance coverage is becoming increasingly expensive. We do not know if we will be able to maintain existing insurance with adequate levels of coverage, and any liability insurance coverage we acquire in the future may not be sufficient to reimburse us for any expenses or losses we may suffer. We currently maintain insurance coverage for losses relating to an interruption of our development, manufacturing or commercialization efforts caused by contamination in an amount of €50,000,000 per claim up to an aggregate cap of €160,000,000 in any two-year period. With the grant of the first marketing approvals for our

COVID-19 vaccine we have acquired additional insurance coverage for losses relating to transportation of our COVID-19 vaccine and product liability claims arising from its use, and the coverage or coverage limits of our insurance policies may not be adequate. If our losses exceed our insurance coverage, our financial condition would be adversely affected. In the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources. Clinical trials or regulatory approvals for any of our product candidates could be suspended, which could adversely affect our results of operations and business, including by preventing or limiting the development and commercialization of any product candidates that we or our collaborators may develop.

Additionally, operating as a public company has made it more expensive for us to obtain director and officer liability insurance. As a result, it may be more difficult for us to attract and retain qualified individuals to serve on our Supervisory Board, our Management Board, or our board committees.

#### **Risks Related to our Business**

***Our business is dependent on the successful development, regulatory approval and commercialization of product candidates based on our technology platforms. If we and our collaborators are unable to obtain approval for and effectively commercialize our product candidates for the treatment of patients in their intended indications, our business would be significantly harmed.***

Even if we complete the necessary preclinical studies and clinical trials, the marketing approval process is expensive, time-consuming and uncertain, and we may not be able to obtain approvals for the commercialization of product candidates we may develop. Any immunotherapy we may develop and the activities associated with its development and commercialization, including design, testing, manufacture, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and by comparable global health authorities. To obtain the requisite regulatory approvals to commercialize any of our product candidates, we and our collaborators must demonstrate through extensive preclinical studies and clinical trials that our products are safe and effective, including in the target populations. Successful completion of clinical trials is a prerequisite to submitting a biologics license application, or BLA, or a new drug application, or NDA, to the FDA, a Marketing Authorization Application, or MAA, to the EMA, and similar marketing applications to comparable global regulatory authorities, for each product candidate and, consequently, the ultimate approval and commercial marketing of any product candidates.

Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate in a given jurisdiction. Although our COVID-19 vaccine has received emergency use authorization or approval in certain countries, it is possible that it will not receive widespread regulatory approval and that none of our other product candidates, or any product candidates we may seek to develop in the future, will ever obtain regulatory approval. We have limited experience in filing and supporting the applications necessary to gain marketing approvals and may need to rely on third-party CROs, regulatory consultants or collaborators to assist us in this process. Although we expect to submit BLAs for our mRNA-based product candidates in the United States, and in the European Union, mRNA therapies have been classified as gene therapy medicinal products, and other jurisdictions may consider our mRNA-based product candidates to be new drugs, not biologics or gene therapy medicinal products, and require different marketing applications. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Any product candidates we develop may not be effective, may be only moderately effective, or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use.

The process of obtaining marketing approvals in the United States, the European Union and elsewhere, is expensive, may take many years if additional clinical trials are required, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application may cause delays in the approval or rejection of an application. The FDA, EMA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that the data are insufficient for approval and require additional preclinical, clinical or other trials. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable. Additional delays or non-approval may result if an FDA panel of experts, referred to as an Advisory Committee, or other regulatory authority recommends non-approval or restrictions on approval.

In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action, or changes in regulatory agency policy during the period of product development, clinical trials, and the review process.

Regulatory agencies also may approve an immunotherapy for fewer or more limited indications than requested or may grant approval subject to the performance of post-marketing studies. In addition, regulatory agencies may not approve the labeling claims that are necessary or desirable for the successful commercialization of our product candidates.

The FDA, EMA and other regulatory agencies review the Quality or Chemistry, Manufacturing and Controls, or CMC, section of regulatory filings. Any aspects found unsatisfactory by regulatory agencies may result in delays in clinical trials and commercialization. In addition, the regulatory agencies typically conduct pre-approval inspections at the time of a BLA, MAA or comparable filing. Any findings by regulatory agencies and failure to comply with requirements may lead to delay in approval and failure to commercialize the potential mRNA product candidate.

If we experience delays in obtaining, or if we fail to obtain, approval of any product candidates we may develop, the commercial prospects for those product candidates will be harmed, and our ability to generate revenues will be materially impaired. Additionally, even if we are successful in obtaining marketing approval for product candidates, because our preclinical studies and clinical trials have not been designed with specific commercialization considerations, the commercial prospects for those product candidates could be harmed, and our ability to generate revenues could be materially impaired.

***mRNA drug development has substantial clinical development and regulatory risks due to limited regulatory experience with mRNA immunotherapies.***

To our knowledge, other than our COVID-19 vaccine and MRNA-1273, no mRNA immunotherapies have been approved or received emergency use authorization or conditional marketing authorization to date by the FDA, the EMA or other comparable regulatory authority. Successful discovery and development of mRNA-based (and other) immunotherapies by either us or our collaborators is highly uncertain and depends on numerous factors, many of which are beyond our or their control. Our product candidates that appear promising in the early phases of development may fail to advance, experience delays in the clinic or clinical holds, or fail to reach the market for many reasons, including:

- discovery efforts aimed at identifying potential immunotherapies may not be successful;
- nonclinical or preclinical study results may show product candidates to be less effective than desired or have harmful or problematic side effects;
- clinical trial results may show the product candidates to be less effective than expected, including a failure to meet one or more endpoints or have unacceptable side effects or toxicities;
- manufacturing or distribution failures or insufficient supply of GMP materials for clinical trials, or higher than expected cost could delay or set back clinical trials, or make our product candidates commercially unattractive;
- our improvements in the manufacturing processes may not be sufficient to satisfy the clinical or commercial demand of our product candidates or regulatory requirements for clinical trials;
- changes that we make to optimize our manufacturing, testing or formulating of GMP materials could impact the safety, tolerability and efficacy of our product candidates;
- pricing or reimbursement issues or other factors could delay clinical trials or make any immunotherapy uneconomical or noncompetitive with other therapies;
- the failure to timely advance our programs or receive the necessary regulatory approvals, or a delay in receiving such approvals, due to, among other reasons, slow or failure to complete enrollment in clinical trials, withdrawal by trial participants from trials, failure to achieve trial endpoints, additional time requirements for data analysis, data integrity issues, BLA, MAA or the equivalent application, discussions with the FDA or the EMA, a regulatory request for additional nonclinical or clinical data, or safety formulation or manufacturing issues may lead to our inability to obtain sufficient funding; and
- the proprietary rights, products and technologies of our competitors may prevent our immunotherapies from being commercialized.

Currently, mRNA is considered a gene therapy product by the FDA. Unlike certain gene therapies that irreversibly alter cell DNA and may cause certain side effects, mRNA-based medicines are designed not to irreversibly change cell DNA. Side effects observed in other gene therapies, however, could negatively impact the perception of immunotherapies despite the differences in mechanism. In addition, the regulatory pathway in the United States and may other jurisdictions for approval is uncertain. The pathway for an individualized therapy, such as our iNeST mRNA-based immunotherapy where each patient receives a different combination of mRNAs, remains particularly unsettled. The number and design of the clinical and preclinical studies required for the approval of these types of medicines have not been established, may be different from those required for gene therapy products or therapies that are not individualized or may require safety testing like gene therapy products. Moreover, the length of time necessary to complete clinical trials and submit an application for marketing approval by a regulatory authority varies significantly from one pharmaceutical product to the next and may be difficult to predict.

***Our product candidates may not work as intended, may cause undesirable side effects or may have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.***

As with most biological products, use of our product candidates could be associated with side effects or adverse events which can vary in severity from minor reactions to death and in frequency from infrequent to prevalent. The potential for adverse events is especially acute in the oncology setting, where patients may have advanced disease, have compromised immune and other systems and be receiving numerous other therapies. Undesirable side effects or unacceptable toxicities caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA, the EMA or comparable regulatory authorities. Results of our trials could reveal a high and unacceptable severity and prevalence of side effects.

If unacceptable side effects arise in the development of our product candidates, we, the FDA, competent authorities of EU member states, ethics committees, the institutional review boards, or IRBs, at the institutions in which our studies are conducted, or the Data Safety Monitoring Board, or DSMB, could suspend or terminate our clinical trials. The FDA or comparable regulatory authorities could also order us to cease clinical trials or deny approval of our product candidates for any or all targeted indications. Treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete any of our clinical trials or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. We expect to have to train medical personnel using our product candidates to understand the side effect profiles for our clinical trials and upon any commercialization of any of our product candidates. Inadequate training in recognizing or managing the potential side effects of our product candidates could result in patient injury or death. Any of these occurrences may harm our business, financial condition and prospects significantly.

***Monitoring the safety of patients receiving our product candidates is challenging, which could adversely affect our ability to obtain regulatory approval and commercialize our product candidates.***

In our ongoing and planned clinical trials, we have contracted, and are expected to continue to contract, with academic medical centers and hospitals experienced in the assessment and management of toxicities arising during clinical trials. Nonetheless, these centers and hospitals may have difficulty observing patients and treating toxicities, which may be more challenging due to personnel changes, inexperience, shift changes, house staff coverage or related issues. This could lead to more severe or prolonged toxicities or even patient deaths, which could result in us or the FDA, the EMA or other comparable regulatory authority delaying, suspending or terminating one or more of our clinical trials, and which could jeopardize regulatory approval. We also expect the centers using our product candidates, if approved on a commercial basis, could have similar difficulty in managing adverse events. Medicines used at centers to help manage adverse side effects of our product candidates may not adequately control the side effects and may have a detrimental impact on the efficacy of the treatment. Use of these medicines may increase with new physicians and centers administering our product candidates.

In addition, even if we successfully advance one of our product candidates into and through clinical trials, such trials will likely only include a limited number of patients and limited duration of exposure to our product candidates. As a result, we cannot be assured that adverse effects of our product candidates will not be uncovered when a significantly larger number of patients are exposed to the product candidate. Further, any clinical trials may not be sufficient to determine the effects and safety consequences of taking our product candidates over a multi-year period.

If any of our product candidates receives marketing approval and we or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw their approval of the product;
- we may be required to recall a product or change the way such product is administered to patients;
- additional restrictions may be imposed on the marketing of the particular product or the manufacturing processes for the product or any component thereof;
- regulatory authorities may require the addition of labeling statements, such as a “black box” warning or a contraindication;
- we may be required to implement a Risk Evaluation and Mitigation Strategy, or REMS, or create a Medication Guide outlining the risks of such side effects for distribution to patients;
- we could be sued and held liable for harm caused to patients;
- the product may become less competitive; and
- our reputation may suffer.

Any of the foregoing events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and result in the loss of significant revenues to us, which would materially and adversely affect our results of operations and business. In addition, if one or more of our product candidates or our immunotherapy approach generally prove to be unsafe, our technology platforms and pipeline could be affected, which would have a material and adverse effect on our business, financial condition, results of operations and prospects.

***Preclinical development is uncertain. Our preclinical programs may experience delays or may never advance to clinical trials, which would adversely affect our ability to obtain regulatory approvals or commercialize these programs on a timely basis or at all and would have an adverse effect on our business.***

Much of our pipeline is in preclinical development and these programs could be delayed or not advance into the clinic. Before we can initiate clinical trials for product candidates, we must complete extensive preclinical studies, including IND-enabling Good Laboratory Practice toxicology testing, that support our planned Investigational New Drug applications, or INDs, in the United States or similar applications in other jurisdictions. We must also complete extensive work on CMC activities (including collecting yield, purity and stability data) to be included in the IND filing. CMC activities for a new category of medicines such as mRNA therapies require extensive manufacturing processes and analytical development, which are uncertain and lengthy. For instance, batch failures have occurred as we scale up our manufacturing and may occur in the future. In addition, we have had in the past, and may in the future have, difficulty identifying appropriate buffers and storage conditions to enable sufficient shelf life of batches of our preclinical or clinical product candidates. If we are required to produce new batches of our product candidates due to insufficient shelf life, it may delay the commencement or completion of preclinical or clinical trials of such product candidates. For example, we cannot be certain of the timely completion or outcome of our preclinical testing and studies and cannot predict if the FDA or other regulatory authorities will accept the results of our preclinical testing or our proposed clinical programs or if the outcome of our preclinical testing, studies and CMC activities will ultimately support the further development of our programs. As a result, we cannot be sure that we will be able to submit INDs or similar applications for our preclinical programs on the timelines we expect, if at all, and we cannot be sure that submission of INDs or similar applications will result in the FDA or other regulatory authorities allowing clinical trials to begin.

***Clinical development involves a lengthy and expensive process with an uncertain outcome, and delays can occur for a variety of reasons outside of our control. Clinical trials of our product candidates may be delayed, and certain programs may never advance in the clinic or may be more costly to conduct than we anticipate, any of which can affect our ability to fund our company and would have a material adverse impact on our business.***

Clinical testing is expensive and complex and can take many years to complete. Its outcome is inherently uncertain. We may not be able to initiate, may experience delays in, or may have to discontinue clinical trials for our product candidates. We and our collaborators also may experience numerous unforeseen events during, or as a result of, any clinical trials that we or our collaborators conduct that could delay or prevent us or our collaborators from successfully developing our product candidates, including:

- the FDA, other regulators, IRBs or ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site for any number of reasons, including concerns regarding safety and aspects of the clinical trial design;
- we may experience delays in reaching, or fail to reach, agreement on favorable terms with prospective trial sites and prospective CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- we have optimized in the past and may in the future optimize our manufacturing processes, including through changes to the scale and site of manufacturing, which may lead to additional studies (including bridging and bioequivalence studies) or potentially significant changes in our clinical trial designs, requiring additional cost and time, and, as a consequence, lead to a delay in plans for progressing one or more product candidates;
- the outcome of our preclinical studies and our early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results;
- we may be unable to establish clinical endpoints that applicable regulatory authorities would consider clinically meaningful;
- in an effort to optimize product features, we have made in the past and may continue to make changes to our product candidates after we commence clinical trials of a medicine which may require us to repeat earlier stages of clinical testing or delay later-stage testing of the medicine;
- clinical trials of any product candidates may fail to show safety or efficacy, or may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional nonclinical studies or clinical trials, or we may decide to abandon product development programs;
- differences in trial design between early-stage clinical trials and later-stage clinical trials may make it difficult to extrapolate the results of earlier clinical trials to later clinical trials;
- preclinical and clinical data are often susceptible to varying interpretations and analyses, and many product candidates believed to have performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval;
- our product candidates may have undesirable side effects or other unexpected characteristics. One or more of such effects or events could cause regulators to impose a clinical hold on the applicable trial, or cause us or our investigators, IRBs or ethics committees to suspend or terminate the trial of that product candidate or any other of our product candidates for which a clinical trial may be ongoing;
- the number of trial participants required for clinical trials of any product candidates may be larger than we anticipate, identification of trial participants for such trials may be limited, enrollment in these clinical trials may be slower than we anticipate due to perceived adverse effects, limited patient populations, competitive trials or other reasons, or participants may withdraw from clinical trials or fail to return for post-treatment follow-up at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, or may deviate from the clinical trial protocol or withdraw from the trial, which may require that we add new clinical trial sites;
- regulators may elect to impose a clinical hold, or we, our investigators, IRBs or ethics committees may elect to suspend or terminate clinical research or trials for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to an unacceptable benefit-risk ratio;
- with respect to infectious disease vaccine trials in particular, we have to wait for particular level of infection in the placebo arm in order to assess protection provided by vaccine, and we cannot control the rate of exposure or infection which can make timing uncertain;
- the cost of preclinical or nonclinical testing and studies and clinical trials of any product candidates may be greater than we anticipate;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials may be insufficient or inadequate;



- safety or efficacy concerns regarding our product candidates may result from any concerns arising from nonclinical or clinical testing of other therapies targeting a similar disease state or other therapies, such as gene therapy, that are perceived as similar to ours; and
- the FDA or other regulatory authorities may require us to submit additional data, such as long-term toxicology studies, or impose other requirements before permitting us to initiate a clinical trial.

We could also encounter delays if a clinical trial is suspended or terminated by us, the FDA or other regulatory authorities, ethics committees, or the IRBs of the institutions in which such trials are being conducted, or if such trial is recommended for suspension or termination by the DSMB. We may in the future be delayed in gaining clearance from the FDA or other regulators to initiate clinical trials through, among other things, the imposition of a clinical hold in order to address comments from such regulators on our clinical trial design or other elements of our clinical trials. A suspension or termination may be imposed due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols; inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold; unforeseen safety issues or adverse side effects; failure to demonstrate a benefit, or adequate benefit-risk ratio, from using a product candidate; failure to establish or achieve clinically meaningful trial endpoints; changes in governmental regulations or administrative actions; or lack of adequate funding to continue the clinical trial. Many of the factors that cause or lead to a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. We could also experience delays if physicians encounter unresolved ethical issues associated with enrolling patients in clinical trials of our product candidates in lieu of prescribing existing treatments that have established safety and efficacy profiles. We must also complete extensive work on CMC activities that require extensive manufacturing processes and analytical development, which are uncertain and lengthy.

We expect the novel nature of our product candidates to create further challenges in obtaining regulatory approval. For example, the FDA and regulatory authorities in other jurisdictions have limited experience with commercial development of several of our technologies. The FDA may require an Advisory Committee to deliberate on the adequacy of the safety and efficacy data to support licensure. The opinion of the Advisory Committee, although not binding, may have a significant impact on our ability to obtain licensure of the product candidates based on the completed clinical trials, as the FDA often adheres to the Advisory Committee's recommendations. Accordingly, the regulatory approval pathway for our product candidates may be uncertain, complex, expensive and lengthy, and approval may not be certain.

Moreover, the FDA and other regulatory authorities have indicated that, prior to commencing later stage clinical trials for our mRNA-based product candidates, we will need to scale up and further refine assays to measure and predict the potency of a given dose of these product candidates. Any delay in the scaling and refining of assays that are acceptable to the FDA or other regulatory authorities could delay the start of future clinical trials. Further, the FDA or other regulatory authorities may disagree with our clinical trial design and our interpretation of data for our clinical trials or may change the requirements for approval even after they have reviewed and commented on the design for our clinical trials.

Significant preclinical or nonclinical testing and studies or clinical trial delays for our product candidates also could allow our competitors to bring products to market before we do, potentially impairing our ability to successfully commercialize our product candidates and harming our business and results of operations. Any delays in the development of our product candidates may harm our business, financial condition and prospects significantly.

***If we or our collaborators encounter difficulties enrolling participants in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.***

We depend on enrollment of participants in our clinical trials for our product candidates. In the past, our collaborators have found, and we or our collaborators may in the future find, it difficult to enroll trial participants in our clinical studies, which could delay or prevent clinical studies of our product candidates. The COVID-19 pandemic has introduced additional challenges in enrolling patients into many of our clinical trials. Identifying and qualifying trial participants to participate in clinical studies of our product candidates is critical to our success. The timing of our clinical studies depends on the speed at which we can recruit trial participants to participate in testing our product candidates. Delays in enrollment may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our product candidates. If trial participants are unwilling to participate in our studies because of negative publicity from adverse events in our trials or other trials of similar products, or those related to specific a therapeutic area, or for other reasons, including competitive clinical studies for similar patient populations, the timeline for recruiting trial participants, conducting studies, and obtaining regulatory

approval of potential products may be delayed. These delays could result in increased costs, delays in advancing our product development, delays in testing the effectiveness of our product, or termination of the clinical studies altogether.

We may not be able to identify, recruit and enroll a sufficient number of trial participants, or those with required or desired characteristics to achieve diversity in a study, to complete our clinical trials in a timely manner. Patient and subject enrollment is affected by factors including:

- severity of the disease under investigation;
- complexity and design of the study protocol;
- size of the patient population;
- eligibility criteria for the study in question;
- proximity and availability of clinical study sites for prospective trial participants;
- availability of competing therapies and clinical trials, including between our own clinical trials;
- efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians;
- ability to monitor trial participants adequately during and after treatment;
- ability to recruit clinical trial investigators with the appropriate competencies and experience;
- clinicians' and trial participants' perceptions of the potential advantages and side effects of the product candidate being studied in relation to other available therapies, including any new drugs or treatments that may be approved for the indications we are investigating;
- our ability to obtain and maintain participant informed consent;
- impacts of the COVID-19 global pandemic; and
- the risk that trial participants enrolled in clinical trials will not complete a clinical trial.

In addition, our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of trial participants available to us because some trial participants who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by a third party. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of trial participants who are available for our clinical trials at such clinical trial sites. Moreover, because in some cases our product candidates represent a departure from more traditional methods for disease treatment and prevention, potential trial participants and their doctors may be inclined to use conventional therapies or other new therapies rather than enroll trial participants in any future clinical trial involving individualized product candidates. Additionally, if new product candidates, such as gene editing therapies, show encouraging results, potential trial participants and their doctors may be inclined to enroll trial participants in clinical trials using those product candidates. If such new product candidates show discouraging results or other adverse safety indications, potential trial participants and their doctors may be less inclined to enroll trial participants in our clinical trials.

In particular, certain conditions for which we plan to evaluate our current product candidates are rare diseases with limited patient pools from which to draw for clinical trials. The eligibility criteria of our clinical trials will further limit the pool of available trial participants. Additionally, the process of finding and diagnosing patients may prove costly. As discussed above, each of the foregoing risks is exacerbated by the COVID-19 pandemic currently affecting the global community and the global economy.

***A variety of risks associated with conducting research and clinical trials abroad and marketing our product candidates internationally could materially adversely affect our business.***

Clinical trials of our product candidates are currently being conducted in several countries, and we plan to commercialize our product candidates, if approved, globally. Accordingly, we are subject to additional risks related to operating in multiple countries, including:

- differing regulatory requirements in such countries;

- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- increased difficulties in managing the logistics and transportation of storing and shipping product candidates produced in Germany and shipping the product candidate to the patient abroad;
- import and export requirements and restrictions;
- economic weakness, including inflation, or political instability in particular economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- taxes, including withholding of payroll taxes;
- currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing operations outside of Germany;
- workforce uncertainty in countries where labor unrest is more common;
- differing payor reimbursement regimes, governmental payors or patient self-pay systems, and price controls;
- potential liability under the U.S. Foreign Corrupt Practices Act of 1977 or comparable regulations in other jurisdictions;
- challenges enforcing our contractual and intellectual property rights, especially in those countries that do not respect and protect intellectual property rights to the same extent as Germany and the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or public health epidemics or pandemics.

The extent to which the COVID-19 pandemic continues to impact our operations, including our clinical trial operations, will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the duration of the outbreak, new information which may emerge concerning the severity of the coronavirus and the actions to contain the coronavirus or treat its impact, among others. In the future, similar events could affect our ability to manufacture and commercialize our product candidates.

These and other risks associated with our international operations and our collaborations with our collaborators may materially adversely affect our ability to attain or maintain profitable operations.

***Interim top-line and preliminary data from studies or trials that we announce or publish from time to time may change as more data become available and are subject to audit and verification procedures that could result in material changes in the final data.***

From time to time, we may publish interim top-line or preliminary data from preclinical studies or clinical trials. Interim data are subject to the risk that one or more of the outcomes may materially change as more data become available. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully evaluate all data. As a result, the top-line results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Preliminary or top-line data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Additionally, interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to disclose publicly regarding a particular study or clinical trial is based on what is typically extensive information, and our securityholders may not agree with what we determine is the material or

otherwise appropriate information to include in our disclosure. Any information we determine not to disclose may ultimately be deemed significant by our securityholders or others with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate or our business. If the top-line data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, product candidates may be harmed, which could significantly harm our business prospects.

***Results of earlier studies and trials of our product candidates may not be predictive of future trial results.***

Success in preclinical studies and early clinical trials does not ensure that later clinical trials will be successful. A number of companies in the biotechnology and pharmaceutical industries have suffered significant setbacks in clinical trials, even after positive results in earlier preclinical studies or clinical trials. These setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway and safety or efficacy observations made in clinical trials, including previously unreported adverse events. Notwithstanding any potential promising results in earlier studies and trials, we cannot be certain that we will not face similar setbacks. Even if our clinical trials are completed, the results may not be sufficient to obtain regulatory approval for our product candidates. In addition, the results of our preclinical studies may not be predictive of the results of outcomes in human clinical trials. For example, our tumor-specific cancer immunotherapy candidates and any future product candidates may demonstrate different chemical, biological and pharmacological properties in patients than they do in laboratory studies or may interact with human biological systems in unforeseen or harmful ways. Product candidates in later stages of clinical trials may fail to show the desired pharmacological properties or safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. Even if we are able to initiate and complete clinical trials, the results may not be sufficient to obtain regulatory approval for our product candidates.

***Our planned clinical trials or those of our collaborators may reveal significant adverse events not seen in our preclinical or nonclinical studies and may result in a safety profile that could delay or terminate clinical trials, or delay or prevent regulatory approval or market acceptance of any of our product candidates.***

There is typically an extremely high rate of attrition for product candidates across categories of medicines proceeding through clinical trials.

These product candidates may fail to show the desired safety and efficacy profile in later stages of clinical trials despite having progressed through nonclinical studies and initial clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in later-stage clinical trials due to lack of efficacy or unacceptable safety profiles, notwithstanding promising results in earlier trials. Most product candidates that commence clinical trials are never approved as products and there can be no assurance that any of our current or future clinical trials will ultimately be successful or support further clinical development of any of our product candidates.

Some of our product candidates are being developed or are intended to be co-administered with other developmental therapies or approved medicines. For example, autogene cevumeran (BNT122) is being developed to be co-administered with checkpoint inhibitors. Such combinations may have additional side effects, which may be difficult to predict in future clinical trials.

If significant adverse events or other side effects are observed in any of our current or future clinical trials, we may have difficulty recruiting trial participants to any of our clinical trials, trial participants may withdraw from trials, or we may be required to abandon the trials or our development efforts of one or more product candidates altogether. We, the FDA or other regulatory authorities, ethics committees or an IRB may impose a clinical hold on, or suspend or terminate, clinical trials of a product candidate at any time for various reasons, including a belief that participants in such trials are being exposed to unacceptable health risks or adverse side effects. Some potential therapeutics developed in the biotechnology industry that initially showed therapeutic promise in early-stage trials have later been found to cause side effects that prevented their further development. Even if the side effects do not preclude the drug from obtaining or maintaining marketing approval, an unfavorable benefit-risk ratio may inhibit market acceptance of the approved product due to its tolerability versus other therapies. Any of these developments could materially harm our business, financial condition and prospects.

*If we are not successful in discovering, developing and commercializing additional product candidates beyond our current portfolio, our ability to expand our business and achieve our strategic objectives would be impaired.*

Although a substantial amount of our efforts will focus on the clinical trials and potential approval of our existing product candidates, a key element of our strategy is to discover, develop and potentially commercialize additional products beyond our current portfolio to treat various conditions and in a variety of therapeutic areas. We intend to do so by investing in our own drug and target discovery efforts, exploring potential collaborations for the development of new products, and in-licensing technologies. Identifying new product candidates requires substantial technical, financial and human resources, whether or not any product candidates are ultimately identified. Even if we identify product candidates that initially show promise, we may fail to develop and commercialize such products successfully for many reasons, including the following:

- the research methodology used may not be successful in identifying potential product candidates;
- competitors may develop alternatives that render our product candidates obsolete;
- product candidates we develop may nevertheless be covered by third parties' patents or other exclusive rights;
- a product candidate may, on further study, be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and
- an approved product may not be accepted as safe and effective by trial participants, the medical community or third-party payors.

If we are unsuccessful in identifying and developing additional products, our potential for growth may be impaired.

***Our future success depends on our ability to retain key employees, consultants and advisors and to attract, retain and motivate qualified senior management and scientific personnel.***

Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We are highly dependent upon members of our management and scientific teams. We may not be able to retain these persons due to the competitive environment in the biotechnology industry. The loss of any of these persons' services may adversely impact the achievement of our research, development, financing and commercialization objectives. We currently do not have "key person" insurance on any of our employees.

In addition, we rely on consultants, contractors and advisors, including scientific and clinical advisors, to assist us in formulating our research and development, regulatory approval and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. The loss of the services of one or more of our current employees or advisors might impede the achievement of our research, development, regulatory approval and commercialization objectives. In addition, we have flexibly grown our workforce through the use of contractors and part-time workers. We may not be able to retain the services of such personnel, which might result in delays in the operation of our business.

Recruiting and retaining other qualified employees, consultants and advisors for our business, including scientific and technical personnel, will be critical to our success as well. Competition for skilled personnel, including in mRNA research, clinical operations, regulatory affairs, therapeutic area management and manufacturing, is intense and the turnover rate can be high. We may not be able to attract and retain personnel on favorable terms given the competition among numerous pharmaceutical and biotechnology companies and academic institutions for individuals with similar skill sets. In addition, adverse publicity, failure to succeed in preclinical studies or clinical trials or applications for marketing approval may make it more challenging to recruit and retain qualified personnel. The inability to recruit, or loss of services of certain executives, key employees, consultants or advisors, may impede the progress of our research, development and commercialization objectives and have a material adverse impact on our business, financial condition, results of operations and prospects.

***Our employees, principal investigators and consultants may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading, which could have an adverse effect on the results of our operations.***

We are exposed to the risk of fraud or other misconduct by our employees, principal investigators and consultants. Misconduct by these parties could include intentional failures to comply with FDA regulations or the regulations applicable in the European Union and other jurisdictions, provide accurate information to the FDA, the EMA and other regulatory authorities, comply with healthcare fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately or disclose unauthorized activities to us. Such misconduct also could involve the improper use of information obtained in the course of clinical trials or interactions with the FDA or other regulatory authorities, which could result in regulatory sanctions and cause serious harm to our reputation. We have adopted a code of conduct applicable to all of our employees, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from government investigations or other actions or lawsuits stemming from a failure to comply with laws or regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, financial condition, results of operations and prospects, including the imposition of significant fines or other sanctions.

***Employee litigation and unfavorable publicity could negatively affect our future business.***

From time to time our employees may bring lawsuits against us regarding injury, creating a hostile work place, discrimination, wage and hour disputes, sexual harassment or other employment issues. In recent years, there has been an increase in the number of discrimination and harassment claims generally. Coupled with the expansion of social media platforms and similar devices that allow individuals access to a broad audience, these claims have had a significant negative impact on some businesses. Certain companies that have faced employment- or harassment- related lawsuits have had to terminate management or other key personnel, and have suffered reputational harm that has negatively impacted their business. If we were to face any employment-related claims, our business could be negatively affected.

***We and our collaborators or other contractors or consultants depend on information technology systems, and any failure of these systems could harm our business. Security breaches, loss of data and other disruptions could compromise sensitive information related to our business or prevent us from accessing critical information and expose us to liability, which could adversely affect our business, results of operations and financial condition.***

Our internal computer systems and those of our current and any future collaborators, vendors, and other contractors or consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, cybersecurity threats, war, and telecommunication and electrical failures. If any such material system failure, accident or security breach were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other proprietary information or other similar disruptions. For example, the loss of clinical trial data from one or more ongoing or completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. In addition, because of our approach to running multiple clinical trials in parallel, any breach of our computer systems may result in a loss of data or compromised data integrity across many of our programs in many stages of development. Any such breach, loss or compromise of clinical trial participant personal data may also subject us to civil fines and penalties, including under the EU General Data Protection Regulation, or the GDPR, relevant law of an EU member state, HIPAA, and other relevant state and federal privacy laws in the United States. To the extent that any disruption or security breach were to result in a loss of, or damage to, data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, our competitive position could be harmed and the further development and commercialization of our product candidates could be delayed.

While we have not experienced any material system failures, accidents or security breaches to date, we and a vendor have separately in the past been subject to a security breach resulting in us unknowingly making payments to third parties that were able to gain unauthorized access to our and the vendor's email systems. Additionally, in December 2020, we were informed by the EMA that the agency was subject to a cyber attack and that some documents relating to our regulatory submission for our COVID-19 vaccine candidate, which was stored on an EMA server, had been unlawfully accessed. None of our systems were breached in connection with this incident and we are unaware that any study participants were identified through the data being accessed.

We have put systems and procedures in place to minimize the likelihood of such incidents reoccurring; however, we cannot guarantee that third parties will not be able to gain unauthorized access to or otherwise breach our systems in the

future. Any such unauthorized access or breach could adversely affect our business, results of operations and financial condition.

***Our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.***

We recognize the need for, and are in the early stages of, developing disaster recovery, business continuity and document retention plans that would allow us to be operational despite casualties or unforeseen events impacting our corporate headquarters or distribution center. Without disaster recovery, business continuity and document retention plans, if we encounter difficulties or disasters with our manufacturing facilities or at our corporate headquarters, our critical systems, operations and information may not be restored in a timely manner, or at all, and this could have an adverse effect on our business.

***Product liability lawsuits against us could cause us to incur substantial liabilities and could limit commercialization of our current or future product candidates.***

We face an inherent risk of product liability exposure related to the testing of any of our current or future product candidates in clinical trials, and an even greater risk related to any commercialized products, such as our COVID-19 vaccine. If we cannot successfully defend ourselves against claims that our product candidates caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidate that we may develop;
- loss of revenue;
- substantial monetary awards to patients, healthy volunteers or their children;
- significant time and costs to defend the related litigation;
- withdrawal of clinical trial participants;
- the inability to commercialize any product candidates that we may develop; and
- injury to our reputation and significant negative media attention.

We carry clinical trial insurance, including product liability insurance, which we believe to be sufficient in light of our current commercial operations and clinical programs; however, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. We have expanded our insurance coverage to include product liability claims arising from the use of BNT162b2; however, the amount of coverage we have obtained may not be adequate, and we may be unable to maintain product liability insurance for our COVID-19 vaccine on commercially reasonable terms in the future. On occasion, large judgments have been awarded in class action lawsuits based on drugs or medical treatments that had unanticipated adverse effects. A successful product liability claim or series of claims brought against us could cause the price of the ADS to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business.

***If our products become subject to a product recall it could harm our reputation, business and financial results.***

The FDA and similar governmental authorities in other jurisdictions have the authority to require the recall of certain commercialized products. In the case of the FDA, the authority to require a recall of a biologic product must be based on an FDA finding that a batch, lot or other quantity of the biologic product presents an imminent or substantial hazard to the public health. In addition, some governmental bodies outside the United States have the authority to require the recall of any product candidate in the event of material deficiencies or defects in design or manufacture. Manufacturers may, under their own initiative, recall a product if any material deficiency in a product is found. A government-mandated or voluntary recall by us could occur as a result of manufacturing errors, design or labeling defects or other deficiencies and issues.

Recalls of any of our product candidates would divert managerial and financial resources and have an adverse effect on our financial condition and results of operations. A recall announcement could harm our reputation with customers and negatively affect our sales, if any.

***Risks Related to the Manufacturing of our COVID-19 vaccine, our Product Candidates and Future Pipeline***

***Our mRNA product candidates are based on novel technologies and any product candidates we develop may be complex and difficult to manufacture. We may encounter difficulties in manufacturing, product release, shelf life, testing, storage, supply chain management or shipping. If we or any of the third-party manufacturers we work with***

*encounter such difficulties, our ability to supply materials for clinical trials or any approved product could be delayed or stopped.*

The manufacturing processes for our COVID-19 vaccine and our product candidates are novel and complex. Due to the novel nature of this technology and limited experience at larger scale production, we may encounter difficulties in manufacturing, product release, shelf life, testing, storage and supply chain management, or shipping. These difficulties could be due to any number of reasons including, but not limited to, complexities of producing batches at larger scale, equipment failure, choice and quality of raw materials and excipients, analytical testing technology, and product instability. In an effort to optimize product features, we have in the past and may in the future make changes to our product candidates in their manufacturing and stability formulation and conditions. This has resulted in the past, and may in the future result, in our having to resupply batches for preclinical, clinical, or commercial activities when there is insufficient product stability during storage and insufficient supply. Insufficient stability or shelf life of our product candidates could materially delay our or our collaborators' ability to continue the clinical trial for that product candidate or require us to begin a new clinical trial with a newly formulated drug product, due to the need to manufacture additional preclinical, clinical or commercial supply.

For example, in March 2021 we received product quality complaints related to our COVID-19 vaccine in Hong Kong. A thorough investigation into these complaints concluded that the reported product quality complaints were due to the combination of a deficient container closure process, or crimping, at one specific contract manufacturing organization when such containers were later shipped at ultra-cold conditions created by shipping on dry ice. The investigation did not identify any safety issues related to the product quality complaints. We and our COVID-19 vaccine in Hong Kong are in the process of supplying Hong Kong with replacement COVID-19 vaccine vials.

Our rate of innovation is high, which has resulted in, and will continue to cause a high degree of, technology change that can negatively impact product comparability during and after clinical development. Furthermore, technology changes may drive the need for changes in, modification to, or the sourcing of, new manufacturing infrastructure or may adversely affect third-party relationships.

The process to generate mRNA medicines is complex and, if not developed and manufactured under well-controlled conditions, can adversely impact pharmacological activity. We may encounter difficulties in scaling up our manufacturing process, thereby potentially impacting clinical and commercial supply. Additionally, for individualized therapies, we may encounter issues with our ability to timely and efficiently manufacture product given the on-demand requirements of such therapies, thereby potentially impacting clinical and commercial supply.

As we continue developing new manufacturing processes for our drug substance and drug product, the changes we implement to the manufacturing process may impact, in turn, specification and stability of the drug product. Changes in our manufacturing processes may lead to failure of lots and this could lead to a substantial delay in our clinical trials or an inability to supply sufficient commercial quantities of drug product. Our mRNA product, if approved, and product candidates may prove to have a stability profile that leads to an unfavorable shelf life. This poses risk in supply requirements, wasted stock and higher cost of goods.

*We are dependent on a number of equipment providers who are also implementing novel technology. Further, we have developed our own custom manufacturing equipment for certain of our product candidates. If such equipment malfunctions or we encounter unexpected performance issues, we could encounter delays or interruptions to clinical and commercial supply.*

Due to the number of different programs, we may have cross contamination of products inside of our factories, CROs, suppliers or in the clinic that affect the integrity of our products. Additionally, for some programs the manufacturing scale is extremely small compared to the standard volumes of supply, such that we run the risk of contaminating the process each time we reopen a container to use remaining supplies.

As we scale the manufacturing output for particular programs, we plan to continuously improve yield, purity and the pharmaceutical properties of our product candidates from IND-enabling studies through commercial launch, including shelf life stability and solubility properties of drug product and drug substance. Due to continuous improvement in manufacturing processes, we may switch processes for a particular program during development. However, after the change in process, more time is required for pharmaceutical property testing, such as six- or 12- month stability testing. That may require resupplying clinical material, or making additional GMP batches to keep up with clinical trial demand before such pharmaceutical property testing is completed.



We are utilizing a number of raw materials and excipients that are either new to the pharmaceutical industry or are being employed in a novel manner. Some of these raw materials and excipients have not been scaled to a level to support commercial supply and could experience unexpected manufacturing or testing failures, or supply shortages. Such issues with raw materials and excipients could cause delays or interruptions to clinical and commercial supply of our COVID-19 vaccine and our product candidates. Further, now and in the future, one or more of our programs may have a single source of supply for raw materials and excipients.

We have established a number of analytical assays, and may have to establish several more, to assess the quality of our mRNA product candidates. We may identify gaps in our analytical testing strategy that might prevent release of product or could require product withdrawal or recall. For example, we may discover new impurities that have an impact on product safety, efficacy or stability. This may lead to an inability to release mRNA product candidates until the manufacturing or testing process is rectified.

Our product and product intermediates are extremely temperature sensitive, and we may learn that any or all of our products are less stable than desired. We may also find that transportation conditions negatively impact product quality. This may require changes to the formulation or manufacturing process for one or more of our product candidates and result in delays or interruptions to clinical or commercial supply. In addition, the cost associated with such transportation services and the limited pool of vendors may also add additional risks of supply disruptions.

***Certain of our product candidates are uniquely manufactured for each patient and we may encounter difficulties in production, particularly with respect to scaling our manufacturing capabilities. If we or any of the third-party manufacturers with whom we contract encounter these types of difficulties, our ability to provide our product candidates for clinical trials or our products for patients, if approved, could be delayed or stopped, or we may be unable to maintain a commercially viable cost structure.***

We custom design and manufacture certain product candidates that are unique and tailored specifically for each patient. Manufacturing unique lots of these product candidates is susceptible to product loss or failure due to issues with:

- logistics associated with the collection of a patient's tumor, blood or other tissue sample;
- shipping such samples to a facility for genetic sequencing;
- next-generation sequencing of the tumor mRNA;
- biopsy of a sufficient quantity of cancerous tissue to allow for proper sequencing and identification of tumor-specific mutations;
- identification of appropriate tumor-specific mutations;
- the use of a software program, including proprietary and open source components, which is hosted in the cloud and a part of our product candidate, to assist with the design of the patient-specific mRNA, which software must be maintained and secured;
- effective design of the patient-specific mRNA that encodes for the required neoantigens;
- batch-specific manufacturing failures or issues that arise due to the uniqueness of each patient-specific batch that may not have been foreseen;
- quality control testing failures;
- unexpected failures of batches placed on stability;
- shortages or quality control issues with single-use assemblies, consumables or critical parts sourced from third-party vendors that must be changed out for each patient-specific batch;
- significant costs associated with individualized manufacturing that may adversely affect our ability to continue development;
- successful and timely manufacture and release of the patient-specific batch;
- shipment issues encountered during transport of the batch to the site of patient care;
- the ability to define a consistent safety profile at a given dose when each participant receives a unique treatment; and

- our reliance on single source suppliers.

We also continue to evolve our own custom manufacturing equipment. This equipment may not function as designed, which may lead to deviations in the drug product being produced. This can lead to increased batch failure and the inability to supply patients enrolled in the clinical trial. If our clinical development plans are expanded, due to the custom nature of the equipment and single-use assemblies, we may not be able to supply this expanded need reliably without significant investments. In addition, there will be considerable time to scale up our facilities or build new facilities before we can begin to meet any commercial demand if one or more of our product candidates are approved. This expansion or addition of new facilities could also lead to product comparability issues, which can further delay introduction of new capacity.

As certain of our product candidates are manufactured for each individual patient, we will be required to maintain a chain of identity with respect to each patient's tissue sample, sequence data derived from such tissue sample, analyze results of such patient's genomic analysis and the custom manufactured product for each patient. Maintaining such a chain of identity is difficult and complex, and failure to do so could result in product mix-up, adverse patient outcomes, loss of product, or regulatory action, including withdrawal of any approved products from the market. Further, as our product candidates are developed through early-stage clinical studies to later-stage clinical trials towards approval and commercialization, we expect that multiple aspects of the complicated collection, analysis, manufacture and delivery processes will be modified in an effort to optimize processes and results. These changes may not achieve the intended objectives, and any of these changes could cause our product candidates to perform differently than we expect, potentially affecting the results of clinical trials.

***Our inability to manufacture sufficient quantities of our COVID-19 vaccine or any of our product candidates, or our failure to comply with applicable regulatory requirements, would materially and adversely affect our business.***

Manufacturing is a vital component of our individualized immunotherapy approach, and we have invested significantly in our manufacturing facilities, including the acquisition of a manufacturing site in Marburg, Germany. All internal manufacturing is performed under GMP guidelines. We also rely on a network of external contract manufacturing organizations, or CMOs, for the manufacture of our COVID-19 vaccine. We do not rely on any external CMOs for the manufacture of our product candidates and at this time, and we have limited redundancy among our facilities. Due to the individualized nature of our product candidates, we do not maintain product reserves. If any of our or our external CMOs' manufacturing facilities experience difficulties, including related to manufacturing, product release, shelf life, testing, storage and supply chain management or shipping, our clinical development programs may be delayed or suspended until we or our external CMOs can resume operations. We may also be required to incur significant expenditures to resolve such difficulties.

Our facilities are subject to various regulatory requirements and may be subject to the inspection of the FDA or other regulatory authorities.

If we or our external CMOs cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA, the EMA or comparable regulatory authorities in other jurisdictions, we may not be able to rely on our or our external CMOs' manufacturing facilities for the manufacture of our product candidates. If the FDA, the EMA or another comparable regulatory authority finds our facilities inadequate for the manufacture of our COVID-19 vaccine or our product candidates or if such facilities are subject to enforcement action in the future or are otherwise inadequate, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our COVID-19 vaccine or our product candidates.

Additionally, we may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments. If we were to encounter any of these difficulties, our ability to provide our COVID-19 vaccine or our product candidates to patients in clinical trials, or to provide products for the treatment of patients, once approved, would be jeopardized.

***We are subject to regulatory and operational risks associated with the physical and digital infrastructure at both our internal manufacturing facilities and at those of our external service providers.***

The designs of our facilities are based on current standards for biotechnology facilities. They have been reviewed and approved by local German authorities and have also received GMP manufacturing licenses. We have designed our facilities to incorporate a significant level of automation of equipment with integration of several digital systems to improve efficiency of operations. We have attempted to achieve a high level of digitization for clinical manufacturing facilities relative to industry standards. While this is meant to improve operational efficiency, this may pose additional risk of

process equipment malfunction and even overall manufacturing system failure or shutdown due to internal or external factors including, but not limited to, design issues, system compatibility or potential cybersecurity breaches. This may lead to delay in supply or shutdown of our facilities. Any disruption in our manufacturing capabilities could cause delays in our production capacity for our drug substances or drug products, impose additional costs, or may require us to identify, qualify and establish an alternative manufacturing site, the occurrence of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

As we expand our development and commercial capacity, we may establish additional manufacturing capabilities and expand to other locations or geographies, which may lead to regulatory delays or prove costly. If we fail to select the correct location, complete the construction in an efficient manner, recruit the required personnel, and generally manage our growth effectively, the development and production of our product candidates could be delayed or curtailed. Additional investments may be needed if changes in our manufacturing process lead to required changes in our infrastructure.

***Our COVID-19 vaccine and certain of our product candidates rely on the availability of specialty raw materials, which may not be available to us on acceptable terms or at all.***

Our product candidates require many specialty raw materials, some of which are manufactured by small companies with limited resources and experience to support a commercial product, and the suppliers may not be able to deliver raw materials to our specifications. In addition, some such suppliers normally support blood-based hospital businesses and generally do not have the capacity to support commercial products manufactured under GMP by biopharmaceutical firms. These suppliers may be ill-equipped to support our needs, especially in non-routine circumstances like an FDA inspection or medical crisis, such as widespread contamination. We also do not have contracts with many of these suppliers, and we may not be able to contract with them on acceptable terms or at all. Accordingly, we have experienced and we may in the future experience delays in receiving key raw materials to support clinical or commercial manufacturing.

In addition, some raw materials are currently available from a single supplier, or a small number of suppliers. We cannot be sure that these suppliers will remain in business or that they will not be purchased by one of our competitors or another company that is not interested in continuing to produce these materials for our intended purpose. In addition, the lead time needed to establish a relationship with a new supplier can be lengthy, and we may experience delays in meeting demand in the event we must switch to a new supplier. The time and effort to qualify a new supplier could result in additional costs, diversion of resources or reduced manufacturing yields, any of which would negatively impact our operating results. Further, we may be unable to enter into agreements with a new supplier on commercially reasonable terms, which could have a material adverse impact on our business.

***We are subject to significant regulatory oversight with respect to manufacturing our product candidates. Our manufacturing facilities or the manufacturing facilities of our third-party manufacturers or suppliers may not meet regulatory requirements. Failure to meet GMP requirements set forth in regulations promulgated by the FDA, the EMA and other comparable regulatory authorities could result in significant delays in and costs of our products.***

The manufacturing of immunotherapies for clinical trials or commercial sale is subject to extensive regulation. GMP requirements govern manufacturing processes and procedures, including record-keeping, and the implementation and operation of quality systems to control and assure the quality of products and materials used in our products and product candidates. Poor control of the GMP production processes can lead to product quality failures that can impact our ability to supply product, resulting in loss of potential product sales revenue, cost overruns and delays to clinical timelines for our clinical programs, which could be extensive. Such production process issues include but are not limited to:

- critical deviations in the manufacturing process;
- facility and equipment failures;
- contamination of the product due to an ineffective quality control strategy;
- facility contamination as assessed by the facility and utility environmental monitoring program;
- ineffective process, equipment or analytical change management, resulting in failed lot release criteria;
- raw material failures due to ineffective supplier qualification or regulatory compliance issues at critical suppliers;
- ineffective product stability;
- failed lot release or facility and utility quality control testing;

- ineffective corrective actions or preventative actions taken to correct or avoid critical deviations due to our developing understanding of the manufacturing process as we scale; and
- failed or defective components or consumables.

We must supply all necessary documentation in support of a BLA or other marketing authorization application on a timely basis and must adhere to the FDA's, the EMA's and other countries' GMP requirements, which are enforced, in the case of the FDA, in part through its facilities inspection program.

Regulatory authorities typically require representative manufacturing site inspections to assess adequate compliance with GMPs and manufacturing controls as described in the filing. If either we or one of our third-party manufacturing sites fails to provide sufficient quality assurance or control, approval to commercialize our product candidates may not be granted. Inspections by regulatory authorities may occur at any time during the development or commercialization phase of products. The inspections may be product-specific or facility-specific for broader GMP inspections or as a follow up to market or development issues that the regulatory agency may identify. Deficient inspection outcomes may influence the ability of our third-party manufacturers or suppliers to fulfill their supply obligations, impacting or delaying supply or delaying programs.

The manufacturing process for any products that we may develop is subject to the FDA's, the EMA's and other regulatory authorities' approval processes, and we may need to contract with manufacturers who we believe can meet applicable regulatory authority requirements on an ongoing basis. If we or our third-party manufacturers are unable to reliably produce product candidates to specifications acceptable to the FDA, the EMA or other regulatory authorities, we or our collaborators may not obtain or maintain the approvals we or they need to commercialize such products. Even if we or our collaborators obtain regulatory approval for any of our immunotherapies, there is no assurance that either we or our CMOs will be able to manufacture our product candidates to specifications acceptable to the FDA, the EMA or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product, or to meet potential future demand. Any of these challenges could delay completion of clinical trials, require bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates, impair commercialization efforts or increase our cost of goods. The occurrence of any of the foregoing could have an adverse effect on our business, financial condition, results of operations and growth prospects.

In addition, we may not have direct control over the ability of our CMOs to maintain adequate quality control, quality assurance and qualified personnel. Furthermore, all of our CMOs are engaged with other companies to supply or manufacture materials or products for such companies, which exposes our CMOs to regulatory risks for the production of such materials and products. As a result, failure to meet the regulatory requirements for the production of those materials and products may generally affect the regulatory status of our CMOs' facilities. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions, and criminal prosecutions, any of which could significantly and adversely affect supplies of our products and product candidates (including those of our collaborators) and our overall business operations. Our potential future dependence upon others for the manufacture of our products, product candidates and raw materials may adversely affect our future profit margins and our ability to commercialize any products that receive regulatory approval on a timely and competitive basis.

The FDA, the EMA and other regulatory authorities may require us to submit product samples of any lot of any approved product together with the protocols showing the results of applicable tests at any time. Under some circumstances, the FDA or other regulatory authorities may require that we do not distribute a lot or lots until the relevant agency authorizes such release. Deviations in the manufacturing process, including those affecting quality attributes and stability, may result in unacceptable changes in the product that could result in lot failures or product recalls. Our CMOs have, in the past, experienced lot failures and some may have experienced product recalls. Lot failures or product recalls with respect to product produced by either our own facilities or those of our third-party manufacturers could cause us and our collaborators to delay clinical trials or product launches, which could be costly to us and otherwise harm our business, financial condition, results of operations and prospects.

We also may encounter problems hiring and retaining the experienced scientific, quality-control and manufacturing personnel needed to operate our manufacturing processes and operations, which could result in delays in production or difficulties in maintaining compliance with applicable regulatory requirements. While we train and qualify all personnel

around the appropriate handling of our products and materials, we may not be able to control for or ultimately detect intentional sabotage or negligence by any employee or contractor.

#### **Risks Related to our Reliance on Third Parties**

***We have entered into several arrangements with a related party for the performance of nonclinical research programs, and these arrangements present potential conflicts of interest.***

We have had a longstanding relationship with Translational Oncology at the University Medical Center of the Johannes Gutenberg University Mainz (*Translationale Onkologie an der Universitätsmedizin der Johannes Gutenberg Universität Mainz gemeinnützige GmbH*), or TRON, a non-profit limited liability company engaged in biopharmaceutical research, for the performance of nonclinical research. For more information about our relationship with TRON, see Item 7.B. Major Shareholders and Related Party Transactions in this Annual Report on Form 20-F, below.

The existence or appearance of a conflict of interest could depress the price of the ADSs or attract scrutiny from shareholders, regulators or other stakeholders. Additionally, any conflicts of interest would create the risk that our officers may favor their personal interests over those of our shareholders.

***We rely on third parties in the conduct of significant aspects of our preclinical studies and clinical trials and intend to rely on third parties in the conduct of future clinical trials. If these third parties do not successfully carry out their contractual duties, fail to comply with applicable regulatory requirements or fail to meet expected deadlines, we may be unable to obtain regulatory approval for our product candidates.***

We currently rely, and expect to continue to rely, on third parties, such as CROs, clinical data management organizations, collaborators, medical institutions and clinical investigators, to conduct various and significant elements of our clinical trials. We currently rely, and expect to continue to rely, on third parties to conduct certain research and preclinical testing activities. In some cases, these third parties may terminate their engagements with us. If we need to enter into alternative arrangements, it would delay our discovery or product development activities.

Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our regulatory or contractual responsibilities. We are responsible for ensuring that each of our preclinical studies and clinical trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards. For example, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial.

Moreover, the FDA requires us to comply with GCP for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within certain timeframes. Failure to do so can result in fines, adverse publicity, and civil and criminal sanctions. For any violations of laws and regulations during the conduct of our preclinical studies and clinical trials, we could be subject to warning letters or enforcement action that may include civil penalties up to and including criminal prosecution.

We and our CROs are required to comply with regulations, including GCP, for conducting, monitoring, recording and reporting the results of preclinical studies and clinical trials to ensure that the data and results are scientifically credible and accurate and that the trial participants are adequately informed, among other things, of the potential risks of participating in clinical trials. We also are responsible for ensuring that the rights of our clinical trial participants are protected. These regulations are enforced by the FDA, the regulatory authorities of the EU member states, and comparable regulatory authorities of other jurisdictions for any product candidates in clinical development. The FDA enforces GCP regulations through periodic inspections of clinical trial sponsors, principal investigators and trial sites. If we or our CROs fail to comply with applicable GCP, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable regulatory authorities of other jurisdictions may require us to perform additional clinical trials before approving our marketing applications. We cannot be sure that, upon inspection, the FDA will determine that any of our future clinical trials will comply with GCP. In addition, our clinical trials must be conducted with product candidates produced in accordance with the requirements of GMP regulations. Our failure or the failure of our CROs to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process and could also subject us to enforcement action.

Although we have designed, and in the future intend to design the clinical trials for certain of our product candidates, our collaborators will design the clinical trials that they are managing (in some cases, with our input) and in the case of clinical trials controlled by us, we expect that CROs will conduct all of the clinical trials. As a result, many important aspects of our development programs, including their conduct and timing, are outside of our direct control. Our reliance on third parties to conduct future preclinical studies and clinical trials results in less direct control over the management of data developed through preclinical studies and clinical trials than would be the case if we were relying entirely upon our own staff. Communicating with outside parties can also potentially lead to mistakes as well as difficulties in coordinating activities. Outside parties may:

- have staffing difficulties;
- fail to comply with contractual obligations;
- experience regulatory compliance issues;
- undergo changes in priorities or become financially distressed;
- form relationships with other entities, some of which may be our competitors;
- have human errors; or
- be subject to cyberattacks.

These factors may materially adversely affect the willingness or ability of third parties to conduct our preclinical studies and clinical trials and may subject us to unexpected cost increases that are beyond our control. If the CROs do not perform preclinical studies and clinical trials in a satisfactory manner, breach their obligations to us or fail to comply with regulatory requirements, the development, regulatory approval and commercialization of our product candidates may be delayed, we may not be able to obtain regulatory approval and commercialize our product candidates, or our development programs may be materially and irreversibly harmed. If we are unable to rely on preclinical and clinical data collected by our CROs, we could be required to repeat, extend the duration of, or increase the size of any clinical trials we conduct and this could significantly delay commercialization and require significantly greater expenditures.

We also rely on other third parties to transport, store and distribute the required materials for our clinical trials. In the past, certain of our third-party vendors have mishandled our materials, resulting in loss of full or partial lots of material. Any further performance failure on the part of these third parties could result in damaged products and could delay clinical development or marketing approval of any product candidates we may develop or commercialization of our medicines, if approved, producing additional losses and depriving us of potential product sales revenue, causing us to default on our contractual commitments, result in losses that are not covered by insurance, and damage our reputation and overall perception of our products in the marketplace. Each of the risks set forth above may be exacerbated by the COVID-19 pandemic currently affecting the global community and the global economy.

***Our existing collaborations, or any future collaboration arrangements that we may enter into, may not be successful, which could significantly limit the likelihood of receiving the potential economic benefits of the collaboration and adversely affect our ability to develop and commercialize our product candidates.***

We have entered into collaborations under which our collaborators have provided, and may in the future provide, funding and other resources for developing and commercializing our product candidates. We expect to enter into additional collaborations to access additional funding, capabilities and expertise in the future. Our existing collaborations, and any future collaborations we enter into, may pose a number of risks, including the following:

- collaborators may not perform or prioritize their obligations as expected;
- the clinical trials conducted as part of such collaborations may not be successful;
- collaborators may not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization of programs based on clinical trial results, changes in the collaborators' focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for clinical trials, stop a clinical trial, abandon a product candidate, repeat or conduct new clinical trials, or require a new formulation of a product candidate for clinical testing;

- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- product candidates developed in collaborations with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the development or commercialization of our product candidates;
- a collaborator with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of any such product;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development of any product candidates, may cause delays or termination of the research, development or commercialization of such product candidates, may lead to additional responsibilities for us with respect to such product candidates, or may result in litigation or arbitration, any of which would be time-consuming and expensive;
- collaborators may not properly maintain, protect, defend or enforce our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- disputes may arise with respect to the ownership of intellectual property developed pursuant to our collaborations;
- collaborators may infringe, misappropriate or otherwise violate the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- collaborations may be terminated for the convenience of the collaborator and, if terminated, the development of our product candidates may be delayed, and we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates;
- future relationships may require us to incur non-recurring and other charges, increase our near- and long-term expenditures, issue securities that dilute our existing shareholders, or disrupt our management and business;
- we could face significant competition in seeking appropriate collaborators, and the negotiation process is time-consuming and complex; and
- our international operations through any future collaborations, acquisitions or joint ventures may expose us to certain operating, legal and other risks not encountered in the United States.

If our collaborations do not result in the successful development and commercialization of programs, or if one of our collaborators terminates its agreement with us, we may not receive any future research funding or milestone, earn-out, royalty or other contingent payments under the collaborations. If we do not receive the funding we expect under these agreements, our development of product candidates could be delayed and we may need additional resources to develop our product candidates. In addition, in general our collaborators have the right to terminate their agreements with us for convenience. If one of our collaborators terminates its agreement with us, we may find it more difficult to attract new collaborators and the perception of us in the business and financial communities could be adversely affected. All of the risks relating to product development, regulatory approval and commercialization described in this report apply to the activities of our collaborators.

***If we are not able to establish collaborations on commercially reasonable terms, we may have to alter our research, development and commercialization plans.***

Our research and product development programs and the potential commercialization of any product candidates we develop alone or with collaborators will require substantial additional cash to fund expenses, and we expect that we will continue to seek collaborative arrangements with others in connection with the development and potential commercialization of current and future product candidates or the development of ancillary technologies. We face significant competition in establishing relationships with appropriate collaborators. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. Whether or not we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include, among other things and as applicable for the type of potential product or technology, an assessment of the opportunities and

risks of our technology, the design or results of studies or trials, the likelihood of approval, if necessary, of the FDA or comparable regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products and technologies and industry and market conditions generally.

Current or future collaborators may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us. Additionally, we may be restricted under existing collaboration agreements from entering into future agreements on certain terms or for certain development activities with potential collaborators. For example, we have granted exclusive rights or options to Pfizer for certain targets, and under the terms of our respective collaboration agreements with them, we will be restricted from granting rights to other parties to use our mRNA technology to pursue potential products that address those targets. Similarly, our collaboration agreements have in the past and may in the future contain non-competition provisions that could limit our ability to enter into collaborations with future collaborators.

Collaborations are complex and time-consuming to negotiate and document. We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we do enter into additional collaboration agreements, the negotiated terms may force us to relinquish rights that diminish our potential profitability from development and commercialization of the subject product candidates or others. If we are unable to enter into additional collaboration agreements, we may have to curtail the research and development of the product candidate or technology for which we are seeking to collaborate, reduce or delay research and development programs, delay potential commercialization timelines, reduce the scope of any sales or marketing activities or undertake research, development or commercialization activities at our own expense. If we elect to increase our expenditures to fund research, development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all.

***We have entered into in-licensing arrangements and may form or seek to enter into additional licensing arrangements in the future, and we may not realize the benefits of such licensing arrangements.***

We are a party to licenses that give us rights to third-party intellectual property, including patents and patent applications, that are necessary or useful for our business. In particular, we have obtained licenses from CellScript LLC and its affiliate, mRNA RiboTherapeutics, Inc., to patent rights claiming certain uses of modified RNA, as well as licenses from certain other parties for intellectual property useful in pharmaceutical formulations. We may enter into additional licenses to third-party intellectual property in the future.

The success of products developed based on in-licensed technology will depend in part on the ability of our current and future licensors to prosecute, obtain, maintain, protect, enforce and defend patent protection for our in-licensed intellectual property. Our current and future licensors may not successfully prosecute the patent applications we license. Even if patents were issued in respect of these patent applications, our licensors may fail to maintain these patents, may determine not to pursue litigation against other companies that are infringing these patents, or may pursue such litigation less aggressively than we would. Without protection for the intellectual property we license, other companies might be able to offer substantially identical products for sale, which could adversely affect our competitive business position and harm our business prospects. In addition, we sublicense our rights under various third-party licenses to our collaborators. Any impairment of these sublicensed rights could result in reduced revenues under our collaboration agreements or result in termination of an agreement by one or more of our collaborators.

Disputes may also arise between us and our licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe, misappropriate or otherwise violate the intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patent and other intellectual property rights to third parties under collaborative relationships;
- our diligence obligations with respect to the use of the licensed intellectual property and technology in relation to our development and commercialization of our product candidates, and what activities satisfy those diligence obligations;



- the ownership of inventions, trade secrets, know-how and other intellectual property resulting from the joint creation or use of intellectual property by our licensors and us and our collaborators; and
- the priority of invention of patented technology.

If disputes over intellectual property that we have in-licensed or other related contractual rights prevent or impair our ability to maintain our current licensing arrangements on favorable terms, we may be unable to successfully develop and commercialize the affected product candidates.

We are generally also subject to all of the same risks with respect to protection of intellectual property that we license, as we are for intellectual property that we own, which are described below. If we, our co-owners or our licensors fail to adequately protect, defend, maintain or enforce this intellectual property, our ability to commercialize products could suffer.

***If we commit certain material breaches and fail to cure them (if such breach is curable), we are required to repurchase shares held by the Bill & Melinda Gates Foundation.***

If we commit a specified material breach under the letter agreement with the Bill & Melinda Gates Foundation, or BMGF, and such breach remains uncured after a specified period of time (if curable), we are required to either (i) repurchase the shares held by BMGF or locate a third party to purchase the shares from BMGF, in either case at a price that is the greater of the original purchase price or the fair market value of the shares at the time of repurchase, or (ii) if we cannot meet the requirements under (i) (e.g., because we do not have sufficient cash reserves), then we must use our best efforts to effect BMGF's withdrawal right as soon as practicable, which may mean acquiring the shares in tranches over time. If we are required to repurchase BMGF's shares, our financial position could be materially and adversely affected.

***We rely on third parties to manufacture certain of our clinical product supplies, and we may have to rely on third parties to produce and process our product candidates, if approved.***

Although we expect to continue using our own clinical manufacturing facilities, we also rely on outside vendors to manufacture supplies and process our product candidates. We have only recently begun to manufacture our COVID-19 vaccine on a commercial scale and may not be able to achieve commercial-scale manufacturing and processing for our product candidates, if approved, and may be unable to create an inventory of mass-produced, off-the-shelf product to satisfy demands for our product candidates, if approved.

We do not yet have sufficient information to reliably estimate the cost of the commercial manufacturing and processing of our product candidates, and the actual cost to manufacture and process our product candidates could materially and adversely affect the commercial viability of our product candidates. As a result, we may not be able to develop commercially viable products other than our COVID-19 vaccine.

In addition, our reliance on a limited number of CMOs exposes us to the following risks:

- we may be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited and the FDA or other regulatory authorities may have questions regarding any replacement contractor. This may require new testing and regulatory interactions. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our products after receipt of regulatory authority questions, if any;
- our CMOs might be unable to timely formulate and manufacture our product or produce the quantity and quality required to meet our clinical and commercial needs, if any;
- CMOs may not be able to execute our manufacturing procedures appropriately;
- our future CMOs may not perform as agreed or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store and distribute our products;
- manufacturers are subject to ongoing periodic unannounced inspection by the FDA, the U.S. Drug Enforcement Administration and corresponding state agencies and by regulatory authorities in other jurisdictions to ensure strict compliance with GMP and other government regulations and corresponding standards in other jurisdictions. We do not have control over CMOs' compliance with these regulations and standards;
- we may not own, or may have to share, the intellectual property rights to any improvements made in the manufacturing process for our products;

- our CMOs could breach or terminate their agreement with us; and
- our CMOs would also be subject to the same risks we face in developing our own manufacturing capabilities, as described above.

Each of these risks could delay our clinical trials, the approval, if any, of our COVID-19 vaccine or product candidates by the FDA or regulatory authorities in other jurisdictions or the commercialization of our COVID-19 vaccine or product candidates, or result in higher costs or deprive us of potential product sales revenue. In addition, we will rely on third parties to perform release tests on our COVID-19 or our product candidates prior to delivery to patients. If these tests are not appropriately done and test data are not reliable, patients could be put at risk of serious harm.

***We are dependent on single source suppliers for some of the components and materials used in, and the processes required to develop, our COVID-19 vaccine and our product candidates.***

We currently depend on single source suppliers for some of the components and materials used in, and manufacturing processes required to develop, our COVID-19 and our product candidates. We cannot ensure that these suppliers or service providers will remain in business, or have sufficient capacity or supply to meet our needs, or that they will not be purchased by one of our competitors or another company that is not interested in continuing to work with us. Our use of single source suppliers of raw materials, components, key processes and finished goods exposes us to several risks, including disruptions in supply, price increases or late deliveries. There are, in general, relatively few alternative sources of supply for substitute components. These vendors may be unable or unwilling to meet our future demands for our clinical trials or commercial sale. Establishing additional or replacement suppliers for these components, materials and processes could take a substantial amount of time and it may be difficult to establish replacement suppliers who meet regulatory requirements. Any disruption in supply from any single source supplier or service provider could lead to supply delays or interruptions which would damage our business, financial condition, results of operations and prospects.

If we have to switch to a replacement supplier, the manufacture and delivery of our product candidates could be interrupted for an extended period, which could adversely affect our business. Establishing additional or replacement suppliers for any of the components or processes used in our COVID-19 vaccine and our product candidates, if required, may not be accomplished quickly. If we are able to find a replacement supplier, the replacement supplier would need to be qualified and may require additional regulatory authority approval, which could result in further delay. While we seek to maintain adequate inventory of the single source components and materials used in our COVID-19 vaccine and our product candidates, any interruption or delay in the supply of components or materials, or our inability to obtain components or materials from alternate sources at acceptable prices in a timely manner, could impair our ability to meet the demand for our COVID-19 vaccine and product candidates.

In addition, as part of the FDA's approval of our product candidates, we will also require FDA review of the individual components of our process, which include the manufacturing processes and facilities of our single source suppliers.

Our reliance on these suppliers, service providers and manufacturers subjects us to a number of risks that could harm our reputation, business and financial condition, including, among other things:

- delays to the development timelines for our product candidates;
- interruption of supply resulting from modifications to or discontinuation of a supplier's operations;
- delays in product shipments resulting from uncorrected defects, reliability issues, or a supplier's variation in a component;
- a lack of long-term supply arrangements for key components with our suppliers;
- inability to obtain adequate supply in a timely manner, or to obtain adequate supply on commercially reasonable terms;
- difficulty and cost associated with locating and qualifying alternative suppliers for our components in a timely manner;
- production delays related to the evaluation and testing of components from alternative suppliers, and corresponding regulatory qualifications;
- delay in delivery due to our suppliers' prioritizing other customer orders over ours;

- damage to our reputation caused by defective components produced by our suppliers; and
- fluctuation in delivery by our suppliers due to changes in demand from us or their other customers.

If any of these risks materialize, costs could significantly increase and our ability to meet demand for our products could be impacted

#### **Risks Related to our Intellectual Property**

*If our efforts to obtain, maintain, protect, defend and/or enforce the intellectual property related to our COVID-19 vaccine or our product candidates and technologies are not adequate, we may not be able to compete effectively in our market.*

Our commercial success depends in part on our ability to obtain, maintain, protect, defend and enforce patent and other intellectual property, including trade secret and know-how, protection for our COVID-19 vaccine and for our product candidates, proprietary technologies and their uses, as well as our ability to operate, develop, manufacture and commercialize our COVID-19 vaccine or one or more of our product candidates without infringing, misappropriating or otherwise violating the intellectual property or other proprietary rights of our competitors or any other third parties, including any non-practicing entities or patent assertion entities. We generally seek to protect our intellectual property position by filing and/or licensing patent applications in the United States and abroad related to our product candidates, proprietary technologies (including methods of manufacture) and their uses that are important to our business. Our patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless, and until, patents issue from such applications, and then only to the extent that the issued claims cover third parties' activities in the countries in which they are performed. We cannot be certain that the claims in any of our patent applications will be considered patentable by the United States Patent and Trademark Office, or the USPTO, courts in the United States or the patent offices and courts in other jurisdictions, including Europe, nor can we be certain that the claims in our issued patents will not be found invalid or unenforceable if challenged. Accordingly, there can be no assurance that our patent applications or those of our licensors will result in additional patents being issued or that issued patents will adequately cover our COVID-19 vaccine or our product candidates, or otherwise afford sufficient protection against competitors with similar technology, nor can there be any assurance that issued patents will not be infringed, designed around, invalidated or held unenforceable. Furthermore, we may not be able to apply for patents on certain aspects of our current or future products or product candidates, proprietary technologies and their uses in a timely fashion, at a reasonable cost, in all jurisdictions, or at all, and any potential patent protection we obtain may not be sufficient to prevent substantial competition.

Even issued patents may later be found invalid or unenforceable, or may be modified or revoked in proceedings before various patent offices or in courts in the United States, Europe or other jurisdictions. The degree of future protection for our intellectual property and other proprietary rights is uncertain. Only limited protection may be available and may not adequately protect our rights or permit us to gain or keep any competitive advantage. If we do not adequately obtain, maintain, protect, defend and enforce our intellectual property and proprietary technology, competitors may be able to use our product candidates and proprietary technologies and erode or negate any competitive advantage we may have, which could have a material adverse effect on our financial condition and results of operations.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our current or future licensors or collaborators will be successful in prosecuting, obtaining, protecting, maintaining, enforcing or defending patents and patent applications necessary or useful to protect our products or product candidates, proprietary technologies (including methods of manufacture) and their uses. These risks and uncertainties include, from time to time, the following:

- the USPTO and various other governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patenting process, the noncompliance with which can result in abandonment or lapse of a patent or patent application or a finding that a patent is unenforceable, and partial or complete loss of patent rights in the relevant jurisdiction;
- patent applications may not result in any patents being issued;
- issued patents that we own (solely or jointly) or have in-licensed may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable or otherwise may not provide any competitive advantage;
- other parties may have designed around our patent claims or developed technologies that may be related or competitive to our COVID-19 vaccine or to our product candidates or other technologies, may have filed or may file patent applications and may have received or may receive patents that overlap or conflict with our patent

filings, either by claiming the same or overlapping methods, products, reagents or devices or by claiming subject matter that could dominate one or more of our patent claims;

- any successful opposition to any patents owned by or in-licensed to us could deprive us of rights necessary for the development and exploitation of our COVID-19 vaccine or our product candidates and other technologies, or the successful commercialization of any product candidates and other technologies that we may develop;
- because patent applications in the United States and most other jurisdictions are confidential for a period of time after filing, we cannot be certain that we, our co-owners or our licensors were the first to file any patent application related to our product candidates, proprietary technologies and their uses;
- a court or patent office proceeding, such as a derivative action or interference, can be provoked or instituted by a third party or a patent office, and might determine that one or more of the inventions described in our patent filings, or in those we licensed, was first invented by someone else, so that we may lose rights to such invention(s);
- a court or other patent proceeding, such as an inter partes review, post grant review or opposition, can be instituted by a third party to challenge the inventorship, scope, validity and/or enforceability of our patent claims and might result in invalidation or revision of one or more of our patent claims, or in a determination that such claims are unenforceable;
- there may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns; existing legislation (for example, in the United States, the Public Readiness and Emergency Preparedness Act, etc.) may be interpreted, and new legislation may be passed, to permit third-party use of patented technologies relating to a public health concern (for example, the COVID-19 pandemic), with little or no compensation to the patent holder(s); and
- countries other than the United States may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing competitors a better opportunity to create, develop and market competing product candidates.

The patent position of biopharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. The standards that the USPTO and its counterparts use to grant patents are not always applied predictably or uniformly and can change. Similarly, the ultimate degree of protection that will be afforded to biotechnology inventions, including ours, in the United States and other countries, remains uncertain and is dependent upon the scope of the protection decided upon by patent offices, courts and lawmakers. Moreover, there are periodic changes in patent law, as well as discussions in the U.S. Congress and in international jurisdictions about modifying various aspects of patent law. There is no uniform, worldwide policy regarding the subject matter and scope of claims granted or allowable in pharmaceutical or biotechnology patents. In certain countries, for example, methods for the medical treatment of humans are not patentable. More generally, the laws of some countries do not protect intellectual property rights to the same extent as U.S. laws, and those countries may lack adequate rules and procedures for granting, maintaining, protecting, defending and enforcing our intellectual property rights.

Furthermore, the patent prosecution process is expensive and time-consuming, and we may not be able to file, prosecute, maintain, protect, defend, enforce or license all necessary or desirable patents or patent applications, as applicable, at a reasonable cost or in a timely manner. It is possible that we will fail to identify patentable aspects of our research and development output in time to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, CROs, CMOs, consultants, advisors and other third parties, any of these parties may breach such agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. We also rely to a certain extent on trade secrets, know-how, and technology, which are not protected by patents, to maintain our competitive position. If any trade secret, know-how or other technology not protected by a patent were to be disclosed to or independently developed by a competitor, our business and financial condition could be materially adversely affected.

The issuance of a patent is not conclusive as to its inventorship, priority date, scope, term, validity or enforceability so that any patents that may issue or that we may license may be challenged in the courts or patent offices in the United States, Europe and other jurisdictions. Once granted, patents may remain open to a variety of challenges, including opposition, interference, re-examination, post-grant review, inter partes review, nullification or derivation action in court or

before patent offices or similar proceedings, and furthermore, may be challenged as a defense in any enforcement action that we might bring; for example, various third parties have filed opposition papers challenging our issued EP patent number 2714071, which relates to our iNeST product candidates, and whose claims recite steps relating to neoantigen selection. Such challenges may result in loss of exclusivity or in patent claims being narrowed, terminated, disclaimed, invalidated, assigned to others or held unenforceable, any or all of which could limit our ability to stop others from using or commercializing similar or identical products, or limit the scope and/or term of patent protection of our products and product candidates and/or eliminate it altogether, thus hindering or removing our ability to limit third parties from making, using or selling products or technologies that are similar or identical to ours, and/or reduce or eliminate royalty payments to us from our licensees. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. Furthermore, our pending and future patent applications may not result in patents being issued which protect our technology or our product(s) or product candidates, or which effectively prevent others from commercializing competitive technologies and products. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

Our ability to enforce our owned and in-licensed patent and other intellectual property rights depends on our ability to detect infringement, misappropriation and other violation of such patents and other intellectual property. It may be difficult to detect infringers, misappropriators and other violators who do not advertise the components or methods that are used in connection with their products and services. Moreover, it may be difficult or impossible to obtain evidence of infringement, misappropriation or other violation in a competitor's or potential competitor's product or service, and in some cases we may not be able to introduce obtained evidence into a proceeding or otherwise utilize it to successfully demonstrate infringement. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded if we were to prevail may not be commercially meaningful.

Furthermore, patents or other intellectual property rights that we may be able to secure for our COVID-19 vaccine or our other COVID-19 vaccine candidates could be restricted or preempted if governments determine that they will not enforce, or will require compulsory licensing of, technologies useful to address the COVID-19 pandemic.

In addition, proceedings to enforce or defend our owned or in-licensed patents could put our patents at risk of being invalidated, held unenforceable or interpreted narrowly. Such proceedings could also provoke third parties to assert claims against us, including that some or all of the claims in one or more of our patents are invalid or otherwise unenforceable. Such challenges may result in loss of patent rights, loss of exclusivity, or in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and product candidates. If any of our owned or in-licensed patents covering our product candidates or other technologies are narrowed, invalidated or found unenforceable, or if a court found that valid, enforceable patents held by third parties covered one or more of our product candidates or other technologies, our competitive position could be harmed or we could be required to incur significant expenses to protect, enforce or defend our rights. If we initiate lawsuits to protect, defend or enforce our patents, or litigate against third-party claims, such proceedings would be expensive and would divert the attention of our management and technical personnel, even if the eventual outcome is favorable to us.

The degree of future protection for our intellectual property and other proprietary rights is uncertain, and we cannot ensure that:

- any of our patents, or any of our pending patent applications, if issued, or those of our licensors, will include claims having a scope sufficient to protect our product(s), our product candidates and other technologies;
- any of our pending patent applications or those of our licensors may issue as patents;
- others will not or may not be able to make, use, offer to sell or sell products that are the same as or similar to our own but that are not covered by the claims of the patents that we own or license;
- we will be able to successfully commercialize our products on a substantial scale, if approved, before the relevant patents that we own or license expire;
- we were the first to make the inventions covered by each of the patents and pending patent applications that we own or license;
- we, our co-owners or our licensors were the first to file patent applications for these inventions;

- others will not develop similar or alternative products or technologies that do not infringe the patents we own or license;
- any of the patents we own or license will be found to ultimately be valid and enforceable;
- any patents issued to us or our licensors will provide a basis for an exclusive market for our commercially viable product candidates and other technologies or will provide us with any competitive advantages;
- a third party may not challenge the patents we own or license and, if challenged, a court would hold that such patents are valid, enforceable and infringed;
- we may develop or in-license additional proprietary technologies that are patentable;
- the patents of others will not have an adverse effect on our ability to issue patents, or otherwise on our business;
- our competitors do not conduct research and development activities in countries where we do not have enforceable patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we will develop additional proprietary technologies, product(s) or product candidates that are separately patentable; and
- our development and commercialization activities, including our manufacturing processes, or products will not infringe patents of our competitors or any other third parties, including any non-practicing entities or patent assertion entities.

***Other companies or organizations may challenge our intellectual property rights or may assert intellectual property rights that prevent us from developing and commercializing our COVID-19 vaccine or our product candidates and other technologies.***

We practice in new and evolving scientific fields, the continued development and potential use of which has resulted in many different patents and patent applications from organizations and individuals seeking to obtain intellectual property protection in the fields. We own and in-license patent applications and issued patents that describe and/or claim certain technologies, including products, reagents, formulations and methods including uses and manufacturing methods, or features or aspects of any of these. These issued patents and pending patent applications claim certain compositions of matter and methods relating to the discovery, development, manufacture and commercialization of therapeutic modalities and our delivery technologies, including lipid nanoparticles, or LNPs. If we, our co-owners or our licensors are unable to obtain, maintain, protect, defend or enforce patent protection with respect to our product candidates and other technology and any products or product candidates and technology we develop, our business, financial condition, results of operations and prospects could be materially harmed.

As the scientific fields mature, our known competitors and other third parties have filed, many of whom have substantially greater resources than we do and many of whom have made significant investments in competing technologies, may seek or may have already obtained patents, and will continue to file, patent applications claiming inventions in the field in the United States and abroad. This may limit, interfere with or eliminate our ability to make, use, sell, import or otherwise exploit our COVID-19 vaccine or our product candidates or other technologies. There is uncertainty about which patents will issue, and, if they do, as to when, to whom and with what claims. With respect to both in-licensed and owned intellectual property, we cannot predict whether the patent applications we and our licensors are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient protection from competitors.

We, our co-owners or our licensors may in the future become a party to patent proceedings or priority disputes in the United States, Europe or other jurisdictions. The Leahy-Smith America Invents Act, or the America Invents Act, includes a number of significant changes that affect the way patent applications are prosecuted and also may affect patent litigation. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent through USPTO-administered post-grant proceedings, including post-grant review, inter partes review and derivation proceedings. We expect that our competitors and other third parties will institute litigation and other proceedings, such as interference, reexamination and opposition proceedings, as well as inter partes and post-grant review proceedings against us and the patents and patent applications that we own and in-license. For example, various third parties have filed opposition papers challenging our issued EP patent 2714071 which relates to our iNeST product candidates, and whose claims recite steps relating to neoantigen selection.

We expect that we will be subject to similar proceedings or priority disputes, including oppositions, in Europe or other foreign jurisdictions relating to patents and patent applications in our portfolio.

If we, our co-owners or our licensors are unsuccessful in any interference proceedings or other priority or validity disputes, including any derivations, post-grant review, inter partes review or oppositions, to which we or they are subject, we may lose valuable intellectual property rights through the narrowing or loss of one or more patents owned or in-licensed, or our owned or in-licensed patent claims may be narrowed, invalidated or held unenforceable. In many cases, the possibility of appeal exists for either us or our opponents, and it may be years before final, unappealable rulings are made with respect to these patents in certain jurisdictions. The timing and outcome of these and other proceedings is uncertain and may adversely affect our business if we are not successful in defending the patentability and scope of our pending and issued patent claims. Even if our rights are not directly challenged, disputes could lead to the weakening of our intellectual property rights. Our defense against any attempt by third parties to circumvent or invalidate our intellectual property rights could be costly to us, could require significant time and attention of our management and could have a material adverse impact on our business and our ability to successfully compete against our current and future competitors.

There are many issued and pending patent filings that claim aspects of technologies that we may need for our mRNA products or product candidates, or other product candidates, including patent filings that relate to relevant delivery technologies. There are also many issued patents that claim targeting genes or portions of genes that may be relevant for immunotherapies we wish to develop. In addition, there may be issued and pending patent applications that may be asserted against us in a court proceeding or otherwise based upon the asserting party's belief that we may need such patents for the development, manufacturing and commercialization of our COVID-19 vaccine or of our product candidates. Thus, it is possible that one or more organizations, ranging from our competitors to non-practicing entities or patent assertion entities, has or will hold patent rights to which we may need a license, or hold patent rights which could be asserted against us. Such licenses may not be available on commercially reasonable terms or at all, or may be non-exclusive. If those organizations refuse to grant us a license to such patent rights on reasonable terms, if we fail to invalidate relevant patents, or if a court or other governing body determines that we need such patent rights that have been asserted against us and we are not able to obtain a license on reasonable terms or at all, we may be unable to perform research and development or other activities or market products covered by such patents, and we may need to cease the development, manufacture and commercialization of one or more of the product candidates we may develop. Any of the foregoing could result in a material adverse effect on our business, financial condition, results of operations or prospects.

***We may not be successful in obtaining, maintaining, protecting or defending the necessary intellectual property rights to allow us to identify and develop product candidates, product components and manufacturing processes for our development pipeline.***

We currently have rights to certain intellectual property through our owned and in-licensed patents and other intellectual property rights, relating to identification and development of our product candidates or other technologies. As our pipeline may involve additional product candidates that could require the use of intellectual property and other proprietary rights held by third parties, the growth of our business could depend in part on our ability to acquire, in-license or use such intellectual property and proprietary rights. In addition, our product candidates may require specific formulations to work effectively and efficiently and these intellectual property and other proprietary rights may be held by others. We may be unable to secure such licenses or otherwise acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify as necessary, on reasonable terms, or at all, for product candidates and other technologies that we may develop. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, cash resources, and greater clinical development and commercialization capabilities.

For example, we sometimes collaborate with academic institutions in certain aspects of our preclinical research or development under written agreements with these institutions. Typically, these institutions provide us with an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration. However, these institutions may not honor our option and right of first negotiation for intellectual property rights or we may otherwise be unable to negotiate a license within the specified time frame or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to other parties, potentially blocking our ability to pursue our program or otherwise continue to develop certain product candidates or other technologies.

Moreover, some of our owned patents and patent applications are, and may in the future be, co-owned with third parties. If we are unable to obtain, or continue to maintain, exclusive rights to any such third-party co-owners' interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technologies. In addition, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

In addition, third parties that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment. If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain, protect, defend or enforce the existing intellectual property rights we have, we may have to abandon the development and commercialization of the relevant program or product candidate, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

***The lifespans of our patents may not be sufficient to effectively protect our products or product candidates, technologies and business.***

Patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after its first effective non-provisional filing date, assuming maintenance fees are timely paid after the patent has issued. Most foreign jurisdictions also provide a 20-year nominal patent term, though many require payment of regular, often annual, annuities to maintain pendency of an application or viability of an issued patent. In some jurisdictions, one or more options for extension of a patent term may be available, but even with such extensions, the lifespan of a patent, and the protection it affords, is limited. Even if patents covering our product candidates, proprietary technologies and their uses are obtained, once the patent term has expired, we may be subject to competition from third parties that can then use the inventions included in such patents to create competing products and technologies. In addition, although upon issuance in the United States a patent's life can be increased based on certain delays caused by the USPTO, this increase can be reduced or eliminated based on certain delays caused by the patent applicant during patent prosecution. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such candidates are commercialized. If any patents that we own or in-license expire, we would not be able to stop others from using or commercializing similar or identical technology and products, and our competitors could market competing products and technology. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

***If we do not obtain patent term extension and data exclusivity for any product candidates we may develop, our business may be materially harmed.***

Depending upon the timing, duration and specifics of any FDA marketing approval of any product candidates we may develop, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, or Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent extension term of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations and prospects could be materially harmed.

***If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.***

We are heavily reliant upon licenses to certain intellectual property and other proprietary rights from third parties that are important or necessary to the development and commercialization of our technology and product(s) or product candidates, and we expect to enter into similar license agreements in the future. Licensing of intellectual property is important to our business and involves complex legal, business and scientific issues and is complicated by the rapid pace of



scientific discovery in our industry. Our licenses may not provide exclusive rights to use such intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technology and products in the future. As a result, we may not be able to prevent competitors from developing and commercializing competitive products in territories included in any or all of our licenses.

Where we obtain licenses from, or collaborate with, third parties, in some circumstances we may not have the right to control the preparation, filing, prosecution, maintenance, enforcement and defense of patents and patent applications covering the technology that we license from third parties, or such activities, if controlled by us, may require the input of such third parties. In some cases, patent prosecution of our in-licensed intellectual property is controlled solely by the licensor. We may also require the cooperation of our licensors and collaborators to enforce or defend any in-licensed patent rights, and such cooperation may not be provided. Therefore, we cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, protected, enforced or defended in a manner consistent with the best interests of our business. Any patents or patent applications that we in-license may be challenged, narrowed, circumvented, invalidated or held unenforceable, or our licensors may not properly maintain such patents or patent applications and they may expire. If our licensors fail to obtain, maintain, defend, protect or enforce the intellectual property we license from them, we could lose our rights to the intellectual property and our competitors could market competing products using the inventions in such intellectual property. In certain cases, we control the prosecution of patents included from in-licensed technology. In the event we breach any of our obligations related to such prosecution, we may incur significant liability to our collaborators. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

Moreover, any failure to satisfy obligations or any material breach under any of our licenses to third-party intellectual property could give the licensor the right to terminate the license. Our existing license agreements impose, and we expect that future license agreements will impose, various diligence, milestone and royalty payment, exclusivity and other obligations on us. If we fail to comply with our obligations under these agreements, or we are subject to a bankruptcy, the licensor may have the right to terminate the license agreement, in which event we would not be able to develop, market and commercialize product(s) or product candidates covered by the license agreement. In spite of our best efforts and even if we disagree, our licensors might still conclude that we have materially breached our license agreements and might therefore terminate the license agreements, thereby removing our ability to develop and commercialize the product(s) or product candidates covered by these license agreements. In the event that any of our license agreements were to be terminated by the licensor, we may need to negotiate new or reinstated agreements, which may not be available to us on equally favorable terms, or at all. If these license agreements are terminated, or if the underlying patents or other intellectual property fail to provide the intended exclusivity, competitors would have the freedom to seek regulatory approval of, and to market and commercialize, products similar or identical to ours. In addition, we may seek to obtain additional licenses from our licensors and, in connection with obtaining such licenses, we may agree to amend our existing license agreements in a manner that may be more favorable to the licensors, including by agreeing to terms that could enable third parties (potentially including our competitors) to receive licenses to a portion of the intellectual property that is subject to our existing licenses.

We are generally also subject to all of the same risks with respect to protection of intellectual property that we license, as we are for intellectual property that we own, which are described in this section. If we, our co-owners or our licensors fail to adequately protect this intellectual property, our ability to develop, market and commercialize our product(s) or product candidates could suffer. Moreover, if disputes over intellectual property that we have in-licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop, market and commercialize the affected product(s) or product candidates, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

***Some of our in-licensed intellectual property has been discovered through government-funded programs and thus may be subject to federal regulations such as “march-in” rights and certain reporting requirements, and compliance with such regulations may limit our exclusive rights and our ability to contract with manufacturers.***

Certain intellectual property rights that have been in-licensed, including patent applications and patents that we in-license from the University of Pennsylvania, the Louisiana State University, the Broad Institute, the National Institute of Health (NIH), Genentech, and Cellscript, have been generated through the use of U.S. government funding and are therefore subject to certain federal regulations. As a result, the U.S. government may have certain rights to intellectual property embodied in our current or future product candidates pursuant to the Bayh-Dole Act of 1980, or the Bayh-Dole Act. These U.S. government rights include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government has the right, under certain limited circumstances, to require the

licensor to grant exclusive, partially exclusive or non-exclusive licenses to any of these inventions to a third party if it determines that (i) adequate steps have not been taken to commercialize the invention, (ii) government action is necessary to meet public health or safety needs or (iii) government action is necessary to meet requirements for public use under federal regulations (also collectively referred to as “march-in rights”). The U.S. government also has the right to take title to these inventions if the licensor fails to disclose the invention to the government or fails to file an application to register the intellectual property within specified time limits. Any exercise by the government of such rights could harm our competitive position, business, financial condition, results of operations and prospects. Intellectual property generated under a government-funded program is also subject to certain reporting requirements, compliance with which may require us to expend substantial resources.

In addition, the U.S. government requires that any products embodying any of these inventions or produced through the use of any of these inventions be manufactured substantially in the United States. This preference for U.S. industry may be waived by the federal agency that provided the funding if the owner or assignee of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture the products substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. We may not be able to obtain a waiver of this preference for U.S. industry, and this preference may limit our ability to contract with non-U.S. product manufacturers for products covered by such intellectual property. To the extent any of our owned or in-licensed future intellectual property is generated through the use of U.S. government funding, the provisions of the Bayh-Dole Act may similarly apply. If we are unable to comply with these manufacturing requirements, we may experience a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

***Our current proprietary position for certain products and product candidates depends upon our owned or in-licensed patent filings covering components, manufacturing-related methods, formulations and/or methods of use, which may not adequately prevent a competitor or other third party from using the same product candidate for the same or a different use.***

Composition of matter patent protection is generally considered to be desirable because it provides protection without regard to any particular method of use or manufacture or formulation. While we have obtained patent protection covering components of certain product candidates, manufacturing-related methods, formulations and/or methods of use, we have not obtained patent protection components for all product candidates, manufacturing-related methods, formulations and/or methods of use. For instance, we do not currently have any claims in our owned or in-licensed issued U.S. patents that cover the overall construct used in our COVID-19 vaccine, or that used in our iNeST product candidates. We also cannot be certain that claims in any future patents issuing from our pending owned or in-licensed patent applications or our future owned or in-licensed patent applications will cover the composition of matter, manufacturing-related methods, formulations and/or methods of use of our current or future product candidates. Method of use patents protect the use of a product for the specified method and formulation patents cover formulations to deliver therapeutics. These types of patents do not prevent a competitor or other third party from developing, marketing or commercializing a similar or identical product for an indication that is outside the scope of the patented method or from developing a different formulation that is outside the scope of the patented formulation. Moreover, with respect to method of use patents, even if competitors or other third parties do not actively promote their product for our targeted indications or uses for which we may obtain patents, physicians may recommend that patients use these products off-label, or patients may do so themselves. Although off-label use may infringe or contribute to the infringement of method of use patents, the practice is common and this type of infringement is difficult to prevent or enforce. Consequently, we may not be able to prevent third parties from practicing our inventions in the United States or abroad.

***Intellectual property rights of third parties could adversely affect our ability to commercialize our product(s) and product candidates, and we might be required to litigate or obtain licenses from third parties in order to develop or market our product(s) and product candidates.***

Because our products and product candidates are still in early stages of development or commercialization, and one or more features of the products or product candidates, or related technologies such as their manufacture, formulation or use, may still change, we cannot be confident that we are aware of all third-party intellectual property that might be relevant to products that we eventually hope to commercialize. Furthermore, even if all aspects of our product(s) or product candidate(s), or of other technology, were known, it is possible that third-party intellectual property, which may or may not currently be public, could develop in a manner (for example, through issuance of additional patents) that could impede our ability to make or use relevant products or product candidates, or other technology. Various third-party competitors practice in relevant spaces, and may have issued patents, or patent applications that will issue as patents in the future, that will

impede or preclude our ability to commercialize products. Furthermore, while U.S. patent laws provide a “safe harbor” to our clinical product candidates under 35 U.S.C. § 271(e)(1), which exempts from patent infringement activities related to pursuing FDA approval for a drug product, that exemption expires when an NDA is submitted. Accordingly, our COVID-19 vaccine was granted emergency use authorization in December 2020, at which the 271(e)(1) safe harbor may no longer provide the same level of protection from third party patent infringement claims for that product. We may become exposed to one or more lawsuits from third parties who consider our COVID-19 vaccine to infringe their patents. Given the uncertainty of clinical trials, we cannot be certain of the timing of their completion and it is possible that we might want to submit an NDA at a time when one or more relevant third-party patents is in force. Thus, it is possible that at the time that we commercialize our product candidates, one or more third parties may have issued patent claims that cover our products or critical features of their production or use. We may not be able to commercialize our products if patents issued to third parties or other third-party intellectual property rights cover, or may be alleged to cover, our products or elements thereof, or their methods of manufacture or use at the time that we seek to commercialize them. In such cases, we may not be in a position to develop or commercialize product candidates unless we successfully pursue litigation to nullify or invalidate the third-party intellectual property right concerned, successfully design around their claims, or enter into a license agreement with the intellectual property right holder(s). Such litigation or licenses could be costly or not available on commercially reasonable terms or at all, and design-around could be prohibitively expensive or impossible.

Additionally, with respect to our COVID-19 vaccine and our other COVID-19 product candidates and related technologies, it is unclear whether the U.S. government, or other governments around the world, will protect vaccine manufacturers for liability from infringement of third party intellectual property, at least during the period of the pandemic. Thus, it is possible that third parties may assert intellectual property rights against us relating to our COVID-19 vaccine, and that we will not be successful in arguing that commercialization of our COVID-19 vaccine is exempted from infringement (for example, under 35 U.S.C. § 271(e)(1), discussed above, or under the Public Readiness and Emergency Preparedness Act, or the PREP Act, etc.). Furthermore, even if such commercialization is deemed protected from infringement during the period of pandemic crisis, once that period has passed, or as otherwise might be established, any such exemption may be terminated so that continuing commercialization could expose us to liability, and might even be precluded if third party(ies) who hold relevant intellectual property rights are able to secure injunction(s) or are unwilling to license to us on commercially feasible terms.

It is also possible that we have failed to identify relevant third-party patents that cover, or applications that will mature into patents that cover, one or more aspects of our platform or product(s) and product candidates. Given that, in most jurisdictions, a patent application is confidential when initially filed, and typically remains so until it is published about 18 months after the initial filing, it may not be possible for us to identify certain relevant filings in time to avoid using the technology that they claim. Additionally, the claims of pending patent applications can, subject to certain limitations, be amended over time, so that even patent applications whose claims did not cover our products or activities when published could be amended to cover one or more aspects of our platform or product candidates over time, and we might not be aware that such amendment had been made.

***We may be involved in lawsuits to protect or enforce our intellectual property or the intellectual property of our licensors, or to defend against third-party claims that we infringe, misappropriate or otherwise violate such third party’s intellectual property, each of which could be expensive, time consuming and unsuccessful.***

There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions, ex parte reexaminations, post-grant review, and inter partes review proceedings before the USPTO and corresponding European and other non-U.S. patent offices.

Competitors and other third parties may infringe, misappropriate or otherwise violate our intellectual property rights or those of our licensors. To prevent infringement, misappropriation or other unauthorized use, we may be required to file claims, which can be expensive and time-consuming. In certain instances, we have instituted and may in the future institute inter partes review proceedings against issued U.S. patents and opposition proceedings against European patents owned by third parties in the field of immunotherapy. We have a number of these opposition proceedings ongoing at the European Patent Office against third-party patents related to mRNA technologies; also, multiple oppositions have been filed against our EP patent number 2714071, which relates to our iNeST product candidates, and whose claims recite steps relating to neoantigen selection. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties.

In addition, in a patent infringement proceeding, our owned or in-licensed patents may be challenged and a court may decide that a patent we own or in-license is not valid, is unenforceable and/or is not infringed. If we or any of our potential future collaborators were to initiate legal proceedings against a third party to enforce a patent directed at one of our product(s) and/or product candidates, the defendant could counterclaim that our patent is invalid and/or unenforceable in whole or in part. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge include an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could include an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution. Third parties may also raise similar claims before the USPTO, even outside the context of litigation. Similar mechanisms for challenging the validity and enforceability of a patent exist in ex-U.S. patent offices and may result in the revocation, cancellation or amendment of any ex-U.S. patents we hold in the future. The outcome following legal assertions of invalidity and unenforceability is unpredictable, and prior art could render our patents or those of our licensors invalid. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on such product and/or product candidate. Such a loss of patent protection would have a material adverse impact on our competitive position, business, financial conditions, results of operations and prospects.

Third parties, ranging from our competitors to non-practicing entities or patent assertion entities, may assert that we are employing their intellectual property and other proprietary technology without authorization. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use, development, manufacture or commercialization of our COVID-19 vaccine or product candidates. As patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our product(s) and/or product candidates may infringe. In addition, third parties may obtain patents in the future and claim that our technologies infringe upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our product(s) and/or product candidates, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may obtain injunctive or other equitable relief, which could effectively block our ability to develop and commercialize such product and/or product candidate unless we obtained a license under the applicable patents, or until such patents expire. Similarly, if any third-party patents were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy, the holders of any such patents may be able to block our ability to develop and commercialize the applicable product and/or product candidate unless we obtained a license or until such patent expires. In either case, such a license may not be available on commercially reasonable terms, or at all, or may be non-exclusive.

Interference or derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms or at all, or if a non-exclusive license is offered and our competitors gain access to the same intellectual property and technology. Our defense of litigation, interference, derivation or similar proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, and our research programs, license necessary technology from third parties or enter into development or manufacturing collaborations that would help us bring our product(s) and/or product candidates to market.

Even if resolved in our favor, litigation or other legal proceedings relating to our intellectual property rights may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace.

In the event of a successful claim of infringement, misappropriation or other violation against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products, or obtain one or more licenses from third parties, which may not be made available on commercially favorable terms, if at all, or may require substantial time and expense.

Such licenses are likely to be non-exclusive and, therefore, our competitors may have access to the same intellectual property and technology licensed to us. If we fail to obtain a required license and are unable to design around a patent, we may be unable to effectively market some of our technology and product(s) and/or product candidates, which could limit our ability to generate revenues or achieve or maintain profitability and possibly prevent us from generating revenue sufficient to sustain our operations. Moreover, certain of our collaborators provide, and we expect additional collaborators to provide, that royalties payable to us for licenses to our intellectual property may be offset by amounts paid by our collaborators to third parties for licenses to such third parties' intellectual property in the relevant fields, which could result in significant reductions in our revenues from products developed through collaborations.

In addition, in connection with certain license and collaboration agreements, we have agreed to indemnify certain third parties for certain costs incurred in connection with litigation relating to intellectual property rights or the subject matter of the agreements. The cost to us of any litigation or other proceeding relating to intellectual property rights, even if resolved in our favor, could be substantial.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments in any litigation or other intellectual property proceedings. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of the ADSs.

***Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.***

Periodic maintenance fees, renewal fees, annuity fees, and various other governmental fees on patents and applications will be due to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents or applications. We have systems in place to remind us to pay these fees and we employ an outside firm and rely on our outside counsel to pay these fees due to non-U.S. patent agencies; however, we cannot guarantee that we will successfully pay these fees. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. We are also dependent on our licensors to take the necessary action to comply with these requirements with respect to our in-licensed intellectual property, and we cannot guarantee that they will do so. In such an event, our competitors might be able to enter the market with similar or identical products or technology, and this would have a material adverse impact on our business, financial condition, results of operations and prospects.

***Changes in patent law in the United States or in other countries could diminish the value of patents in general, thereby impairing our ability to protect our products.***

As is the case with other biotechnology companies, our success is heavily dependent on our intellectual property rights, particularly patents that we own and in-license. Obtaining and enforcing patents in the biotechnology industry involve both technological and legal complexity, and therefore obtaining and enforcing biotechnology patents is costly, time-consuming and inherently uncertain. Moreover, there are periodic changes in patent law. For example, after March 2013, under the America Invents Act, the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. The America Invents Act also includes a number of significant changes that affect the way patent applications will be prosecuted and also may affect patent litigation. The America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts and the USPTO, and their equivalents in other jurisdictions, the laws and regulations governing patents could change in unpredictable ways that could

have a material adverse effect on our existing patent portfolio and our ability to obtain, maintain, protect, defend or enforce our intellectual property in the future.

***If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.***

In addition to seeking patent protection for some of our technology, product(s) and product candidates, we also seek to rely on trade secret protection and confidentiality agreements to maintain our competitive position and protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce and any other elements of our product discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. However, trade secrets and know-how may be difficult to protect.

We seek to protect these trade secrets, know-how and other proprietary technology, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, CROs, CMOs, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants and require all of our employees and key consultants who have access to our trade secrets, proprietary know-how, information or technology to enter into confidentiality agreements. We cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes. Despite our best efforts, any of these parties may breach the agreements and we cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. We may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret or know-how is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets and know-how. If any of our trade secrets or know-how were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, operating results, financial condition and prospects.

***We may be subject to claims that we have wrongfully hired an employee from a competitor, or that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties or that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.***

We have received confidential and proprietary information from third parties in the course of our research and other collaborations with others in the industry, academic institutions and other third parties. In addition, many of our employees, consultants and advisors are currently or were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants, independent contractors and advisors do not use the confidential or proprietary information, trade secrets or know-how of others in their work for us, we may be subject to claims that we have inadvertently or otherwise used or disclosed confidential or proprietary information, trade secrets or know-how of these third parties, or that our employees, consultants, independent contractors or advisors have inadvertently or otherwise used or disclosed confidential information, trade secrets or know-how of such individual's current or former employer. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial cost and be a distraction to our management and employees. Claims that we, our employees, consultants or advisors have misappropriated the confidential or proprietary information, trade secrets or know-how of third parties could have a material adverse effect on our business, financial condition, results of operations and prospects.

***We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.***

In the future, we may be subject to claims that current or former employees, consultants, independent contractors, collaborators or other third parties have an interest in our patents or other intellectual property as an inventor or co-inventor. While it is our policy to require our employees, consultants, independent contractors, collaborators and other third parties who may be involved in the conception, development or reduction to practice of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives, develops or reduces to practice such intellectual property that we regard as our own. In addition, certain such agreements, even if successfully executed may distribute ownership or control of intellectual property rights between

or among parties, for example based on subject matter, relationship to other intellectual property, and/or one or more aspects of development of the intellectual property; after the agreements are in place disputes may arise over such distribution principles or over proper treatment of particular developed intellectual property in accordance with them. Disagreements may be difficult or impossible to resolve, may be expensive to address, and may result in our failing to secure or maintain ownership in or control of intellectual property necessary or important to our business.

The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached. For example, we may have inventorship or ownership disputes arise from conflicting obligations of employees, consultants, independent contractors, collaborators or other third parties who are involved in developing and commercializing our product(s) and/or product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business, operating results and financial condition. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Furthermore, the laws of some other countries do not protect intellectual property and other proprietary rights or establish ownership of inventions to the same extent or in the same manner as the U.S. laws. A majority of our employees work in Germany and are subject to German employment law. Ideas, developments, discoveries and inventions made by such employees and consultants are subject to the provisions of the German Act on Employees' Inventions, which regulates the ownership of, and compensation for, inventions made by employees. We face the risk that disputes can occur between us and our employees or former employees pertaining to alleged non-adherence to the provisions of this act that may be costly to defend and take up our management's time and efforts whether we prevail or fail in any such dispute. There is a risk that the compensation we provided to employees who assign patents to us may be deemed to be insufficient and we may be required under German law to increase the compensation due to such employees for the use of the patents. In those cases, where employees' rights have not been assigned to us, we may need to pay compensation for the use of those patents. If we are required to pay additional compensation or face other disputes under the German Act on Employees' Inventions, our business, results of operations and financial condition could be adversely affected.

***We will not seek to protect our intellectual property rights in all jurisdictions throughout the world, and we may not be able to adequately enforce our intellectual property rights even in the jurisdictions where we seek protection.***

Filing, prosecuting and defending patents on product(s) and/or product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some countries do not protect intellectual property rights to the same extent as laws in Germany and the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and to the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own product candidates and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our product(s) and/or product candidates, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in certain jurisdictions, particularly outside of the United States. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement, misappropriation or other violation of our patents and other intellectual property or development, marketing and commercialization of competing products in violation of our intellectual property and other proprietary rights generally. Proceedings to enforce our intellectual property rights in such jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or in-license.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government

contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors is forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

***If our trademarks and trade names are not adequately protected, we may not be able to build name recognition in our markets of interest and our business may be adversely affected.***

Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential collaborators or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected. We may license our trademarks and trade names to third parties, such as distributors. Though these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and trade names by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks, and trade names. Our efforts to enforce or protect our proprietary rights related to trademarks, trade names, trade secrets, know-how, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our business, financial condition, results of operations and prospects.

***Intellectual property rights do not necessarily address all potential threats to our competitive advantage.***

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make COVID-19 vaccines or therapies, and/or personalized cancer immunotherapies that are similar to our COVID-19 vaccine and/or any product candidates we may develop and commercialize or utilize similar technologies that are not covered by the claims of the patents that we now or may in the future own or have exclusively in-licensed;
- we, our co-owners or our licensors or future collaborators might not have been the first to make the inventions covered by the issued patents or pending patent applications that we own or have exclusively in-licensed;
- we, our co-owners or our licensors or future collaborators might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our owned or in-licensed intellectual property rights;
- it is possible that our pending patent applications or those that we may own or in-license in the future will not lead to issued patents;
- issued patents that we own or have exclusively in-licensed may be held invalid or unenforceable, including as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may have an adverse effect on our business; and
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations and prospects.



## Risks Related to Government Regulation

*We may not be able to develop or obtain approval for companion diagnostics required for commercialization of some of our product candidates.*

Administration of some of our product candidates may require the use of immuno-assays and bioinformatic tools in which patients are screened for optimal target antigens of our product candidates. If safe and effective use of a biologic product depends on an *in vitro* diagnostic, then the FDA generally requires approval or clearance of the diagnostic, known as a companion diagnostic, concurrently with approval of the therapeutic product. To date, the FDA has generally required *in vitro* companion diagnostics intended to select the patients who will respond to cancer treatment to obtain a pre-market approval, or PMA, for that diagnostic, which can take up to several years, simultaneously with approval of the biologic product. Similarly, in the European Union, an *in vitro* companion diagnostic may be placed on the market only if it conforms to certain “essential requirements” and bears the Conformité Européenne Mark, or CE Mark, and the conformity assessment process to obtain the CE Mark can be lengthy.

For our individualized immunotherapy candidates, the FDA and comparable regulatory authorities outside of the United States may require the development and regulatory approval of a companion diagnostic assay as a condition to approval. The FDA may require PMA supplemental approvals for use of that same companion diagnostic as a condition of approval of additional individualized therapeutic candidates. We do not have experience or capabilities in developing or commercializing companion diagnostics and plan to rely in large part on third parties to perform these functions. Companion diagnostic assays are subject to regulation by the FDA and other comparable regulatory authorities in other jurisdictions as medical devices and require separate regulatory approval prior to the use of such diagnostic assays with our individualized therapeutic candidates. If we, or any third parties that we engage to assist us, are unable to successfully develop companion diagnostic assays for use with our individualized therapeutic candidates, or are unable to obtain regulatory approval or experience delays in either development or obtaining regulatory approval, we may be unable to identify patients with the specific profile targeted by our product candidates for enrollment in our clinical trials. Accordingly, further investment may be required to further develop or obtain the required regulatory approval for the relevant companion diagnostic assay, which would delay or substantially impact our ability to conduct additional clinical trials or obtain regulatory approval.

*Because we are developing some of our product candidates for the treatment of diseases in which there is little clinical experience and, in some cases, using new endpoints or methodologies, the FDA, the EMA or other regulatory authorities may not consider the endpoints of our clinical trials to provide clinically meaningful results.*

There may not be pharmacologic therapies approved to treat the underlying causes of many diseases that we may address in the future. For instance, we and our collaborators are applying our technology to develop therapeutics in indications such as certain rare diseases, including some for which no or few clinical trials have been attempted. As a result, any future design and conduct of clinical trials of product candidates for the treatment of certain rare diseases may take longer, be more costly, or be less effective as part of the novelty of development in these diseases. Even if we decide to conduct clinical trials and the FDA does find our success criteria to be sufficiently validated and clinically meaningful, we may not achieve the pre-specified endpoint to a degree of statistical significance in any pivotal or other clinical trials we or our collaborators may conduct for our programs. Further, even if we do achieve the pre-specified criteria, our trials may produce results that are unpredictable or inconsistent with the results of the more traditional efficacy endpoints in the trial. The FDA also could give overriding weight to other efficacy endpoints over a primary endpoint, even if we achieve statistically significant results on that endpoint, if we do not do so on our secondary efficacy endpoints. The FDA also weighs the benefits of a product against its risks and the FDA may view the efficacy results in the context of safety as not being supportive of licensure. Other regulatory authorities in Europe and other countries may make similar findings with respect to these endpoints.

*The FDA, the EMA or other comparable regulatory authorities may disagree with our regulatory plan and we may fail to obtain regulatory approval of our product candidates.*

If the results of our clinical trials are sufficiently compelling, we or our collaborators intend to discuss with the FDA submission of a BLA for our product candidates. However, we do not have any agreement or guidance from the FDA that our regulatory development plans will be sufficient for submission of a BLA for any of our product candidates. The FDA, the EMA or other regulatory agencies may grant accelerated approval for our product candidates and, as a condition for accelerated approval, the FDA, the EMA or other regulatory agencies may require a sponsor of a drug or biologic receiving accelerated approval to perform post-marketing studies to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical endpoint, and the drug or biologic may be subject to withdrawal procedures by the FDA, the EMA or other regulatory agencies that are more accelerated than those available for regular approvals. In addition, the

standard of care may change with the approval of new products in the same indications that we are studying. This may result in the FDA, the EMA or other regulatory agencies requesting additional studies to show that our product candidate is superior to the new products.

Our clinical trial results may also not support approval. In addition, our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA, the EMA or comparable regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA, the EMA or comparable regulatory authorities that our product candidates are safe and effective for any of their proposed indications;
- the results of clinical trials may not meet the level of statistical significance required by the FDA, the EMA or comparable regulatory authorities for approval, including due to the heterogeneity of patient populations;
- we may be unable to demonstrate that our product candidates' clinical and other benefits outweigh their safety risks;
- the FDA, the EMA or comparable regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to the satisfaction of the FDA, the EMA or comparable regulatory authorities to support the submission of a BLA or other comparable submissions or to obtain regulatory approval in the United States or elsewhere;
- the FDA, the EMA or comparable regulatory authorities will inspect our manufacturing facilities and may not approve our facilities; and
- the approval policies or regulations of the FDA, the EMA or comparable regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

***We may not be able to file INDs with the FDA, clinical trial applications with the competent authorities of the member states of the European Union or similar applications with other comparable regulatory authorities to commence additional clinical trials on the timelines we expect, and even if we are able to, one or more of these regulatory authorities may not permit us to proceed.***

The timing of filing on our product candidates is dependent on further preclinical, clinical and manufacturing success. We cannot be sure that submission of an IND or IND amendment with the FDA, a clinical trial application with the regulatory authorities of the EU member states or similar application with other comparable regulatory authorities will result in the FDA, the regulatory authorities of the EU member states or any comparable regulatory authority allowing testing and clinical trials to begin, or that, once begun, issues will not arise that result in the suspension or termination of such clinical trials. Additionally, even if such regulatory authorities agree with the design and implementation of the clinical trials set forth in an IND, clinical trial application or similar applications, we cannot guarantee that such regulatory authorities will not change their requirements in the future.

***We may seek orphan drug designation for some or all of our product candidates across various indications, but we may be unable to obtain such designations or to maintain the benefits associated with orphan drug designation, including market exclusivity, which may cause our revenue, if any, to be reduced.***

Our strategy includes filing for orphan drug designation where available for our product candidates. Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug or biologic intended to treat a rare disease or condition, which is defined as one occurring in a patient population of fewer than 200,000 in the United States, or a patient population of 200,000 or greater in the United States where there is no reasonable expectation that the cost of developing the drug or biologic will be recovered from sales in the United States. In the United States, orphan drug designation entitles a party to financial incentives, such as opportunities for grant funding toward clinical trial costs, tax advantages, and user-fee waivers. In addition, if a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications, including a full new drug application or a BLA, to market the same drug or biologic for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or where the original manufacturer is unable to assure sufficient product quantity. Similar rules apply in the European Union with respect to drugs or biologics designated as orphan medicinal products.

In addition, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan-designated indication or may be lost if the FDA later determines that the request for designation was materially defective. Further, even if we obtain orphan drug exclusivity for a product, that exclusivity may not protect the product effectively from competition because different drugs with different active moieties may receive and be approved for the same condition, and only the first applicant to receive approval will receive the benefits of marketing exclusivity. Even after an orphan-designated product is approved, the FDA can subsequently approve a later drug with the same active moiety for the same condition if the FDA concludes that the later drug is clinically superior if it is shown to be safer, more effective, or makes a major contribution to patient care. Similar considerations apply in the European Union with respect to drugs or biologics designated as orphan medicinal products. Orphan drug designation neither shortens the development time or regulatory review time of a drug, nor gives the drug any advantage in the regulatory review or approval process. In addition, while we may seek orphan drug designation for our product candidates, we may never receive such designations.

***We may seek breakthrough therapy or fast-track designation for one or more of our product candidates, but we may not receive such designations. Even if we do, it may not lead to a faster development or regulatory review or approval process, and it may not increase the likelihood that such product candidates will receive marketing approval.***

We may seek a breakthrough therapy designation in the United States for one or more of our product candidates. A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated as breakthrough therapies by the FDA are also eligible for priority review if supported by clinical data at the time of the submission of the BLA.

Designation as a breakthrough therapy is at the discretion of the FDA. Accordingly, even if we believe that one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a breakthrough therapy designation for a drug may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures and it would not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that the product candidate no longer meets the conditions for qualification or it may decide that the time period for FDA review or approval will not be shortened.

We may also seek Fast Track Designation in the United States for some of our product candidates. If a therapy is intended for the treatment of a serious or life-threatening condition and the therapy demonstrates the potential to address significant unmet medical needs for this condition, the drug sponsor may apply for Fast Track Designation. The FDA has broad discretion whether or not to grant this designation, and even if we believe a particular product candidate is eligible for this designation, we cannot be sure that the FDA would decide to grant it. Even if we do receive Fast Track Designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw Fast Track Designation if it believes that the designation is no longer supported by data from our clinical development program. Fast Track Designation alone does not guarantee qualification for the FDA's priority review procedures.

***We expect some of the product candidates we develop will be regulated as biologics in the United States and therefore they may be subject to competition from biosimilars approved through an abbreviated regulatory pathway.***

The ACA includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or the BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-approved reference biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first approved by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first approved.

During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of the other company's product.

The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation and meaning are subject to uncertainty.

We believe that any of our product candidates approved as a biological product under a BLA should qualify for a 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

***Some of our product candidates are classified as gene therapies by the FDA and the EMA, and the FDA has indicated that our product candidates will be reviewed within its Center for Biologics Evaluation and Research, or CBER. Even though our mRNA product candidates are designed to have a different mechanism of action from gene therapies, the association of our product candidates with gene therapies could result in increased regulatory burdens, impair the reputation of our product candidates, or negatively impact our platform or our business.***

**There have been few approvals of gene therapy products in the United States and other jurisdictions, and there have been well-reported significant adverse events associated with their testing and use.** Gene therapy products have the effect of introducing new DNA and potentially irreversibly changing the DNA in a cell. **In contrast, mRNA is highly unlikely to localize to the nucleus, integrate into cell DNA, or otherwise make any permanent changes** to cell DNA. Consequently, we expect that our product candidates will have a different potential side effect profile from gene therapies because they lack risks associated with altering cell DNA irreversibly. Further, we may avail ourselves of ways of mitigating side effects in developing our product candidates to address safety concerns that are not available to all gene therapies, such as lowering the dose of our product candidates during repeat dosing or stopping treatment to potentially ameliorate undesirable side effects.

Regulatory requirements governing gene and cell therapy products have evolved and may continue to change in the future, and the implications for mRNA-based therapies is unknown. For example, the FDA has established the Office of Tissues and Advanced Therapies within CBER to consolidate the review of gene therapy and related products, and convenes the Cellular, Tissue and Gene Therapies Advisory Committee to advise CBER on its review. In the **European Union, mRNA has been characterized as a Gene Therapy Medicinal Product.** In certain countries, mRNA therapies have not yet been classified or any such classification is not known to us. Specifically, in Japan, the Pharmaceuticals and Medical Devices Agency has not taken a position on the regulatory classification. Notwithstanding the differences between our mRNA product candidates and gene therapies, the classification of some of our mRNA product candidates as gene therapies in the United States, the European Union and potentially other countries could adversely impact our ability to develop our product candidates, and could negatively impact our platform and our business. For instance, a clinical hold on gene therapy products across the field due to risks associated with altering cell DNA irreversibly may apply to our mRNA product candidates irrespective of the mechanistic differences between gene therapies and mRNA.

Adverse events reported with respect to gene therapies or genome editing therapies could adversely impact one or more of our programs. Although our mRNA product candidates are designed not to make any permanent changes to cell DNA, regulatory agencies or others could believe that adverse effects of gene therapy products caused by introducing new DNA and irreversibly changing the DNA in a cell could also be a risk for our mRNA investigational therapies, and as a result may delay one or more of our trials or impose additional testing for long-term side effects. Any new requirements and guidelines promulgated by regulatory review agencies may have a negative effect on our business by lengthening the regulatory review process, requiring us to perform additional or larger studies, or increasing our development costs, any of which could lead to changes in regulatory positions and interpretations, delay or prevent advancement or approval and commercialization of our product candidates or lead to significant post-approval studies, limitations or restrictions. As we advance our product candidates, we will be required to consult with these regulatory agencies and advisory committees and comply with applicable requirements and guidelines. If we fail to do so, we may be required to delay or discontinue development of some or all of our product candidates.

*The regulatory landscape that will govern our product candidates is uncertain. Regulations relating to more established gene therapy and cell therapy products are still developing, and changes in regulatory requirements could result in delays or discontinuation of development of our product candidates or unexpected costs in obtaining regulatory approval.*

**The regulatory requirements to which our product candidates will be subject are not entirely clear. Even with respect to more established products that fit into the categories of gene therapies or cell therapies, the regulatory landscape is still developing.** For example, regulatory requirements governing gene therapy products and cell therapy products have changed frequently and may continue to change in the future. Moreover, there is substantial, and sometimes uncoordinated, overlap in those responsible for regulation of existing gene therapy products and cell therapy products. Although the FDA decides whether individual gene therapy protocols may proceed, the review process and determinations of other reviewing bodies can impede or delay the initiation of a clinical study, even if the FDA has reviewed the study and approved its initiation. Conversely, the FDA can place an IND application on clinical hold even if such other entities have provided a favorable review. Furthermore, gene therapy clinical trials are also subject to review and oversight by an institutional biosafety committee, or IBC, a local institutional committee that reviews and oversees basic and clinical research conducted at the institution participating in the clinical trial. In addition, adverse developments in clinical trials of gene therapy products conducted by others may cause the FDA or other regulatory bodies to change the requirements for approval of any of our product candidates.

Complex regulatory environments exist in other jurisdictions in which we might consider seeking regulatory approvals for our product candidates, further complicating the regulatory landscape. For example, in the European Union, a special committee called the Committee for Advanced Therapies, or CAT, was established within the EMA in accordance with Regulation (EC) No 1394/2007 on advanced-therapy medicinal products, or ATMPs, to assess the quality, safety and efficacy of ATMPs, and to follow scientific developments in the field. ATMPs include gene therapy products as well as somatic cell therapy products and tissue engineered products.

These various regulatory review committees and advisory groups and new or revised guidelines that they promulgate from time to time may lengthen the regulatory review process, require us to perform additional studies, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of our product candidates or lead to significant post-approval limitations or restrictions. As the regulatory landscape for our CAR-T cell immunotherapy product candidates is new, we may face even more cumbersome and complex regulations than those emerging for gene therapy products and cell therapy products. Furthermore, even if our product candidates obtain required regulatory approvals, such approvals may later be withdrawn as a result of changes in regulations or the interpretation of regulations by applicable regulatory agencies.

Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring a potential product to market could decrease our ability to generate sufficient product sales revenue to maintain our business.

***We may be unable to obtain regulatory approval for our product candidates under applicable international regulatory requirements.***

The denial or delay of such approval would delay commercialization of our product candidates and adversely impact our potential to generate revenue, our business and our results of operations.

Approval by the FDA in the United States, if obtained, does not ensure approval by regulatory authorities in other countries or jurisdictions. In order to market our product candidates in any other jurisdiction, we must establish and comply with numerous and varying regulatory requirements on a jurisdiction-by-jurisdiction basis regarding safety and efficacy. In addition, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not guarantee regulatory approval in any other country. Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods.

Seeking regulatory approval in other jurisdictions could result in difficulties and costs for us and require additional preclinical studies or clinical trials which could be costly and time-consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. The European Union and other jurisdictions' regulatory approval processes involve all of the risks associated with the FDA approval. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of our products will be unrealized.

*A third-party investigational drug used in combination with our product candidates may be unable to obtain regulatory approval, which may delay commercialization of our product candidates.*

We are developing several of our product candidates to be used in combination with our and third-party drugs. Even if any product candidate we develop were to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA, the EMA or comparable regulatory authorities in other jurisdictions could revoke approval of the therapy used in combination with our product or that safety, efficacy, manufacturing or supply issues could arise with any of those existing therapies. If the therapies we use in combination with our product candidates are replaced as the standard of care for the indications we choose for any of our product candidates, the FDA, the EMA or comparable regulatory authorities in other jurisdictions may require us to conduct additional clinical trials. The occurrence of any of these risks could result in our own products, if approved, being removed from the market or being less successful commercially. We also plan to evaluate current and future product candidates in combination with one or more therapies that have not yet been approved for marketing by the FDA, the EMA or comparable regulatory authorities in other jurisdictions. We will not be able to market any product candidate we develop in combination with an unapproved therapy if that unapproved therapy does not ultimately obtain marketing approval. In addition, unapproved therapies face the same risks described with respect to our product candidates currently in development and clinical trials, including the potential for serious adverse effects, delay in their clinical trials and lack of FDA, EMA or comparable regulatory authority approval.

If the FDA, the EMA or comparable regulatory authorities in other jurisdictions do not approve these other drugs or revoke their approval of, or if safety, efficacy, manufacturing or supply issues arise with, the drugs we choose to evaluate in combination with any product candidate we develop, we may be unable to obtain approval of or market any product candidate we develop.

*Our COVID-19 vaccine and any other product candidates for which we receive approval or emergency use authorization are subject to continuing regulatory oversight, and we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. We may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.*

Our COVID-19 vaccine and any other product candidates for which we receive approval or emergency use authorization are subject to continuing regulatory oversight, including the review of additional safety information, and the applicable regulatory authority may still impose significant restrictions on the indicated uses or marketing of our product or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance. For example, the holder of an approved BLA is obligated to monitor and report adverse events and any failure of a product to meet the specifications in the BLA. The holder of an approved BLA must also submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. Advertising and promotional materials must comply with FDA rules and are subject to FDA review, in addition to other potentially applicable federal and state laws.

If we fail to comply with applicable regulatory requirements following approval of any of our product candidates, a regulatory agency may:

- issue a warning letter asserting that we are in violation of the law;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval or revoke a license;
- suspend any ongoing clinical studies;
- refuse to approve a pending BLA or supplements to a BLA submitted by us;
- seize product; or
- refuse to allow us to enter into supply contracts, including government contracts.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize any approved products and generate revenues.

If any of our product candidates cause undesirable side effects, it could delay or prevent their regulatory approval, limit the commercial potential, or result in significant negative consequences following any potential marketing approval.

Product candidates we may develop may be associated with an adverse immune response or other serious adverse events, undesirable side effects or unexpected characteristics. In addition to serious adverse events or side effects caused by any of our product candidates, the administration process or related procedures also can cause undesirable side effects. If any such events occur, the clinical trials of any of our product candidates could be suspended or terminated.

If in the future we are unable to demonstrate that such adverse events were caused by factors other than our product candidate, the FDA, the EMA or other regulatory authorities could order us to cease further development of, or deny approval of, any of our product candidates for any or all targeted indications. Even if we are able to demonstrate that all future serious adverse events are not product-related, such occurrences could affect patient recruitment or the ability of enrolled trial participants to complete the trial. Moreover, if we elect, or are required, to delay, suspend or terminate any clinical trial of any of our product candidates, the commercial prospects of such product candidates may be harmed and our ability to generate product sale revenues from any of these product candidates may be delayed or eliminated. Any of these occurrences may harm our ability to identify and develop product candidates, and may harm our business, financial condition, result of operations and prospects significantly.

Additionally, following regulatory approval of a product candidate, the FDA or other regulatory authority could require us to adopt a REMS or a risk management plan, or RMP, to ensure that the benefits of treatment with such product candidate outweigh the risks for each potential patient, which may include, among other things, a medication guide outlining the risks of the product for distribution to patients, a communication plan to health care practitioners, extensive patient monitoring, or distribution systems and processes that are highly controlled, restrictive, and more costly than what is typical for the industry.

Furthermore, if we or others later identify undesirable side effects caused by any product that we develop, several potentially significant negative consequences could result, including:

- regulatory authorities may suspend or withdraw approvals or revoke licenses of such product;
- regulatory authorities may require additional warnings on the label;
- we may be required to change the way a product is administered or conduct additional clinical trials;
- we could be sued and held liable for harm caused to patients and their children; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of any products we may identify and develop and could have a material adverse effect on our business, financial condition, results of operations and prospects.

If we are successful in gaining approval for any of our product candidates, we will continue to face significant regulatory oversight of the manufacturing and distribution of our products. Product manufacturers and their facilities are subject to payment of user fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with GMP and adherence to commitments made in the BLA. If we or a regulatory agency discovers previously unknown problems with a product such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions relative to that product or the manufacturing facility, including requiring recall or withdrawal of the product from the market or suspension of manufacturing.

***We may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, and other healthcare laws. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.***

We may be subject to additional healthcare regulation and enforcement by the U.S. federal government and by authorities in the United States, the European Union and other jurisdictions in which we conduct our business.

If we obtain FDA approval for any of our product candidates and begin commercializing those products in the United States, our operations will be directly, or indirectly through our prescribers, customers and purchasers, subject to various federal and state fraud and abuse laws and regulations, including, without limitation, the federal Health Care Program Anti-Kickback Statute, the federal civil and criminal False Claims Act, and the Physician Payments Sunshine Act and regulations. Many states and other jurisdictions have similar laws and regulations, some of which may be broader in scope.

These laws will impact, among other things, our proposed sales, marketing and educational programs. In addition, we may be subject to patient privacy laws enacted by both the federal government and the states in which we conduct our business. The laws that will affect our operations include, but are not limited to the following:

- The federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, in return for the purchase, recommendation, leasing or furnishing of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand, and prescribers, purchasers, and formulary managers on the other. The ACA amends the intent requirement of the federal Anti-Kickback Statute to provide that a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it.
- The federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, false or fraudulent claims for payment or approval from Medicare, Medicaid or other government payors. The ACA provides, and recent government cases against pharmaceutical and medical device manufacturers support, the view that federal Anti-Kickback Statute violations and certain marketing practices, including off-label promotion, may implicate the False Claims Act.
- The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit a person from knowingly and willfully executing a scheme or making false or fraudulent statements to defraud any healthcare benefit program, regardless of the payor (*e.g.*, public or private).
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and their implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization by entities subject to the rule, such as health plans, health care clearinghouses and health care providers.
- The U.S. Federal Food, Drug, and Cosmetic Act, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices.
- The U.S. Public Health Service Act, which prohibits, among other things, the introduction into interstate commerce of a biological product unless a biologics license is in effect for that product.
- Federal transparency laws, including the federal Physician Payment Sunshine Act, which require disclosure of payments and other transfers of value provided to physicians and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members and applicable group purchasing organizations.
- State law equivalents of each of the above federal laws, state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures, and state laws governing the privacy and security of health information in certain circumstances which are also applicable to us, and many of them differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts in certain circumstances.
- The U.S. Foreign Corrupt Practices Act of 1977, as amended, which prohibits, among other things, U.S. companies and their employees and agents, as well as non-U.S. companies that are registered with the SEC, from authorizing, promising, offering or providing, directly or indirectly, corrupt or improper payments or anything else of value to foreign government officials, employees of public international organizations and foreign government owned or affiliated entities, candidates for foreign political office, and foreign political parties or officials thereof; and
- Similar healthcare laws and regulations in the European Union and other jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers.

Due to the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. If our operations are found to be in violation of any of the laws described above or any other government regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from participation in government health care programs, such as Medicare and Medicaid, imprisonment, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.



The provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is prohibited in the European Union. The provision of benefits or advantages to physicians is also governed by the national anti-bribery laws of European Union member states, such as the U.K. Bribery Act 2010. Infringement of these laws could result in substantial fines and imprisonment.

Payments made to physicians in certain EU member states must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization or the regulatory authorities of the individual EU member states. These requirements are provided in the national laws, industry codes, or professional codes of conduct, applicable in the EU member states. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

***We are subject to certain anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations. We can face serious consequences for violations.***

Among other matters, anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations, which are collectively referred to as "trade laws," prohibit companies and their employees, agents, CROs, legal counsel, accountants, consultants, contractors and other collaborators from authorizing, promising, offering, providing, soliciting, or receiving directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of trade laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. We plan to engage third parties for clinical trials and/or to obtain necessary permits, licenses, intellectual property (including patents) and other regulatory approvals, and we can be held liable for the corrupt or other illegal activities of our personnel, agents or collaborators, even if we do not explicitly authorize or have prior knowledge of such activities.

***We are subject to stringent privacy laws, information security policies and contractual obligations governing the use, processing, and cross-border transfer of personal information and our data privacy and security practices.***

We receive, generate and store significant and increasing volumes of sensitive information, such as employee, personal and patient data.

We are subject to a variety of local, state, national and international laws, directives and regulations that apply to the collection, use, storage, retention, protection, disclosure, transfer and other processing of personal data, collectively referred to as "data processing", in the different jurisdictions in which we operate, including comprehensive regulatory systems in the United States and Europe. Legal requirements relating to data processing continue to evolve and may result in ever-increasing public scrutiny and escalating levels of enforcement, sanctions and increased costs of compliance.

Compliance with U.S. and international data protection laws and regulations could cause us to incur substantial costs or require us to change our business practices and compliance procedures in a manner adverse to our business. Moreover, complying with these various laws could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. Failure to comply with U.S. and international data protection laws and regulations could result in government enforcement actions (which could include civil or criminal penalties), private litigation and/or adverse publicity and could negatively affect our operating results and business. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time consuming to defend, could result in adverse publicity and could have a material adverse effect on our business, financial condition and results of operations.

The collection and use of personal health data in the European Union had previously been governed by the provisions of the GDPR. While the Data Protection Directive did not apply to organizations based outside the European Union, the GDPR has expanded its reach to include any business, regardless of its location, that provides goods or services to residents in the European Union. The GDPR imposes strict requirements on controllers and processors of personal data, including special protections for "sensitive information" which includes health and genetic information of patients residing in the European Union. The GDPR also imposes strict rules on the transfer of personal data out of the European Union to the United States and other countries. In addition, the GDPR provides that EU member states may make their own further laws and regulations limiting the processing of personal data, including genetic, biometric or health data.

Since we are located in the European Union, we are subject to the GDPR. Additionally, as the GDPR applies extraterritorially, we are also subject to the GDPR even where our data processing activities occur outside of the European Union if such activities involve the personal data of individuals located in the European Union. GDPR regulations have imposed additional responsibility and liability in relation to the personal data that we process and we may be required to put in place additional mechanisms to ensure compliance with the new data protection rules. This may be onerous and may interrupt or delay our development activities, and adversely affect our business, financial condition, results of operations and prospects.

Other jurisdictions outside the European Union are similarly introducing or enhancing privacy and data security laws, rules and regulations, which could increase our compliance costs and the risks associated with non-compliance. We cannot guarantee that we are, or will be, in compliance with all applicable international regulations as they are enforced now or as they evolve. For example, our privacy policies may be insufficient to protect any personal information we collect, or may not comply with applicable laws, in which case we may be subject to regulatory enforcement actions, lawsuits or reputational damage, all of which may adversely affect our business. There is significant uncertainty related to the manner in which data protection authorities will seek to enforce compliance with the GDPR, especially with regard to clinical trial conduct. For example, it is not clear if the authorities will conduct random audits of companies doing business in the European Union, or if the authorities will wait for complaints to be filed by individuals who claim their rights have been violated. Enforcement uncertainty and the costs associated with ensuring GDPR compliance may be onerous and adversely affect our business, financial condition, results of operations and prospects. If we fail to comply with the GDPR and the applicable national data protection laws of the EU member states, or if regulators assert we have failed to comply with these laws, it may lead to regulatory enforcement actions, which can result in monetary penalties of up to €20,000,000 or up to 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher, and other administrative penalties. If any of these events were to occur, our business and financial results could be significantly disrupted and adversely affected.

Although we take measures to protect sensitive data from unauthorized access, use or disclosure, our information technology and infrastructure may be vulnerable to attacks by hackers or viruses or breached due to employee error, malfeasance or other malicious or inadvertent disruptions. Any such breach or interruption could compromise our networks and the information stored there could be accessed by unauthorized parties, manipulated, publicly disclosed, lost or stolen. Any such access, breach or other loss of information could result in legal claims or proceedings, and liability under federal or state laws that protect the privacy of personal information, as well as regulatory penalties. In the United States, notice of breaches must be made to affected individuals and the U.S. Secretary of HHS, and for extensive breaches, notice may need to be made to the media or U.S. state Attorneys General. Such a notice could harm our reputation and our ability to compete. HHS has the discretion to impose penalties without attempting to resolve violations through informal means. In addition, U.S. state Attorneys General are authorized to bring civil actions seeking either injunctions or damages in response to violations that threaten the privacy of state residents. Although we have implemented security measures to prevent unauthorized access to patient data, such data is currently accessible through multiple channels, and there is no guarantee we can protect our data from breach. Unauthorized access, loss or dissemination could also damage our reputation or disrupt our operations, including our ability to conduct our analyses, deliver test results, process claims and appeals, provide customer assistance, conduct research and development activities, collect, process and prepare company financial information, provide information about our tests and other patient and physician education and outreach efforts through our website, and manage the administrative aspects of our business.

***If we or our third-party suppliers fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business.***

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also may produce hazardous waste products. We generally anticipate contracting with third parties for the disposal of these materials and wastes. We will not be able to eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from any use by us of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

***Our business operations and current and future relationships with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers will be subject to applicable healthcare regulatory laws, which could expose us to penalties.***

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers, may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute our product candidates, if approved.

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations.

If any of the physicians or other providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government-funded healthcare programs and imprisonment, which could affect our ability to operate our business. Further, defending against any such actions can be costly and time-consuming and may require significant personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

#### **Risks Related to Ownership of the ADSs**

***We have experienced and may continue to experience significant volatility in the market price of the ADSs representing our ordinary shares.***

Biopharmaceutical companies that are developing potential therapeutics and vaccines to combat COVID-19, including BioNTech SE, have experienced significant volatility in the price of their securities upon publication of preclinical and clinical data as well as news about their development programs. For example, during 2020 the closing sales price of the ADSs representing our ordinary shares on the Nasdaq Global Select Market ranged from \$29.21 to \$129.54, with significant volatility occurring shortly after announcements related to the development, approval, and commercialization of our COVID-19 vaccine. Given the attention being paid to the COVID-19 pandemic and the public scrutiny of COVID-19 development and commercialization announcements, and given that our COVID-19 vaccine is among the first vaccines to receive emergency use authorization, we expect that the public announcements we and Pfizer intend to make in the coming months regarding additional supply agreements and any news regarding manufacturing and distribution of our COVID-19 vaccine or unanticipated side effects of our COVID-19 vaccine will attract significant attention and scrutiny and that, as a result, the price of the ADSs representing our ordinary shares likely will continue to be volatile.

***If we engage in future acquisitions, joint ventures or collaborations, this may increase our capital requirements, dilute our shareholders, cause us to incur debt or assume contingent liabilities, and subject us to other risks. We may not realize the benefits of these acquisitions, joint ventures or collaborations.***

We may evaluate various acquisitions and collaborations, including licensing or acquiring complementary products, intellectual property rights, technologies or businesses. Any potential acquisition, joint venture or collaboration may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent liabilities;
- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel;

- the diversion of our management’s attention from our existing product programs and initiatives in pursuing such a strategic merger or acquisition;
- retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and regulatory approvals; and
- our inability to generate revenue from acquired technology or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

In addition, if we undertake acquisitions, we may utilize our cash, issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense.

Moreover, we may not be able to locate suitable acquisition or collaboration opportunities and this inability could impair our ability to grow or obtain access to technology or products that may be important to the development of our business.

***Our Articles of Association designate specific courts in the United States as the exclusive forum for certain U.S. litigation that may be initiated by our shareholders, which could limit our shareholders’ ability to obtain a favorable judicial forum for disputes with us.***

Our Articles of Association provide that the United States District Court for the Southern District of New York shall be the competent court of jurisdiction for the resolution of any litigation on the grounds of or in connection with U.S. federal or state capital market laws. In the absence of these provisions, under the Securities Act of 1933, as amended, or the Securities Act, U.S. federal and state courts have been found to have concurrent jurisdiction over suits brought to enforce duties or liabilities created by the Securities Act. This choice of forum provision will not apply to suits brought to enforce duties or liabilities created by the Securities Exchange Act of 1934, as amended, which already provides that such federal district courts have exclusive jurisdictions over such suits.

The choice of forum provision contained in our Articles of Association may limit a shareholder’s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our executive officers, directors, or other employees, or impose additional litigation costs on shareholders in pursuing any such claims, particularly if the shareholders do not reside in or near the state of New York, which may discourage such lawsuits. In addition, while the Delaware Supreme Court ruled in March 2020 that federal forum selection provisions purporting to require claims under the Securities Act be brought in federal court are “facially valid” under Delaware law, there is uncertainty as to whether other U.S. or German courts will enforce our choice of forum provision. The enforceability of similar choice of forum provisions in other companies’ governing documents has been challenged in recent legal proceedings, and it is possible that a court in the relevant jurisdictions with respect to us could find the choice of forum provision contained in our Articles of Association to be inapplicable or unenforceable. If the relevant court were to find the choice of forum provision contained in our articles of association to be inapplicable or unenforceable, we may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect our business, financial condition and operating results. The choice of forum provision may also impose additional litigation costs on shareholders who assert that the provision is not enforceable or invalid. The United States District Court for the Southern District of New York may also reach different judgments or results than would other courts, including courts where a shareholder considering a U.S.-based action may be located or would otherwise choose to bring the action, and such judgments may be more or less favorable to us than our shareholders.

***Holders of the ADSs may not be able to participate in any future preemptive subscription rights issues or elect to receive dividends in shares, which may cause additional dilution to their holdings.***

Under German law, the existing shareholders of a company generally have a preemptive right in proportion to the amount of shares they hold in connection with any issuance of ordinary shares, convertible bonds, bonds with warrants, profit participation rights and participating bonds. However, our shareholders in a shareholders’ meeting may vote, by a majority representing at least three-quarters of the share capital represented at the meeting, to waive this preemptive right provided that, from the company’s perspective, there exists good and objective cause for such waiver.

The deposit agreement provides that the depositary need not make rights available to you unless the distribution to ADS holders of both the rights and any related securities are either registered under the Securities Act or exempted from

registration under the Securities Act. We are under no obligation to file a registration statement with respect to any such rights or securities or to endeavor to cause such a registration statement to be declared effective. Moreover, we may not be able to establish an exemption from registration under the Securities Act. Accordingly, ADS holders may be unable to participate in our future rights offerings and may experience dilution in their holdings. For example, ADS holders were unable to participate in our summer 2020 rights offering. In addition, if the depository is unable to sell rights that are not exercised or not distributed or if the sale is not lawful or reasonably practicable, it will allow the rights to lapse, in which case you will receive no value for these rights.

***Our principal shareholders and management own a significant percentage of our ordinary shares and will be able to exert significant control over matters subject to shareholder approval.***

Our executive officers, directors, five percent shareholders, and their affiliates beneficially own a majority of our ordinary shares (including ordinary shares represented by ADSs) as of December 31, 2020, and will have the ability to influence us through their ownership positions. For example, these shareholders, acting together, may be able to exert significant influence over matters such as elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our ordinary shares that shareholders may believe are in their best interest. Such insiders may also act in concert to waive rights to participate in rights offerings, as was done in our summer 2020 rights offering, which would have the effect of permitting the ADSs or shares underlying such waived rights to be offered to the public in an underwritten offering without contravening German law pricing requirements.

***The large number of shares eligible for sale or subject to rights requiring us to register them for sale could cause the market price of the ADSs to drop significantly, even if our business is performing well.***

We have filed a registration statement on Form S-8 under the Securities Act, to register all ordinary shares issued or issuable under our equity plans. Such Form S-8 registration statements and any other registration statements on Form S-8 we file in the future become effective upon filing, upon which shares registered under such registration statements become available for sale in the open market.

Additionally, certain sales of ADSs or our ordinary shares that we have made included holding period restrictions or registration rights. Sales of ADSs or our ordinary shares as restrictions end or pursuant to registration rights may make it more difficult for us to finance our operations through the sale of equity securities in the future at a time and at a price that we deem appropriate. These sales also could cause the trading price of the ADSs to fall and make it more difficult to sell the ADSs on favorable terms.

#### **Item 4. Information on the Company**

##### **A. History and Development of the Company**

We were founded and incorporated on June 2, 2008 as Petersberg 91, V AG, a German stock corporation (*Aktiengesellschaft*). We changed our name to BioNTech AG on December 11, 2008. On March 8, 2019, we converted to a European stock corporation (*Societas Europaea*, or SE) under the laws of Germany and the European Union called BioNTech SE. We completed our initial public offering in October 2019. ADSs representing our ordinary shares are currently listed on the Nasdaq Global Select Market under the symbol "BNTX."

Our principal executive offices are located at An der Goldgrube 12, D-55131 Mainz, Germany. Our telephone number is +49 6131-9084-0. Our website address is <http://www.biontech.de>. The information contained on, or that can be accessed through, our website is not part of this document. Our agent for service of process in the United States is c/o BioNTech US Inc., 40 Erie Street, Suite 110, Cambridge, Massachusetts 02139, +1 (617) 337-4701.

##### **B. Business Overview**

###### **I. Overview**

BioNTech was founded in 2008 on the understanding that every cancer patient's tumor is unique and that in order to effectively address this challenge, we must create individualized treatments for each patient. To realize this vision, we combine decades of groundbreaking research in immunology, cutting-edge therapeutic platforms and a suite of patient profiling and bioinformatic tools to develop immunotherapies for cancer and other diseases. We leverage powerful new therapeutic mechanisms and exploit a diverse array of biological targets to harness the power of each patient's immune system to address the unique molecular signature of each patient's underlying disease. The breadth of our immunotherapy

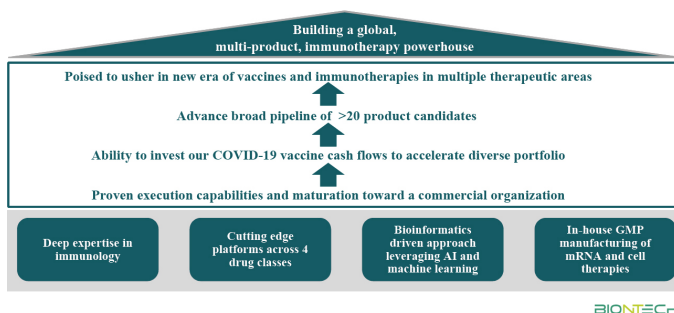
technologies and expertise enables us to develop potential therapies to address a range of rare and infectious diseases, and we rapidly mobilized these to address the COVID-19 pandemic with our COVID-19 vaccine, referred to as COMIRNATY® in the European Union and other locations where we have received marketing approval.

We believe our successful development of a first-in-class COVID-19 mRNA vaccine in less than one year validates our execution capabilities and the power of our technologies to change lives.

We intend to invest the revenues we generate from sales of our COVID-19 vaccine to accelerate the maturation of our oncology and infectious disease pipeline and the expansion into additional therapeutic areas, such as autoimmunity, allergy, regenerative medicine and inflammatory diseases.

We believe we are well positioned to develop and commercialize the next generation of immunotherapies with the potential to transform treatment paradigms for many severe diseases and significantly improve clinical outcomes for patients.

### Opportunity in 2021 and beyond



Our immunotherapy product candidates span the following four distinct drug classes:

- **mRNA Therapeutics.** We are utilizing messenger ribonucleic acid, or mRNA, to deliver genetic information to cells, where it is used to express proteins for therapeutic effect. We are developing a portfolio of immunotherapies that utilize four different mRNA formats and three different formulations to derive five distinct platforms for the treatment of cancer. Four of these platforms are currently in human testing: (i) our off-the-shelf shared antigen immunotherapy, or FixVac; (ii) our individualized neoantigen specific immunotherapy, or iNeST, in collaboration with Genentech, Inc.; (iii) our intratumoral immunotherapy, in collaboration with Sanofi, S.A.; and (iv) our mRNA encoding for specific cytokines, or RiboCytokines. In addition, we are developing another platform in which we use mRNA to express directly in the patient particular antibodies, or RiboMabs. We are also leveraging our mRNA technology to address COVID-19, influenza and other infectious diseases and rare diseases. In December 2020, our COVID-19 vaccine became the first mRNA vaccine to be authorized or approved for emergency or temporary use or granted conditional marketing authorization in over 65 countries worldwide.
- **Cell Therapies.** We are developing a range of cell therapies, including chimeric antigen receptor T cells, or CAR-T, neoantigen-based T cell therapies and T cell receptor, or TCR, therapies, in which the patient's T cells are modified or primed to target cancer-specific antigens. We are also combining our mRNA FixVac platform with our first CAR-T product candidates to enhance the persistence of CAR-T cells *in vivo*. Our first CARVac product candidate entered into clinical testing in solid tumors in February 2021.
- **Antibodies.** We are developing, in collaboration with Genmab A/S, next-generation bispecific antibodies that are designed to target immune checkpoints that modulate the patient's immune response to cancer. We are also

exploring additional targeted cancer antibody approaches utilizing our in-house capabilities. Our first two product candidates under this collaboration are in clinical testing.

- **Small Molecule Immunomodulators.** We use small molecules to augment the activity of other drug classes by inducing specific and discrete patterns of immunomodulation. We have a small molecule toll-like receptor 7, or TLR7, immunomodulator for the treatment of solid tumors in clinical testing.

We have leveraged these four drug classes to build a robust pipeline of over 20 product candidates in oncology and additional product candidates in infectious disease. We believe our technology and expertise is broadly applicable across a number of therapeutic areas, such as oncology, infectious diseases and rare diseases. Longer-term, we see applications for the technology in the fields of auto-immune diseases, allergy, inflammatory disease, and even regenerative medicine.

Our first commercial stage program is our BNT162 vaccine program to prevent COVID-19, which includes our COVID-19 vaccine development program, BNT162. We are co-developing BNT162 with Pfizer, Inc., or Pfizer, worldwide (ex-China) and with Shanghai Fosun Pharmaceutical (Group) Co., Ltd., or Fosun Pharma in China. We initiated the BNT162 program in late January 2020 and as of March 2021, our COVID-19 vaccine has been authorized or approved for emergency use or temporary use or granted conditional marketing authorization in over 65 countries around the world, including the United States, the United Kingdom, and Canada and has received conditional marketing authorization following rolling submissions with the EMA. Our COVID-19 vaccine has not been approved or licensed by the U.S. FDA, but has been authorized for emergency use by the FDA under an Emergency Use Authorization, or EUA, to prevent COVID-19 for use in individuals 16 years of age and older, as well as for emergency use in several other countries around the world. As of March 23, 2021, we and Pfizer have supplied 200 million doses of our COVID-19 vaccine globally.

In our oncology therapeutic programs, we have to-date treated over 800 patients across more than 20 solid tumor types. We also are developing more than four additional preclinical programs and expect to initiate clinical testing with several of them in 2021. In our Phase 1 trial for BNT111, our lead FixVac off-the-shelf product candidate, we have observed antigen-specific immune responses in over 90% of advanced melanoma patients treated with BNT111 as a single agent. In addition, we have observed single-agent antigen-specific immune responses in patients treated with the precursor to autogene cevumeran (RO7198457, BNT122), our iNeST product candidate. In both trials, we have observed durable objective responses (reduction in tumor volume) in both the monotherapy and checkpoint-combination settings.

#### ***Our Team***

Our team combines proven biotechnology entrepreneurs, world-renowned immunologists and sophisticated biopharma investors. We were founded in 2008 by our scientific founders, Prof. Ugur Sahin, M.D., Prof. Christoph Huber, M.D. and Özlem Türeci, M.D., with a seed investment of €150 million from the Strüngmann family, through its investment vehicle, AT Impf, and MIG Fonds, or MIG. Andreas and Thomas Strüngmann are serial entrepreneurs, having co-founded Hexal AG, a German pharmaceutical firm, which they built and sold to Novartis, along with their majority stake in Eon Labs, Inc., a U.S. public pharmaceutical firm, for a combined €5.6 billion (at the time, \$8.3 billion). Helmut Jeggle and Michael Motschmann, on behalf of the Strüngmann family and MIG, respectively, along with Dr. Huber, were founding members of our Supervisory Board.

BioNTech has been supported since its inception by Prof. Rolf Zinkernagel, M.D., Ph.D. and Prof. Hans Hengartner, Ph.D., who serve on our Scientific Advisory Board. Dr. Zinkernagel is a Professor Emeritus at the University of Zurich, University Hospital, and former head of the Institute of Experimental Immunology in Zurich. Prof. Zinkernagel was awarded the Nobel Prize in 1996 for the discovery of how the immune system recognizes virus-infected cells. Prof. Hengartner is a world-renowned immunologist and Professor Emeritus at the Federal Institute of Technology ETH Zurich and the University of Zurich.

Our initial group of scientific founders have been joined by experienced pharmaceutical executives, immunologists and biotechnology specialty investors. Sean Marett, our Chief Business Officer and Chief Commercial Officer, led the business development teams at Evotec, and previously was an executive at GlaxoSmithKline in the United States. Dr. Sierk Poetting, our Chief Financial Officer and Chief Operating Officer, joined us from Sandoz, where he served as the Chief Financial Officer in North America. Ryan Richardson, our Chief Strategy Officer, joined us from J.P. Morgan Securities LLC, where he served as Executive Director, Healthcare Investment Banking. We have also attracted talented scientists such as Katalin Karikó, our Senior Vice President & Head of RNA Protein Replacement, who has more than 30 years of experience working with RNA, has published more than 70 peer-reviewed papers and is co-inventor on mRNA-related patents, including a foundational patent relating to modified mRNA.

**II. Our Products and Pipeline of Product Candidates**

We are advancing a deep and broad portfolio of product candidates derived from our four drug classes focused on the treatment of cancer, infectious and rare diseases to complement our commercial product, our COVID-19 vaccine:

Drug class	Platform	Product Candidate	Indication (Targets)	Preclinical	Phase 1	Phase 2	Phase 3	Rights Collaborator	Milestones
mRNA	FitVac (broad combinations of shared cancer antigens)	BNT111	advanced melanoma	█	█			fully-owned	FPD <sup>1</sup> phase 2: 1H 2021
		BNT112	prostate cancer	█	█			fully-owned	
		BNT113	HPV16+ head and neck cancer <sup>1</sup>	█	█			fully-owned	FPD <sup>1</sup> phase 2: 1H 2021
		BNT114	triple negative breast cancer	█	█			fully-owned	
		BNT115	ovarian cancer <sup>2</sup>	█	█			fully-owned	
	Intratumoral Immunotherapy	antigen cross-presentation (BNT122)	HL melanoma	█	█	█		Genentech (global 50-50 profits/loss)	Phase 2 trial planned in adjuvant CRC; FPD <sup>1</sup> in 1H 2021
		SAR441000 (BNT133)	solid tumors (IL-12 $\alpha$ , IL-15 $\alpha$ , GM-CSF, IFN $\alpha$ )	█	█			Sandoz (global profits/loss share)	
		Ribocytolins (mRNA-encoded Cytokines)	BNT151	solid tumors (optimal IL-2)	█	█		fully-owned	To be confirmed - FPD <sup>1</sup> expected Feb 15
		Next-Gen CP <sup>3</sup> Immunomodulators	GEN186 (BNT111), GEN184 (BNT132)	solid tumors (PD-L1 + TIGIT) (CD137 + TIGIT)	█	█		Genmab (global 50-50 profits/loss)	Data update: 2H 2021
		Targonal Cancer Antibodies	BNT321 (MYT-5873)	pancreatic cancer (Lea)	█	█		fully-owned	Data update: 2H 2021
SMDM <sup>4</sup>	Fc $\gamma$ Receptor Binding	BNT411	solid tumors (TLR7)	█	█		fully-owned	Data update: 2H 2021	
Cell Therapies	CAR-T Cells	BNT211	solid tumors (CD19)	█	█		fully-owned	Data update: 2H 2021	

<sup>1</sup>BNT111 and BNT115 are currently being studied in investigator-sponsored Phase 1 trials.  
<sup>2</sup>Checkpoint inhibitors.  
<sup>3</sup>Next-Generation Immunomodulators.  
<sup>4</sup>FPD = First Patient Dosed.

Drug class	Platform	Product Candidate	Indication (Targets)	Preclinical	Phase 1	Phase 2	Phase 3	Rights Collaborator	Milestones
mRNA	FitVac	BNT116	NSCLC	█	█			fully-owned	
		BNT141	solid tumors	█	█			fully-owned	Phase 1 start in 2H 2021
		BNT142	solid tumors (CD3-CD19)	█	█			fully-owned	Phase 1 start in 2H 2021
Cell Therapies	CAR-T Cells	BNT152, BNT153	solid tumors (IL-7, IL-2)	█	█			fully-owned	Phase 1 start in 1H 2021
		BNT222	pancreatic, other cancers (CD19/IL2)	█	█			fully-owned	
Cell Therapies	Neonatal-based T cell therapy	BNT221 (NDO-PTC-41)	solid tumors	█	█			fully-owned	Phase 1 start in 1H 2021
		TCRs	to be selected	█	█			fully-owned	

Drug Class	Product Candidate	Indication (Targets)	Pre-clinical	Phase 1	Phase 2	Phase 3	Commercial	Rights / Collaborator
mRNA Vaccine	COMINATY	COVID-19	█	█	█	█	█	Pfizer/Fosun
	BNT162-2 (mRNA)	COVID-19	█	█	█	█	█	Pfizer/Fosun
	BNT162B3 (modRNA)	COVID-19	█	█	█	█	█	Pfizer/Fosun
	BNT161	Seasonal Influenza	█	█				Pfizer
	Un-named program	Tuberculosis	█	█				BMGF*
	Un-named program	HIV	█	█				BMGF*
Antibodies	5 un-named programs	Undisclosed indications	█	█				Fully-owned
	Undisclosed program	COVID-19	█	█				Fully-owned

\*BMGF - Bill & Melinda Gates Foundation



#### **A. Commercial Product: COVID-19 Vaccine**

Our mRNA-based COVID-19 vaccine product has been authorized or approved for emergency or temporary use or granted conditional marketing authorization in over 65 countries worldwide.

In response to the COVID-19 pandemic, we initiated our COVID-19 vaccine development program, BNT162, in late January 2020, leveraging our proprietary mRNA platform, and assembled a global consortium of partners including Pfizer (worldwide collaboration outside of China) and Fosun Pharma (China). In April 2020, we initiated a first-in-human clinical trial of BNT162b2 following preclinical studies. In July 2020, we initiated, along with our partner Pfizer, a phase 3 clinical trial of BNT162b2 and published the clinical results in November 2020. Subsequently, our COVID-19 vaccine has been authorized or approved for emergency use or temporary use or granted conditional marketing authorization in over 65 countries around the world, including the United States, the United Kingdom, and Canada and has received CMA following rolling submissions with the EMA.

We seek to drive long-term sustainable revenues from our COVID-19 vaccine program by increasing patient access through enhancing manufacturing and supply capabilities, broadening distribution geographies, expanding the label, and optimizing the formulation.

#### **Clinical Research and Development**

We and Pfizer have jointly conducted clinical trials for COVID-19 vaccine candidates across approximately 150 clinical trial sites globally. In late April 2020, we and Pfizer announced that the German regulatory authority, the Paul-Ehrlich-Institut, approved the Phase 1/2 clinical trial and the first patients in the first cohort of the Phase 1/2 clinical trial were dosed shortly thereafter. In early May 2020, we and Pfizer initiated a clinical trial for BNT162 in the U.S. and the first participants were dosed shortly thereafter.

Based on preclinical and clinical data observed, we and Pfizer progressed our BNT162 program into a Phase 2b/3 trial which commenced in late July 2020. For the initial Phase 2b/3 trial, we selected our nucleoside-modified mRNA (modRNA) vaccine candidate variant targeting the 2P-mutated full spike protein, BNT162b2. Both BNT162b2 and our BNT162b1 vaccine candidate, which uses modRNA and encodes the receptor binding domain antigen, received Fast Track status from the FDA. On the basis of data collected and analyzed for BNT162b1 and BNT162b2, including the overall observed safety, tolerability and immunogenicity profiles for each vaccine candidate at different dose levels, along with input from the FDA, we selected BNT162b2 as our lead candidate to take into a Phase 2b/3 trial.

The Phase 3 clinical trial of BNT162b2 began in July 2020 and enrolled more than 44,000 participants from approximately 150 clinical trials sites in the United States, Germany, Turkey, South Africa, Brazil and Argentina. The Phase 3 trial is designed as a 1:1 vaccine candidate to placebo, randomized, observer-blinded study to obtain safety, immune response, and efficacy data needed for regulatory review.

In August 2020, we and Fosun initiated a Phase 1 study to evaluate safety and immunogenicity in Chinese participants. In November 2020, we initiated a Phase 2 clinical trial of vaccine candidate BNT162b2 in Jiangsu Province, China to assess the safety and immunogenicity of the vaccine candidate and to support future Biologic License Application (BLA) in China.

On October 6, 2020, we announced the initiation of a rolling submission to the European Medicines Agency (EMA) for BNT162b2. The EMA's decision to start a rolling review follows the encouraging preliminary results from pre-clinical and early clinical studies in adults, which suggest that BNT162b2 triggers the production of neutralizing antibodies and TH-1 dominant CD4+ and CD8+ T cells that target SARS-CoV-2. A combination of an antibody and T cell response is believed to be important in eliciting protection against viral infection and disease.

On October 21, 2020 we and Pfizer announced initiation of a Phase 1/2 clinical trial in Japan to evaluate safety, tolerability and immunogenicity of two doses separated by 21 days and a single dose of BNT162b2.

On November 18, 2020, we and Pfizer announced that, after conducting the final efficacy analysis in our ongoing Phase 3 study, BNT162b2 met all of the study's primary efficacy endpoints. In this pivotal Phase 3 trial of BNT162b2, there were over 44,000 participants who were 16 years and older, 21,720 of whom received the two-dose regimen of 30 µg BNT162b2, which was given 21 days apart, and 21,728 of whom received the placebo. Among 36,523 participants who had no evidence of existing or prior SARS-CoV-2 infection at the time of the immunizations, there were 170 cases of COVID-19 observed at least seven days after the second dose. Of these 170 cases of COVID-19, 162 cases occurred among placebo

recipients and eight cases occurred in vaccine recipients, corresponding to 95.0% vaccine efficacy. Among participants with and without evidence of prior SARS CoV-2 infection, there were nine cases of COVID-19 among vaccine recipients and 169 among placebo recipients, corresponding to a 94.6% vaccine efficacy. The cumulative incidence of COVID-19 cases over time among placebo and vaccine recipients began to diverge by 12 days after the first dose, and 52.4% vaccine efficacy was observed between the first and second doses, indicating the early onset of a partially protective effect of immunization. Two doses of vaccine provide the maximum protection observed. Ten cases of severe COVID-19 were observed with onset after the first dose. Nine cases occurred among placebo recipients and one among BNT162b2 recipients.

BNT162b2 exhibited a favorable tolerability and safety profile. Based on a data cut-off date of October 9, 2020, 37,706, participants had a median of at least two months of safety data available after the second dose and contributed to the main safety dataset. Among these participants, 49% were female; 83% were White; 9% were Black or African American; 28% were Hispanic/Latinx; 35% were obese (BMI  $\geq 30.0$  kg/m<sup>2</sup>); and 21% had at least one underlying comorbidity. The median age was 52 years, and 42% were older than 55 years. The most common adverse events of BNT162b2 were transient, mild to moderate pain at the injection site, fatigue and headache, and these generally resolved within two days. These reactions were less common and milder in older adults than younger adults. Severe reactions (Grade 3) were reported in fewer than 2% of vaccine recipients after either dose except for fatigue (3.8%) and headache (2.0%). Fever ( $\geq 38$  °C) was reported in similar proportions of younger (16%) and older (11%) vaccine recipients. Rates of serious adverse events were similar between vaccine and placebo groups (0.6% and 0.5%). There were no COVID-19-related deaths.

All trial participants will continue to be monitored to assess long-term protection and safety for an additional two years after their second dose. Data from this study, including longer term safety, comprehensive information on duration of protection, efficacy against asymptomatic SARS-CoV-2 infection, and safety and immunogenicity in adolescents 12 to 15 years of age will be gathered.

On December 10, 2020, results from the Phase 3 trial of BNT162b2 were published in The New England Journal of Medicine. We have also published several scientific papers on the new rapidly spreading variants of SARS-CoV-2 and how they might affect the efficacy of BNT162b2. In December 2020, we published data on a panel of 18 SARS-CoV-2 RBD variants identified through publicly available information. Sera collected seven days after the booster dose of BNT162b2 showed high neutralising titers to each of the SARS-CoV-2 S variants, demonstrating the breadth of the neutralising response against circulating strains.

In January 2021, we released three other publications on the vaccine efficacy against new SARS-CoV-2 strains. One publication showed that sera from vaccinated individuals neutralized SARS-CoV-2 with an introduced N501Y mutation, a key target of virus neutralizing antibodies, as efficiently as SARS-CoV-2 without the mutation. Another publication showed that pseudovirus bearing the U.K. strain SARS-CoV-2 spike with the full set of mutations was inhibited by BNT162b2-immune sera with a neutralization range that is biologically equivalent to the unmutated SARS-CoV-2 Spike. A third set of data was published by Xie et al. demonstrating that three recombinant SARS-CoV-2 variants containing key spike mutations from the newly emerged U.K. and South African variants (N501Y from the United Kingdom and South Africa; 69/70-deletion+N501Y+D614G from the United Kingdom; and E484K+N501Y+D614G from South Africa) were neutralized by sera from vaccinated individuals with a GMT neutralization rate against the wild-type strain of 1.46, 1.41, and 0.81, respectively. In March, we and Pfizer published data in the New England Journal of Medicine from an in vitro study of the neutralizing activity of BNT162b2-elicited serum against the variants first detected in the United Kingdom (B.1.1.2 lineage), Brazil (P.1 lineage), and South Africa (B.1.351 lineage). Sera neutralized all the viruses tested and showed no significant reduction in activity against both B.1.1.7-spike and P.1-spike viruses. While neutralization of the B.1.351-spike virus was lower, it was still robust. Thus, the neutralization data provide support that BNT162b2 will continue to protect against the variants first detected in the United Kingdom and Brazil.

While these findings do not indicate an immediate need for a new vaccine to address the emerging variants, we will continue to monitor emerging SARS-CoV-2 strains and continue to conduct studies to monitor the vaccine's real-world effectiveness. We intend to respond quickly if a variant of SARS-CoV-2 shows clinical evidence of escaping immunity from our vaccine and will proactively prepare new vaccine constructs if needed. We believe that the flexibility of our proprietary mRNA vaccine platform is well suited to develop new vaccine variants if required (requiring potentially as short as six weeks to design a new product candidate).

In February 2021, we and Pfizer announced that the first participants had been dosed in a global Phase 2/3 study to further evaluate the safety, tolerability, and immunogenicity of BNT162b2 in preventing COVID-19 in healthy pregnant

women 18 years of age and older. We and Pfizer are also planning studies to further evaluate the vaccine in people with compromised immune systems. Additionally, we announced that safety and efficacy data from the global Phase 3 study with subjects 12 to 15 years of age are expected to be submitted to the regulatory authorities in the second quarter of 2021.

On February 25, 2021, we and Pfizer announced the initiation of a trial to evaluate the safety and immunogenicity of a third dose of our COVID-19 vaccine on prolonging immunity against COVID-19 and to address potential newly emerging SARS-CoV-2 variants. In March 2021, the U.S. FDA approved an additional amendment to the study protocol of the global Phase 1/2/3 trial for an additional dose of BNT162b2 or its modified version carrying the spike protein sequence of the so-called South African variant (BNT162b2<sub>SA</sub>) in order to further describe duration of protection, and protection against the emerging variants of concern. An additional dose of either BNT162b2 or BNT162b2<sub>SA</sub> will be given to approximately 600 Phase 3 participants approximately five to seven months after their second dose of BNT162b2. A further dose of BNT162b2<sub>SA</sub> will be given to approximately 30 of those participants who receive BNT162b2<sub>SA</sub>. Approximately 300 BNT162b2-naïve participants will be enrolled and receive 2 doses of BNT162b2<sub>SA</sub> to describe protection against the emerging variants of concern and reference strains. The part of the trial with BNT162b2<sub>SA</sub> is expected to start in the second quarter of 2021.

In March 2021, we also announced real-world evidence demonstrating dramatically lower incidence rates of COVID-19 disease in individuals fully vaccinated with our COVID-19 vaccine in Israel, underscoring the observed substantial public health impact of Israel's nationwide immunization program. These new data, collected by the Israel Ministry of Health, demonstrate the vaccine's effectiveness in preventing symptomatic SARS-CoV-2 infections, COVID-19 cases, hospitalizations, severe and critical hospitalizations, and deaths. Additionally, the analysis from the Israel Ministry of Health showed that two weeks after the second vaccine dose protection vaccine effectiveness was at least 97% in preventing symptomatic disease, severe/critical disease and death. The analysis also showed a vaccine effectiveness of 94% against asymptomatic SARS-CoV-2 infections. Since this observational analysis was conducted when the variant B.1.1.7 was the dominant strain in Israel, it also provides real-world evidence of the effectiveness of BNT162b2 for prevention of COVID-19 infections, hospitalizations, and deaths due to variant B.1.1.7.

In March 2021, the first participants were dosed in a Phase 1/2/3 study in healthy children 6 months to under 12 years of age. The Phase 1 dose finding portion is evaluating the safety, tolerability and immunogenicity of two doses of BNT162b2 separated by 21 days in up to three age groups ( $\geq 5$  to  $<12$  years,  $\geq 2$  to  $<5$  years, and  $\geq 6$  months to  $<2$  years of age). Once the preferred dose level of BNT162b2 is identified for each age group, a Phase 2/3 trial to evaluate the safety, tolerability and immunogenicity in each age group will start. Efficacy against confirmed COVID-19 and asymptomatic infection will also be assessed.

Additionally, in March 2021, we announced that we will start a Phase 3 trial to evaluate the safety, tolerability and immunogenicity of lyophilized BNT162b2 presented in single-dose vials and of frozen liquid BNT162b2 in multidose vials. This trial will also assess the noninferiority of the lyophilized formulation. The trial will be conducted in healthy adults 18 through 55 years of age and will start in the United States in April.

#### **Regulatory**

As of March 2021, our COVID-19 vaccine has been authorized or approved for emergency use or temporary use in over 65 countries around the world, including the United States, the United Kingdom, the European Union and Canada. Our COVID-19 vaccine has not been approved or licensed by the U.S. FDA, but has been authorized for emergency use by the FDA under an EUA, to prevent COVID-19 for use in individuals 16 years of age and older.

Under our collaboration with Pfizer, we are the designated regulatory authorization worldwide. Pfizer has marketing and distribution rights worldwide with the exception of China, Germany, and Turkey. Fosun Pharma has marketing and distribution rights in China.

On January 28, 2021, the EMA published a safety update from its Pharmacovigilance Risk Assessment Committee, or PRAC. The safety data reviewed for our COVID-19 vaccine are in line with the vaccine's known benefit-risk profile. The review covered all new safety data emerging since December 21, 2020, including the first Summary Monthly Safety Report from the marketing authorization holder. PRAC noted that a recent analysis in the United States estimated the frequency of anaphylaxis as approximately 11 cases per million doses of our COVID-19 vaccine administered. With respect to reports of suspected side effects with fatal outcome, specifically in frail elderly individuals, PRAC stated that in many cases concerning individuals above 65 years of age, progression of (multiple) pre-existing diseases seemed to be a plausible explanation for death. In some individuals, palliative care had already been initiated before vaccination. PRAC concluded

that based on the current data there was no need to amend the product information regarding how our COVID-19 vaccine should be used, including in frail elderly individuals. PRAC requested continued thorough review of all reports of suspected side effects with fatal outcome.

On February 25, 2021, the U.S. FDA, and on March 26, 2021, the EMA, approved that undiluted frozen vials of BNT162b2 may be transported and stored at conventional temperatures commonly found in pharmaceutical freezers (-25°C to -15°C or -13°F to 5°F) for a period of up to two weeks. Further formulation optimization activities are ongoing.

#### **Manufacturing and Delivery Capabilities**

We and Pfizer continue to work in collaboration with governments and health ministries around the world that will distribute the vaccine, subject to country authorization or approval and terms of supply agreements, to help ensure it can reach those most in need as quickly as possible. We and Pfizer are leveraging Pfizer's leading vaccine manufacturing and distribution capabilities to quickly scale, manufacture and distribute large quantities of the vaccine at high quality, complementing BioNTech's mRNA manufacturing expertise gained over almost a decade. Based on projections as of March 2021, Pfizer's and BioNTech's combined manufacturing network has the potential to supply globally up to 2.5 billion doses by the end of 2021 (subject to regulatory approval or authorization). Additionally, as of March 23, 2021 we and Pfizer have supplied 200 million doses of our COVID-19 vaccine globally.

Through our existing mRNA production sites in Germany, we were able to begin producing our COVID-19 vaccine for commercial supply before receiving regulatory authorization or approval. We have increased and will continue to increase our manufacturing capacity, including through our acquisition of a manufacturing site in Marburg, Germany. Our Marburg site is one of the key factors in the expansion of our manufacturing network and will become one of the largest mRNA manufacturing sites in Europe with an annual production capacity of up to one billion doses of our COVID-19 vaccine, once fully operational. We and Pfizer also leverage Pfizer's manufacturing site in Puurs, Belgium, one of Pfizer's largest sterile injectable sites, for European supply and as back up supply to the primary manufacturing site for the U.S. market, which is in Kalamazoo, Michigan. Our European manufacturing network has continually expanded from three partners in December 2020 when we received our first authorizations to 13 sites (including the Marburg facility) as of March 2021, and we are continuing to strengthen this network.

Pfizer has vast experience and expertise in cold-chain shipping and has an established infrastructure to supply the vaccine worldwide, including distribution hubs where vaccine can be stored until its expiration. Pfizer's distribution is built on a flexible just-in-time system that can ship the frozen vials quickly to designated points of vaccination at the time of need, minimizing the need for long term storage. Vaccination in a pandemic situation is expected to be rapid, and we do not expect that the product will need to be stored at any location for more than 30 days. To assure product quality, we and Pfizer have developed specially designed, temperature-controlled shippers for the vaccine, which can maintain recommended shipping conditions (-80°C to -60°C (-112°F to -76°F)) for extended periods of time with dry ice. The shipper can maintain temperature for 10 days unopened which allows for transportation to markets globally. Once open, a vaccination center may store the vaccine in an ultra-low temperature freezer at (-75°C ±15°C) for up to six months, or use the specially designed shippers as a temporary storage solution to maintain the required temperatures for up to 30 days with re-icing every five days in accordance with the handling instructions. Alternatively, pursuant to the U.S. FDA's and the EMA's approvals in February and March 2021, respectively, the vials may be stored at -25°C to -15°C (-13°F to 5°F), temperatures more commonly found in pharmaceutical freezers and refrigerators. Once thawed, the vaccine vial can be stored safely for up to five days at refrigerated (2-8°C) conditions.

#### **Commercial update**

As of March 2021, we have signed orders for more than 1.4 billion doses in 2021, and discussions for additional dose commitments are ongoing. This includes agreements with the governments in the United States, United Kingdom, Japan, Canada and the European Union.

In December 2020, we and Pfizer announced a second agreement with the U.S. government to supply an additional 100 million doses of our COVID-19 vaccine. In February 2021, we and Pfizer announced that the U.S. government exercised its option for an additional 100 million doses of our COVID-19 vaccine. This agreement brings the total number of doses to be delivered to the United States to 300 million. Consistent with the original agreement announced in July 2020, the U.S. government will pay \$1.95 billion for the additional 200 million doses.

In addition, in December 2020, we and Pfizer announced we and Pfizer will supply an additional 100 million doses of our COVID-19 vaccine to the EU member states in 2021, as a result on an option exercised under an advanced purchase

agreement with the European Commission, or the EC. In February 2021 we and Pfizer announced a new agreement with the EC to supply an additional 200 million doses of our COVID-19 vaccine, with the option to request a supply of an additional 100 million doses. This agreement brings the total number of doses to be delivered to the European Union to 500 million, with the potential to increase to 600 million based on the option granted in the new agreement.

## B. Our Clinical Stage Product Candidates in Oncology

We are developing a broad and deep pipeline of over 20 product candidates across our four drug classes. 13 oncology product candidates are currently being investigated in 14 clinical trials.

### 1. Our mRNA Product Class in Oncology

#### a) FixVac

FixVac is our wholly owned, systemic, off-the-shelf mRNA-based cancer immunotherapy platform, from which we are developing several first-in-human and potential first-in-class product candidates. Our FixVac product candidates contain selected combinations of pharmacologically optimized uridine mRNA encoding known cancer-specific shared antigens. FixVac product candidates feature our proprietary immunogenic mRNA backbone and proprietary RNA-LPX delivery formulation, which are designed to enhance stability and translation as well as trigger both innate and adaptive immune responses.

#### i. BNT111: Our FixVac Cancer Immunotherapy for the Treatment of Advanced Melanoma

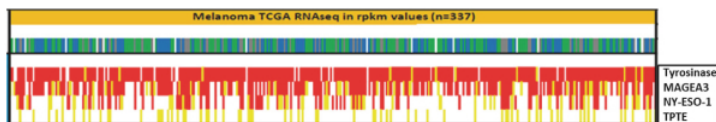
We are developing our mRNA-based FixVac product candidate BNT111 for the treatment of advanced melanoma in patients with metastatic tumors and as an adjuvant treatment after tumor resection. We are currently studying BNT111 in an ongoing Phase 1 clinical trial and expect to start a randomized Phase 2 clinical trial in first half of 2021.

#### Our BNT111 Targets

BNT111 is designed to elicit an immune response to the following four antigens that have each been found to be associated with melanoma:

- New York esophageal squamous cell carcinoma 1, or NY-ESO-1, a well-known cancer-testis antigen that is also expressed in numerous cancers, including melanoma;
- melanoma-associated antigen A3, or MAGE-A3, which is not expressed in normal tissues, except the testis;
- tyrosinase, an enzyme that is required for melanin production and that is expressed at high levels in melanoma; and
- trans-membrane phosphatase with tensin homology, or TPTE, a novel cancer/testis antigen that we discovered internally.

Sequencing data from 337 melanoma tumors showed that at least one of these four antigens is detected in over 90% of such melanoma tumors.



**BNT111 antigens detected in over 90% of melanoma tumors.** The graphic above shows expression of BNT111 target antigens on a patient by patient basis. Each row at the bottom of the graphic represents an antigen, and each vertical line represents a patient, depicting whether or not that patient's tumor expressed each antigen. Red/yellow = antigen is expressed in patient's tumor; white = no expression.

### **Our BNT111 Clinical Trials**

#### *Ongoing Phase 1 Trial in Advanced Melanoma Patients (LIPOMERIT trial)*

We are conducting a multi-center, open-label, first-in-human, Phase 1 dose escalation study evaluating the safety and tolerability of multiple intravenous administrations of BNT111 in patients with advanced melanoma. This is the first clinical trial worldwide in which an mRNA-based cancer immunotherapy is administered intravenously for systemic treatment.

The trial employed a conventional 3+3 design in which patients were dosed in groups of three at incrementally greater dosages until the maximum tolerated dose was identified, during the dose escalation phase, which was then followed by expanded dose cohorts. Patients were treated with doses from 7.2µg up to the highest administered dose of 400µg of total RNA.

#### *July 2020 Data from BNT111 Lipo-MERIT Trial published in Nature*

In July 2020 we published interim Phase 1 data in the journal *Nature*. The publication titled “An RNA vaccine drives immunity in checkpoint-inhibitor-treated melanoma” summarizes the findings of the exploratory interim analysis (data extraction date July 29, 2019).

Overall, the preliminary Phase 1 results from the Lipo-MERIT trial with data from 89 patients highlight a favorable tolerability profile of BNT111 in advanced melanoma patients.

- No dose-limiting toxicities to BNT111 have been reported. The overall adverse event profile was dominated by mild-to-moderate, transient and manageable flu-like symptoms. These symptoms were managed by pre-medication with non-steroidal antipyretics, such as ibuprofen and acetaminophen. Eight patients dosed with BNT111 experienced related treatment-emergent serious adverse events, or TESAEs. There were confounding factors, such as treatment with other therapies or underlying medical conditions, for the patients with related TESAEs. We could not establish a clear causal relationship between BNT111 and the cases of anaphylactic reaction, retinopathy, encephalopathy syndrome, seizure and suspected pancreatitis. There have been no deaths in this trial that were assessed by the investigators as related to BNT111.

The efficacy analysis in a subset of 42 checkpoint-inhibitor (CPI)-experienced metastatic melanoma patients showed that BNT111 mediates durable responses both as a single agent and in combination with anti-PD-1 antibodies. Durable objective responses by BNT111 were associated with activation and strong expansion of tumor-antigen-specific CD4+ and CD8+ T cells.

Clinical activity was assessed in 25 patients that received BNT111 as a monotherapy, and 17 patients that received BNT111 in combination with an anti-PD-1 checkpoint inhibitor, or CPI (either pembrolizumab or nivolumab). In the BNT111 monotherapy cohort, we observed clinical activity for all 25 patients. All of these patients had received at least one line of prior treatment with a checkpoint inhibitor (CPI), and 24 of the 25 patients had failed prior sequential or combination treatment with anti-PD-1 and anti-CTLA4 antibodies. Three of 25 patients (12%) showed a partial response, or PR, one patient had a metabolic complete response and seven patients (28%) demonstrated stable disease. The clinical benefit rate, or CBR, is 44%. In the cohort treated with BNT111 in combination with a PD-1 CPI, 16 of the 17 patients had prior treatment with CPI. Six patients (35%) showed a partial response, and two patients (12%) demonstrated stable disease. The CBR is 47%. Objective responses were observed across all dose levels explored in expansion cohorts (14µg, 50µg and 100µg).

This interim data suggests that BNT111 alone and in combination with PD-1 checkpoint blockade, while being well tolerated, may mediate durable objective responses in melanoma patients that had progressed on or after prior checkpoint blockade. Vaccine-induced antigen-specific memory T cells persisted for more than one year under continuous monthly vaccination.

#### *Phase 2 Trial with anti-PD-1 Therapy*

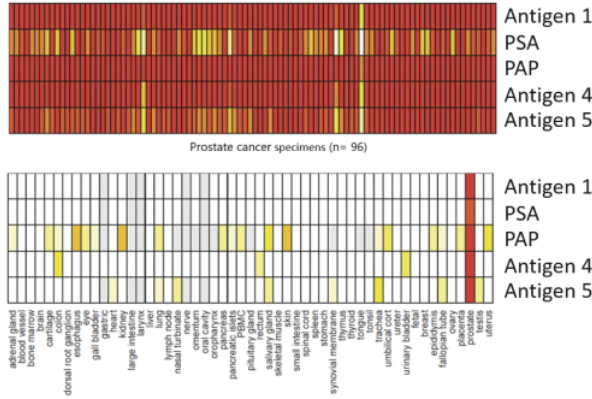
In July 2020, we announced a strategic collaboration with Regeneron to jointly conduct a randomized Phase 2 trial for the treatment of patients with advanced melanoma progressing during or after prior therapy with a PD-1 inhibitor, utilizing a combination of BNT111 and Regeneron and Sanofi's Libtayo (cemiplimab). Our IND for this trial in the United States is active. We received CTA approval in Spain and clinical trial applications are under review in Australia and five European countries (France, Germany, Italy, Poland, and the United Kingdom). We are targeting commencement of the

**ii. BNT112: Our FixVac Cancer Immunotherapy for the Treatment of Prostate Cancer**

We are developing BNT112 for the treatment of prostate cancer.

**Our BNT112 Targets**

BNT112 is designed to elicit an immune response to five prostate cancer-specific antigens, including prostate-specific antigen, or PSA, a transmembrane protein that is expressed by virtually all prostate cancers, prostatic acid phosphatase, or PAP, and three additional tumor-associated antigens.



**Our BNT112 Clinical Trials**

**Ongoing Phase 1/2 Clinical Trial (PRO-MERIT)**

PRO-MERIT is a first-in-human, dose titration and expansion trial to evaluate safety, immunogenicity and preliminary efficacy of BNT112 monotherapy and in combination with cemiplimab in patients with prostate cancer. The study is a Phase 1/2a, open-label, multicenter trial for metastatic castration resistant prostate cancer patients (mCRPC) and patients with high-risk, localized prostate cancer (LPC) eligible for treatment with androgen deprivation therapy (ADT) followed by radical prostatectomy. The Phase 1/2a trial consists of two parts: dose titration (Part 1) and dose expansion (Part 2). The trial started end of 2019. In January 2021 we enrolled the first patient in the expansion part of the trial.

The primary objectives of this study are to establish the safety and tolerability profile of BNT112 monotherapy or in combination with cemiplimab (Parts 1 and 2), and to evaluate preliminary anti-tumor activity of BNT112 monotherapy and in combination with cemiplimab in patients with mCRPC based on ORR (Part 2). The secondary objectives of the trial are to examine the immunogenicity of BNT112 alone or in combination with cemiplimab, to evaluate anti-tumor activity based on levels of PSA, and to evaluate preliminary anti-tumor activity of BNT112 monotherapy and in combination with cemiplimab in patients with mCRPC based on ORR (Part 1).

Part 1 is a first-in-human, single arm design for mCRPC patients. It starts with an intra-patient dose titration in Cycle 1 for the initial safety assessment and recommended expansion dose range assessment. Part 2 consists of four arms (1A, 1B, 2 and 3), with similar intra-patient dose titration in Cycle 1, for both mCRPC and LPC indications, and targeting to enroll approximately 106 patients. Arms 1A and 1B are designed to treat mCRPC patients with a combination treatment (BNT112 and cemiplimab) and monotherapy (BNT112), respectively. Arms 2 and 3 are designed to treat LPC patients with a combination treatment (BNT112 and cemiplimab) and monotherapy (BNT112), respectively, plus a background medication of an androgen-deprivation therapy (e.g. goserelin acetate).

**iii. BNT113: Our FixVac Cancer Immunotherapy for the Treatment of HPV16+ Head and Neck Cancer**

We are developing BNT113 for the treatment of HPV+ head and neck cancer.

**Our BNT113 Targets**

BNT113 is designed to elicit an immune response against the well-characterized HPV16-derived oncoproteins E6 and E7, which are strongly immunogenic, viral neoantigens that are found in HPV16+ solid cancers such as head and neck squamous cell carcinoma.

**Our BNT113 Clinical Trials**

*Ongoing Phase 1/2 Basket Trial (Investigator-Sponsored)*

BNT113 is being studied by the University of Southampton in an investigator sponsored open-label, Phase 1/2 dose escalation basket study with two different arms in approximately 44 patients with HPV16+ head and neck and other cancers. The first arm will perform dose escalation in patients with previously treated HPV16+ head and neck cancer using two dose cohorts to establish a safe, tolerable and recommended dose of BNT113. The second arm will perform dose escalation in patients with advanced HPV16+ cancers, including head and neck, anogenital, penile and cervical cancers, using a single cohort to establish a safe, tolerable and recommended dose.

*Planned BNT113 Phase 2 Trial*

We expect to start an open-label, controlled, multi-site, interventional, 2-arm, Phase 2 trial evaluating BNT113 in combination with pembrolizumab versus pembrolizumab monotherapy as a first-line treatment in patients with unresectable recurrent or metastatic HPV16+ head and neck squamous cell carcinoma (HNSCC) expressing PD-L1 in the first half of 2021 in US and EU

The BNT113 IND was activated in the United States in October 2020 and since then we have received CTA approval from Health Canada (December 2020) and Hungary (January 2021).

The FDA placed a partial clinical hold on the second arm, part B, of the Phase 2 trial in October 2020. BNT113 has not been combined with anti-PD1 before and the Phase 2 trial will start with a run in portion designed to demonstrate the safety of the combination of BNT113 and pembrolizumab. These data is required to address the partial clinical hold on the subsequent randomized part of the Phase 2 trial.

**iv. BNT114: Our FixVac Cancer Immunotherapy for the Treatment of Triple Negative Breast Cancer**

We are studying eight antigens selected for BNT114 in a three-arm clinical trial as both a monotherapy and in combination with our individualized neoantigen specific vaccine in patients with triple negative breast cancers (TNBC).

**Our BNT114 Targets**

Patients are treated with individualized combinations of BNT114 antigens. BNT114 is designed to provide patients with an optimal combination of antigens and to elicit an immune response to selected antigens that are expressed in the patients' tumor.

**Our BNT114 Clinical Trial**

*Ongoing Phase 1 Clinical Trial (BNT114 monotherapy and in combination with our neoantigen vaccine)*

We are conducting an international, multi-center, open-label, three-arm Phase 1 study of BNT114 as a monotherapy and in combination with our individualized neoantigen specific immunotherapy in TNBC patients who had previously received the standard of care therapy (i.e., surgery, chemotherapy and/or radiotherapy). The primary endpoints of the study are to assess safety, feasibility and tolerability. These endpoints will be analyzed by occurrence of treatment emergent adverse events or TEAEs within a patient and by regular assessment of clinical and laboratory parameters. The secondary endpoint of the study is to determine vaccine-induced T-cell responses resulting from multiple vaccination cycles.

Patients in the first arm receive BNT114, patients in the second arm receive a combination of optional BNT114 followed by individualized neoantigen specific immunotherapy and patients in the third arm receive BNT114 in combination with RNA-LPX encoding tetanus-toxoid-derived helper epitopes.

Recruitment and treatment were completed in 2020 in all three arms.



On September 18, 2020, a data update was presented at the ESMO Virtual Congress 2020 for the second treatment arm investigating the individualized neoantigen vaccine encoding up to 20 cancer neoantigens determined by next generation sequencing. The preliminary analysis showed that the neoantigen vaccine is highly efficient in inducing strong poly-epitopic T-cell responses in the post- (neo) adjuvant setting. In all 14 patients vaccine-induced T-cell responses against up to 10 neoantigens could be detected of which the majority was de novo. In 12 out of 14 patients T-cell responses were of such high magnitude that they could be detected directly *ex vivo*.

**v. BNT115: Our FixVac Cancer Immunotherapy for the Treatment of Ovarian Cancer**

We are developing BNT115 for the treatment of ovarian cancer. BNT115 is currently being studied in an ongoing investigator-initiated and -sponsored Phase 1 trial.

**Our BNT115 Targets**

BNT115 is designed to elicit an immune response to selected antigens that are found in ovarian cancers.

**Our BNT115 Clinical Trial**

*Ongoing Phase 1 Trial (Investigator-Initiated and Sponsored)*

BNT115 is being studied in an investigator-initiated and -sponsored, first-in-human, open label, Phase 1 dose escalation trial in 10 evaluable ovarian cancer patients eligible for standard-of-care treatment with (neo-) adjuvant chemotherapy. Eight doses of BNT115 will be administered prior to and in combination with the (neo-) adjuvant chemotherapy to induce an anti-tumor immune response. Systemic immune responses will be determined using peripheral blood mononuclear cells collected before, during and after vaccinations. Intratumoral accumulation of T-cells recognizing vaccine-encoded tumor-associated antigens will be determined before vaccination in a tumor biopsy and in tumor tissue derived from interval surgery after 3 cycles of chemotherapy and 5 vaccinations. The trial is currently recruiting.

**vi. Other FixVac Indications**

We are also exploring FixVac development candidates in other cancer indications, including non-small cell lung cancer (BNT116).

**b) Individualized Neoantigen Specific Immunotherapy (iNeST)**

iNeST is an individualized cancer immunotherapy that targets specific neoantigens that are present on a patient's tumor. Our iNeST immunotherapies contain pharmacologically optimized uridine mRNA encoding up to 20 patient-specific neoantigens, as well as our proprietary RNA-LPX formulation. We are developing our iNeST cancer immunotherapy in collaboration with Genentech.

**i. Autogene cevumeran (BNT122): Our iNeST Cancer Immunotherapy for Multiple Potential Indications**

We and our collaborator Genentech are developing autogene cevumeran (BNT122) for the treatment of metastatic melanoma and other solid tumors. We are currently conducting a randomized Phase 2 trial of autogene cevumeran in collaboration with Genentech in first-line melanoma in combination with pembrolizumab. In collaboration with Genentech, we are also studying autogene cevumeran as a monotherapy and in combination with atezolizumab in a Phase 1a/1b study of patients with locally advanced or metastatic solid tumors (including melanoma, non-small cell lung cancer, bladder cancer as well as other solid tumors). The Phase 1a/1b trial is a non-registrational, signal-seeking study recruiting mostly patients with late-stage advanced cancers including patients who failed multiple lines of prior treatment.

**Our autogene cevumeran (BNT122) Targets**

Autogene cevumeran (BNT122) is an individualized neoantigen-specific immunotherapy. Each autogene cevumeran dose includes up to 20 different neoantigens selected on a patient-by-patient basis. We believe that neoantigen-specific T cells induced by autogene cevumeran may be able to enhance the therapeutic efficacy of immune checkpoint blockade.

**Our autogene cevumeran (BNT122) Clinical Trials**

*Ongoing Phase 2 Clinical Trial (First-line melanoma with pembrolizumab)*

We and Genentech are investigating the safety and efficacy of autogene cevumeran (BNT122) in 126 patients with previously untreated metastatic melanoma in a Phase 2, open-label, multi-center, randomized clinical trial. Patients in the

experimental arm will receive pembrolizumab by intravenous infusion every three weeks, plus a selected dose of autogene cevumeran at defined intervals. Patients in the active comparator arm will receive 200mg of pembrolizumab by intravenous infusion every three weeks. Patients in the comparator arm experiencing confirmed disease progression will be permitted to cross over to combination therapy with autogene cevumeran.

The primary endpoint is:

- progression-free survival, or PFS, of patients treated with autogene cevumeran compared with patients receiving pembrolizumab alone, according to RECIST v1.1.

Secondary endpoints include:

- objective response rate, or ORR, in patients treated with autogene cevumeran compared with patients receiving pembrolizumab alone, defined as the proportion of participants with complete response, or CR, or partial response, or PR;
- overall survival, or OS, of patients treated with autogene cevumeran compared with patients receiving pembrolizumab only;
- duration of response according to RECIST v1.1 of patients treated with autogene cevumeran compared with patients receiving pembrolizumab only;
- mean change in health-related quality of life, scores of patients treated with autogene cevumeran compared with patients receiving pembrolizumab only;
- percentage of patients with CR or PR following cross-over from pembrolizumab monotherapy to combination therapy following cross-over, according to RECIST v1.1; and
- incidence and severity of adverse events.

#### *Ongoing Phase 1 Clinical Trial*

The Phase 1a (monotherapy)/1b (in combination with atezolizumab) trial is a non-registrational, signal seeking study recruiting patients with locally advanced or metastatic solid tumors, including patients with melanoma, non-small cell lung cancer, bladder cancer, colorectal cancer, TNBC, renal cancer, head and neck cancer and sarcomas as well as other solid tumors. The study is designed to enroll both patients with and without prior checkpoint inhibitor regimens.

The primary objective of the study was to assess safety (including dose-limiting toxicities), and additional objectives included evaluation of immunogenicity and preliminary assessment of anti-tumor activity. The trial included a Phase 1a (monotherapy) dose escalation, a Phase 1b (combination) dose escalation, and multiple Phase 1b expansion cohorts. Patients received nine doses of the vaccine administered I.V. in weekly and bi-weekly intervals during the 12-week induction stage and every 24 weeks during the maintenance stage. In the Phase 1b portion of the trial, atezolizumab was administered on day one of each 21-day cycle.

Autogene cevumeran was manufactured on a per-patient basis including in-house determination of cancer mutation profiles, computational prediction of neoantigens, design, and manufacturing of autogene cevumeran based on liposomally formulated RNA (RNA-LPX). Each drug product contained up to 20 patient-specific neoantigens.

#### *June 2020 Monotherapy Data Update Phase 1a/basket trial*

At the 2020 AACR conference, we presented data from monotherapy dose-finding cohorts of our autogene cevumeran phase 1 trial in multiple solid tumors in which autogene cevumeran was observed to have a manageable safety profile and induced strong neoantigen-specific immune responses in patients with low and intermediate mutational load tumor types. This data related to 31 patients enrolled in cohorts with doses ranging from 25-100µg. Most patients enrolled had a low level of PD-L1 expression in the tumor as determined by immunohistochemistry. The majority of adverse events were Grade 1 or Grade 2 and those occurring in more than 20% of patients included infusion related reaction (IRR), fatigue, cytokine release syndrome (CRS), nausea, and diarrhea. IRR and CRS were transient and reversible and presented primarily as Grade 1 or Grade 2 chills and fever. A single dose-limiting toxicity of Grade 3 CRS occurred at the 100µg dose level. None of the patients discontinued autogene cevumeran due to AEs. *Ex vivo* T cell responses were detected in approximately 86% of patients treated with autogene cevumeran as a monotherapy. Autogene cevumeran induced T cells against multiple neoantigens were detected in post-treatment tumor biopsies. Of 26 patients that underwent at least one tumor assessment,

one patient with gastric cancer and metastatic liver lesions had a durable best response of confirmed complete response and remained on study after 1.5 years (3.8%) and 12 patients had stable disease (46.2%).

#### *June 2020 Combination Therapy Data Update Phase 1b/basket trial*

At AACR conference 2020, we presented data from 142 patients enrolled in cohorts with doses ranging from 15µg to 50µg of autogene cevumeran in combination with 1200mg atezolizumab. The most common tumor types enrolled were NSCLC, TNBC, melanoma and colorectal cancer with a median of three lines of prior therapies (range 1-11). The patient population included both CPI experienced and inexperienced patients. Most patients enrolled had low level of PD-L1 expression in the tumor as determined by immunohistochemistry (93% patients with <5% PD-L1 expression on tumor cells (TC0/1) and 79% patients with <5% PD-L1 expression on immune cells (IC0/1)). The majority of adverse events were Grade 1 or Grade 2 and those occurring in more than 15% of patients included infusion related reaction (IRR), fatigue, nausea, cytokine release syndrome (CRS) and diarrhea. IRR and CRS were transient and reversible and presented primarily as Grade 1 or Grade 2 chills and fever. There were no dose limiting toxicities. Eight patients (5.6%) discontinued due to AEs related to study drugs. Autogene cevumeran induced a self-limiting increase of pro-inflammatory cytokines with each dose, consistent with the TLR agonist activity of RNA. *Ex vivo* T cell responses were observed in peripheral blood in 46 out of 63 (73%) patients. Induction of up to 5.7% MHC multimer-stained CD8+ T-cells with effector memory phenotype was observed in the peripheral blood. Autogene cevumeran induced T cells against multiple neoantigens were detected in post-treatment tumor biopsies. Of 108 patients that underwent at least one tumor assessment, 1 patient had a complete response as their best response (0.9%), 8 patients had partial responses (7.4%), and 53 patients had stable disease (49.1%).

Based on data from our study of BNT121 (a prior iNeST precursor to autogene cevumeran) as an adjunct to surgery in patients with metastatic melanoma, we believe that autogene cevumeran is potentially well suited to control metastatic relapses in patients with a lower tumor burden. Additionally, autogene cevumeran as a monotherapy and in combination with atezolizumab has been observed to have a manageable safety profile to date and to induce significant levels of neoantigen-specific immune responses, even in late-stage, heavily pre-treated patients. Accordingly, we and our collaborator, Genentech, believe that autogene cevumeran is best suited for adjuvant and minimal residual disease settings. Therefore, we are evaluating options for treating early disease cancer patients with autogene cevumeran.

#### *Planned Phase 2 Trial in adjuvant colorectal cancer*

We plan to start a randomized, multi-site, open-label Phase 2 trial to compare the efficacy and safety of autogene cevumeran versus watchful waiting in resected, Stage II (High Risk) and Stage III colorectal cancer patients who are ctDNA positive following resection. The IND was approved in the United States in July 2020. First dosing is expected in the first half of 2021.

#### *Planned Phase 2 Trial in adjuvant NSCLC discontinued*

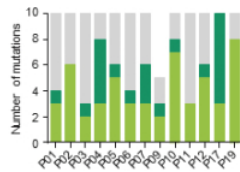
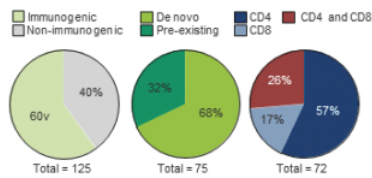
Given challenging accrual timelines in the context of the SARS-CoV2 pandemic and the evolving landscape of treatment options in NSCLC, we and Genentech have jointly decided not to go forward with the IMcode002 study in ctDNA+ early stage NSCLC and are evaluating other options for treating early disease cancer patients with autogene cevumeran.

#### *Completed Phase 1 Clinical Trial (First Generation iNeST)*

In 2017, we published the results of a 13-patient, first-in-human trial of our first-generation intranodal iNeST product candidate in patients with late-stage malignant melanoma. The objective of this clinical trial was to study the feasibility, safety, tolerability, immunogenicity and potential anti-tumoral activity of iNeST. All patients had stable disease at enrollment with a high risk for relapse.

All 13 patients developed T cell immune responses against multiple immunotherapy neoantigens at up to high single-digit percentages. As shown below, 60% of the selected neoantigens elicited a T cell response. The detected immune response comprised both CD4+ and CD8+ T cells and the majority of the response was induced *de novo*, which we believe to be an important requirement for an effective immune response and an added benefit beyond checkpoint inhibition alone.

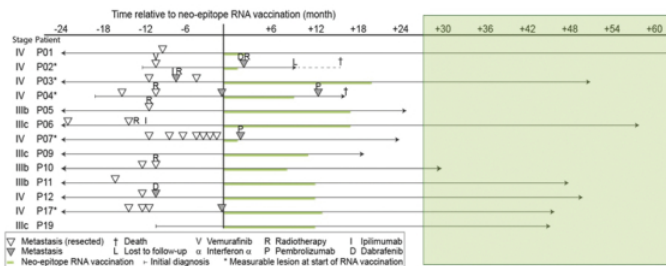
No severe adverse drug reactions were reported in the study. Common adverse events included flu-like symptoms.



**Immune responses documented in our prior BNT121 study.** Patients showed immune responses, including both CD4+ and CD8+ responses, against multiple neoantigens. Source: Nature 547, 222-226 (13 July 2017).

In addition, metastases resected from two patients following treatment with BNT121 demonstrated evidence of BNT121-induced infiltration with neoantigenspecific T cells and neoantigenspecific killing of tumor cells. The cumulative rate of metastatic events was significantly reduced after the start of treatment, resulting in a sustained progression-free survival. Of the 13 patients entering the trial, eight patients that had no radiologically detectable lesions at start of neoantigen treatment were relapse free and remained recurrence-free for the whole follow-up period (12 to 23 months). Five patients experienced melanoma relapses shortly after inclusion in the trial and despite initiation of standard treatment had progressing metastases at start of their BNT121 treatment. Of these, two patients developed BNT121-treatment-related objective clinical responses. One of these patients exhibited a complete response and remained relapse-free for 26 months. The second patient had an immunotherapy-related partial response. This patient had a late relapse owing to outgrowth of  $\beta$ 2-microglobulin-deficient melanoma cells as an acquired resistance mechanism. A third patient developed a complete response to treatment in combination with PD-1 blockade therapy.

As of October 2019, nine out of 13 patients had remained recurrence free through follow-up of up to 60 months post-vaccination.



**Metastatic relapses before and after treatment with BNT121.** The chart above shows the 27 metastatic relapses of patients before and 3 after treatment with BNT121. Each horizontal line represents the time course of a single patient. The vertical line indicates the treatment start of BNT121. Source: Nature 547, 222-226 (October 2019).

### c) Intratumoral Immunotherapy

We, in collaboration with Sanofi, are developing intratumoral immunotherapies utilizing our proprietary mRNA technology. These immunotherapies are designed to be administered directly into the tumor in order to alter the tumor microenvironment and enhance the immune system's ability to recognize and fight cancer within the tumor (proximal) as well as in other untreated locations (distal).

#### i. SAR441000 (BNT131): Our Initial Intratumoral Immunotherapy for the Treatment of Solid Tumors

In a collaboration with Sanofi, we are developing SAR441000 (BNT131) as a novel intratumoral immunotherapy for the treatment of solid tumors. SAR441000 (BNT131) consists of modified mRNA encoding immunomodulatory cytokines for direct intratumoral injection. Once delivered into the tumor, the cytokine mRNAs are expected to be taken up by tumor and other resident cells and translated into functional cytokine proteins which are thought to modulate the tumor microenvironment. SAR441000 (BNT131) is being studied in a Sanofi-sponsored Phase 1 clinical trial as monotherapy and in combination with an anti-PD-1/PD-L1 checkpoint inhibitor in patients with advanced solid tumors.

#### Our SAR441000 (BNT131) Targets

SAR441000 (BNT131) comprises mRNA encoding the cytokines IL-12sc, IL-15sushi, IFN- $\alpha$  and GM-CSF, that we have identified as mediators of tumor regression across different murine tumor models. By expressing these cytokines in the tumor microenvironment, the immune system may more easily recognize and fight cancer. Combining the mRNAs with checkpoint inhibitors enhanced antitumor responses in both injected and non-injected tumors, improving survival and tumor regression in mice.

#### Our SAR441000 (BNT131) Clinical Trials

##### Ongoing Phase 1 Clinical Trial

Sanofi, in collaboration with us, commenced a first-in-human, multi-center, open-label, Phase 1, dose escalation and expansion trial to evaluate the safety, pharmacokinetics, pharmacodynamics and anti-tumor activity of SAR441000 (BNT131) administered intratumorally as monotherapy and in combination with cemiplimab, with an estimated enrollment of up to 231 patients with certain advanced solid tumors.

In this trial, eligible patients are treated with weekly intratumoral administration of SAR441000 (BNT131) in the monotherapy arm or in combination with a fixed dose of 350 mg cemiplimab q3wks in the combination arm. Plasma samples and tumor biopsies are collected to characterize the pharmacokinetic/pharmacodynamic profile of SAR441000 (BNT131), immune cell tumor infiltration and the presence of tumor proinflammatory signatures.

Interim data were presented at SITC 2020: As of July 2020, 17 patients across various solid tumor types had received SAR441000 (BNT131) as a monotherapy at varying dose levels. Six patients received SAR441000 (BNT131) in combination therapy. No dose limited toxicities were observed, and no grade three, four, or five adverse events related to study treatment were reported. Adverse events related to study treatment in two or more patients in both treatment groups combined were nonserious grade one or two fatigue, vomiting, nausea, local injection site reaction, chills, diarrhea, and rash. In some patients, increases in plasma IP10 and IFN gamma and CD8+ T cell infiltration in tumor biopsies were observed.

#### **d) RiboMabs**

Our RiboMab product candidates, BNT141 and BNT142, are designed to encode secreted antibodies for expression *in vivo* by the patient's cells. RiboMab product candidates consist of our proprietary nucleoside-modified mRNA that is designed to minimize the immunomodulatory activity of the mRNA, and these candidates are formulated using liver-targeting LNPs for intravenous delivery. RiboMabs potentially address the limitations of recombinant antibodies, including costly manufacturing processes and unfavorable pharmacokinetics, such as short plasma half-life. We are conducting preclinical studies for two development candidates, and have published compelling preclinical data.

##### **i. BNT141: Our Initial RiboMab for the Treatment of Solid Tumors**

BNT141 is our RiboMab product candidate for the treatment of solid tumors. BNT141 encodes an IgG antibody which upon injection is secreted into the bloodstream.

##### **Our BNT141 Targets**

BNT141 is designed to encode an antibody targeting multiple epithelial solid tumors, including gastric and pancreatic cancers.

##### **Planned BNT141 Clinical Trials**

We anticipate starting an open-label, multi-site, Phase I/IIa dose escalation, safety, and pharmacokinetic trial of BNT141 followed by expansion cohorts in patients with CLDN18.2-positive tumors. First dosing is expected in the second half of 2021.

The trial design consists of three parts. The first part will perform dose escalation as monotherapy in patients with unresectable or metastatic Claudin 18.2-positive gastric cancer, gastroesophageal junction (GEJ) and esophageal cancer of the adenocarcinoma subtype, colorectal cancer, pancreatic cancer, biliary tract cancers, and mucinous ovarian cancer, for which there is no available standard therapy likely to confer clinical benefit. Part 1B is a dose escalation in combination with standard of care (SOC) nab-paclitaxel and gemcitabine in patients with advanced unresectable or metastatic CLDN18.2-positive pancreatic adenocarcinoma or cholangiocarcinoma who are eligible for treatment with SOC nab-paclitaxel and gemcitabine. Part 1B intends to define the MTD and/or RP2D of the combination. Part 2 (expansion) consists of the following pre-defined expansion cohorts: (1) CLDN18.2-positive unresectable locally advanced or metastatic pancreatic adenocarcinoma eligible for treatment with SOC nab-paclitaxel and gemcitabine; and (2) CLDN18.2-positive unresectable locally advanced or metastatic cholangiocarcinoma eligible for treatment with SOC nab-paclitaxel and gemcitabine. Part 2 will be further defined via an amendment after careful evaluation of all available safety, PK and PD, and efficacy data generated in Parts 1A and 1B by the Safety Review Committee (SRC).

##### **ii. BNT142: Our Second RiboMab for the Treatment of Solid Tumors**

BNT142 is our RiboMab product candidate for the treatment of solid tumors. BNT142 is designed to encode a secreted bispecific antibody that targets CD3 and CLDN6.

##### **Our BNT142 Targets**

BNT142 is designed to encode bispecific antibodies that target CD3, a T cell receptor that plays a key role in the activation of CD8+ and CD4+ T cells, and CLDN6, a highly specific oncofetal cell surface antigen that is found in solid tumors, but not in normal cells.

#### **Planned BNT142 Clinical Trials**

We expect to start a Phase 1 clinical trial for BNT142 in the second half of 2021.

#### **e) RiboCytokines**

Our RiboCytokine product candidates, BNT151, BNT152 and BNT153, utilize mRNA that encodes the desired cytokines for expression *in vivo* by the patient's cells. RiboCytokine product candidates consist of modified mRNA designed to encode secreted cytokines that are formulated to use liver-targeting LNP for intravenous delivery.

Our RiboCytokine product candidates are designed to address the limitations of recombinantly expressed cytokines, including limited serum half-life and production costs. We are developing RiboCytokines to be used primarily in combination with other drugs, including our other pipeline candidates.

#### **i. BNT151: Our Initial RiboCytokine for the Treatment of Solid Tumors**

We are developing BNT151, our RiboCytokine designed to encode a modified version of the human interleukin-2, or optimized IL-2, cytokine for the treatment of solid tumors. BNT151 is designed to stimulate T cells without triggering immunosuppression in the tumor microenvironment.

#### **Our BNT151 Target**

BNT151 comprises our nucleoside-modified mRNA that encodes mRNA for a function-modified IL-2. IL-2 is a key cytokine in T cell immunity, supporting the differentiation, proliferation, survival and effector functions of T cells.

Recombinant IL-2, aldesleukin, was the first approved cancer immunotherapy, and has been marketed globally for the treatment of late stage melanoma and renal cell cancer for decades. Most patients with complete responses after IL-2 treatment remain regression free for more than 25 years after initial treatment, but overall response rates are low due in part to the limitations of recombinant cytokines. Recombinant IL-2 has a very short half-life, requiring high and frequent dosing and a partially unfavorable activity profile, which leads to increased side effects, thus limiting its utility as a cancer treatment.

#### **Our BNT151 Clinical Trials**

##### **Ongoing Phase I/IIa trial**

We dosed the first patient in February 2021 in an open-label, multicenter Phase I/IIa trial. The trial evaluates dose escalation, safety, pharmacokinetics and pharmacodynamics of BNT151 with expansion cohorts in various solid tumor indications. The trial consists of three parts with adaptive design elements. The monotherapy dose escalation (Part 1) of this clinical trial will enroll patients with various solid tumors that are metastatic (Stage IV) or unresectable for whom there is no available standard therapy likely to confer clinical benefit, or patients who are not candidates for such available therapy. During combination dose escalation (Part 2A), patients of different specific solid tumors (one cohort per indication) will be enrolled and treated with a combination of BNT151 and the respective standard of care treatment. Part 2B is the expansion phase where a predefined number of patients in each indication cohort will be treated with the confirmed recommended phase II dose of BNT151 in combination with respective standard of care treatment. We estimate to enroll up to 54 study participants.

#### **ii. BNT152: Our Second RiboCytokine for the Treatment of Solid Tumors**

We are developing BNT152, our RiboCytokine designed to encode IL-7 for the treatment of solid tumors.

#### **iii. BNT153: Our Third RiboCytokine for the Treatment of Solid Tumors**

We are developing BNT153, our RiboCytokine designed to secrete IL-2 for the treatment of solid tumors.

#### **Our BNT152+153 Clinical Trials**

##### **Planned Phase 1 Dose Escalation Trial of BNT152+153**

We plan to start in the first half of 2021 an open-label, multisite Phase I dose escalation trial, which will evaluate the safety, pharmacokinetics and pharmacodynamics, and preliminary anti-tumor activity of BNT152+153. The clinical trial will enroll patients with various solid tumors that are metastatic or unresectable for whom there is no available standard therapy likely to confer clinical benefit, or patients who are not candidates for such available therapy.

The trial consists of 2 parts with adaptive design elements. Part 1 consists of Groups A and B.

- Group A is a BNT153 monotherapy dose escalation in patients with advanced solid malignancies until the maximal tolerated dose (MTD) is defined.
- Group B is a BNT152 monotherapy dose escalation in patients with advanced solid malignancies until the MTD or optimal biological dose (OBD) is defined, whichever occurs earlier.

Part 2 will start once Part 1 is completed, *i.e.*, when dose escalations for both BNT152 and BNT153 monotherapy are completed, and will evaluate the combination treatment of BNT152 and BNT153.

## **2. Our Oncology Cell Therapy Product Candidates**

### **a) CAR-T**

We are advancing multiple CAR-T product candidates, the most advanced of which, BNT211, is targeting the novel and highly specific target CLDN6+ in solid tumors. We plan to use our initial CAR-T cell product candidates in combination with a FixVac immunotherapy that encodes the same target as the CAR-T. The FixVac selectively targets dendritic cells, which leads to uptake, antigen expression and maturation of the dendritic cells. The co-stimulation provided by dendritic cell maturation has been shown in preclinical studies to amplify and expand CAR-T cells *in vivo*, leading to increased persistence of the CAR-T.

#### ***i. BNT211: Our CAR-T Cell Therapy for the Treatment of CLDN6+ Solid Tumors***

BNT211 is our CAR-T cell therapy for the treatment of CLDN6+ solid tumors. BNT211 targets CLDN6 and will initially be evaluated in combination with a CARVac that encodes CLDN6.

#### ***Our BNT211 Target***

BNT211 targets Claudin 6, or CLDN6, a highly specific oncofetal cell surface antigen that is found in multiple cancers, including ovarian, testicular and lung cancers, but not in normal cells.

#### ***Ongoing Phase 1/2a Clinical Trial***

We started a Phase 1/2a open-label, multi-center dose escalation and dose expansion basket trial of BNT211 with or without a CLDN6 CARVac immunotherapy with first patient dosed with BNT211 in February 2021. We are enrolling patients with CLDN6-positive relapsed or refractory advanced solid tumors, including ovarian and testicular cancers. The trial assesses CLDN6 CAR-T cell immunotherapy in combination with a CLDN6 RNA vaccine for improved expansion and persistence of CAR-T cells (CARVac). The primary outcome measure of the trial will be safety, with secondary efficacy outcome measures to include objective response rate, disease control rate and duration of response. Part 1 is the dose escalation with CLDN6 CAR-T cell therapy after lymphodepletion, followed by part 2 dose escalation that combines CLDN6 CAR-T cell therapy plus CLDN6 RNA-LPX vaccination.

We expect a data update in the second half of 2021.

#### ***b) Neoantigen-Targeting T Cells.***

Our neoantigen-targeting T cell stimulation platform can be utilized to develop product candidates across several neoantigen-targeting non-engineered and engineered T cell therapies. Our lead product candidate under this platform is our individualized neoantigen-targeting T cell therapy, BNT221.

We are also developing NEO-STC-01 (BNT222), targeting shared RAS neoantigens prevalent across many solid tumor types.

#### ***i. BNT221 (NEO-PTC-01): Our Individualized Neoantigen-targeting T Cell Therapy for the Treatment of Cancer***

BNT221 (NEO-PTC-01) is our individualized neoantigen-targeting T cell therapy for the treatment of cancer. BNT221 (NEO-PTC-01) targets selected sets of individualized neoantigens.

#### ***Our BNT221 (NEO-PTC-01) Target***

BNT221 (NEO-PTC-01) is a personal neoantigen-targeted T cell therapy candidate derived from patients' peripheral



blood cells. The product consists of multiple CD8+ and CD4+ T cell populations targeting multiple selected neoantigens from each patient's tumor.

The proprietary stimulation process allows for the induction of T cells from the naïve, as well as expansion of T cells from the memory compartment. Other product characteristics are i. cells with high specificity profile towards the mutant epitope; ii. cells exhibiting multiple effector functions; iii. a product that contains both central and effector memory T cells; iv. cells that have cytotoxic response towards endogenously processed and presented antigens as well as recognition of autologous tumor.

The neoantigens are selected using our proprietary RECON bioinformatics engine.

#### **Planned Phase 1 Clinical Trial**

We are focusing the initial clinical development of BNT221 (NEO-PTC-01) in solid tumors, where we believe we can generate *de novo* neoantigen T cell populations *ex vivo*. A CTA was filed with the Dutch Health Authority in December 2019 to evaluate BNT221 (NEO-PTC-01) in a first-in-human clinical trial in patients with advanced or metastatic melanoma refractory to checkpoint inhibitor therapy.

Dosing of the first patient in the first-in-human trial is expected in the first half of 2021. Major objectives of this study include evaluation of the safety and feasibility of administering BNT221 (NEO-PTC-01), as well as evaluations of immunogenicity and clinical efficacy.

Based on data from the first in human trial, we will decide how to best proceed with further clinical development of BNT221 (NEO-PTC-01), including expanding to other tumor types and potential development in the United States.

### **3. Our Antibody Product Candidates in Oncology**

#### **a) Next-Generation Checkpoint Immunomodulators**

In our 50:50 collaboration program with Genmab, we are currently studying two bispecific antibody checkpoint immunomodulators.

##### **i. GEN1046 (BNT311): Our Jointly Owned DuoBody® PD-L1x4-1BB Bispecific Antibody for the Treatment of Solid Tumors**

GEN1046 (BNT311), our jointly owned PD-L1x4-1BB product candidate, is a potential first-in-class bispecific antibody combining PD-L1 checkpoint inhibition with 4-1BB checkpoint activation. The first patient in a Phase 1/2a trial of GEN1046 (BNT311) for the treatment of malignant solid tumors was dosed in 2019.

##### **Our GEN1046 (BNT311) Targets**

GEN1046 (BNT311) is a PD-L1x4-1BB bispecific antibody that induces activation of T cells through conditional 4-1BB stimulation which is dependent on simultaneous binding to PD-L1. In addition, the PD-L1-specific arm of DuoBody-PD-L1x4-1BB functions as a classical immune checkpoint inhibitor by blocking the PD-1/PD-L1 axis, even in the absence of 4-1BB binding. PD-L1 is a validated target that is expressed on tumor cells. 4-1BB is a trans-membrane receptor belonging to the TNF super-family and is expressed predominantly on activated T cells. DuoBody® is a registered trademark of Genmab.

##### **GEN1046 (BNT311) Trials**

###### **Ongoing Phase 1/2a Clinical Trial**

The ongoing Phase 1/2a, open-label, single-arm GEN1046 (BNT311) trial with multiple expansion cohorts, conducted in collaboration with Genmab, is expected to enroll approximately 192 patients with malignant solid tumors. The trial consists of a dose escalation part and an expansion part. The dose escalation part will determine the safety profile of GEN1046 (BNT311) in patients with certain relapsed or refractory, advanced and/or metastatic malignant solid tumors who are no longer candidates for standard therapy. The expansion part will be initiated once the recommended Phase 2 dose has been established in Phase 1. In the expansion part, GEN1046 (BNT311) will be administered intravenously once every 21 days. The primary endpoints of the trial are dose-limiting toxicities, adverse events and safety laboratory parameters, including hematology, biochemistry, coagulation and endocrinology.

Dose escalation has been finalized and seven dose expansion cohorts are currently recruiting. The expansion phase 2

dose is 100 mg Q3W.

Interim data from the Phase 1/2a trial of GEN1046 (BNT311) (DuoBody-PD-L1x4-1BB) in 61 heavily pretreated patients with advanced solid tumors was presented at SITC 2020. In the dose escalation phase, GEN1046 (BNT311) demonstrated a manageable safety profile and encouraging early single-agent clinical activity. Most adverse events were mild to moderate and treatment-related Grade 3 transaminase elevations resolved with corticosteroids. No treatment-related bilirubin increases or Grade 4 transaminase elevations were observed. Clinical benefit was observed across tumor types and dose levels, including in patients resistant to prior immunotherapy and with tumor types less sensitive to immune checkpoint inhibitors. Disease control was achieved in 65.6% of patients in the dose escalation portion, including partial responses in one TNBC patient, one ovarian cancer patient and two immune checkpoint inhibitor pre-treated NSCLC patients. In the expansion cohort, which includes patients with PD-L1 relapsed/refractory NSCLC, two of 12 patients that could be objectively assessed achieved confirmed single-agent partial responses. One patient had an unconfirmed partial response and four patients demonstrated stable disease.

We expect a data update in the second half of 2021.

**ii. GEN1042 (BNT312): Our Jointly Owned DuoBody® CD40x4-1BB Bispecific Antibody for the Treatment of Solid Tumors**

GEN1042 (BNT312), our jointly owned CD40x4-1BB antibody product candidate, is a potential first-in-class bispecific antibody designed to induce conditional immune activation by crosslinking CD40 and 4-1BB positive cells. We and Genmab began recruitment and screening for a Phase 1/2a trial of GEN1042 (BNT312) for the treatment of malignant solid tumors in 2019. We expect the first data disclosure in the second half of 2021.

**GEN1042 (BNT312) Targets**

GEN1042 (BNT312) is a bispecific antibody designed to enhance an anti-tumor immune response by crosslinking CD-40 on antigen presenting cells with 4-1BB+ T cells to induce conditional stimulation and co-stimulatory activity in both types of cells. It has demonstrated increased tumor infiltrating lymphocyte expansion in human tumor tissue cultures *ex vivo*, and induces activation of B cells in the presence of 4-1BB+ cells. Both 4-1BB and CD40 are members of the tumor necrosis factor receptor superfamily.

**b) Targeted Cancer Antibodies**

**i. BNT321 (MVT-5873): Our Targeted Cancer Antibody for the Treatment of Pancreatic Cancer**

In 2019, we acquired certain antibody assets from MabVax Therapeutics Holding, Inc., including MVT-5873 (BNT321), a clinical-stage targeted cancer antibody.

**Our MVT-5873 (BNT321) Target**

BNT321 (MVT-5873) is a fully human IgG1 monoclonal antibody targeting sialyl Lewis A (sLea), an epitope on CA19-9 that is expressed in pancreatic and other gastrointestinal cancers that plays a role in tumor adhesion and metastasis formation, and is a marker of an aggressive cancer phenotype.

**Ongoing BNT321 (MVT-5873) Trial**

BNT321 (MVT-5873) is being investigated in an open-label, multi-center, non-randomized dose escalation/expansion trial evaluating the safety and recommended Phase 2 dose of BNT321 (MVT-5873) for a Q2 and Q4 week schedule in approximately 108 patients with pancreatic and other CA19-9+ malignancies. Secondary objectives include evaluating tumor response rate by RECIST 1.1, duration of response, and determining pharmacokinetics. This study utilizes a conventional 3+3 design to identify the recommended Phase 2 dose.

**4. Our Oncology Small Molecule Immunomodulator Product Candidates**

**i. BNT411: Our Small Molecule TLR7 Agonist for the Treatment of Solid Tumors, Including Small Cell Lung Cancer**

BNT411 is our novel small molecule TLR7 agonist product candidate. BNT411 is designed to activate both the adaptive and innate immune system through the TLR7 pathway. We are developing BNT411 to be used both as a monotherapy and in combination with chemotherapy and checkpoint inhibitors.

#### **Our BNT411 Target**

BNT411 is a TLR7 agonist that is designed to activate both the adaptive and innate immune system through the TLR7 pathway. This activity and the release of cytokines and chemokines are designed to result in the potent stimulation of antigen-specific CD8+ T cells, B cells and innate immune cells such as NK cells and macrophages.

#### **Ongoing Phase 1/2a Trial**

The initiated phase 1/2a, first-in-human, open-label, dose-escalation trial with expansion cohorts evaluates safety, PK, PD, and preliminary efficacy of BNT411 as a monotherapy in patients with solid tumors and in combination with atezolizumab, carboplatin and etoposide in patients with chemotherapy-naïve ES-SCLC. We dosed the first patient in July 2020 and expect a first data update in the second half of 2021.

#### **5. Our Infectious Disease mRNA Product Candidates**

We view our infectious disease program as representing a long-term growth pillar. There is substantial unmet medical need in an increasing number of highly unaddressed indications. The successful development of a COVID-19 vaccine in less than one year validates our ability to develop technologies and execute on our long-term strategies.

#### **Our Infectious Disease mRNA Product Candidates**

##### **a) Prophylactic Vaccine for the Prevention of COVID-19**

We hold conditional marketing approvals, emergency use authorizations or equivalent in multiple countries worldwide for our COVID-19 vaccine. We are collaborating with Pfizer and Fosun Pharma to obtain additional marketing approvals of our COVID-19 vaccine. We and Pfizer are continuing to jointly conduct clinical trials for the COVID-19 vaccine development program and life cycle management worldwide excluding China. Furthermore, we are jointly evaluating strategies to optimize the current product with regards to transport, stability and, against newly emerging SARS-CoV-2 strains. We and Fosun are continuing to conduct clinical trials for the COVID-19 vaccine development program in China.

##### **i. Our BNT162 Targets and mRNA Formats**

The overall development program initially included multiple vaccine candidate variants, some of which target the entire 2P-mutated full spike protein antigen and others which target the more specific receptor binding domain subunit of the antigen protein. The Phase 1 clinical studies are conducted with several different candidates, however to-date we have only advanced further development on BNT162b2. Clinical development programs for other BNT162 candidates are ongoing.

<b>BNT 162 Candidate or Product</b>	<b>Target</b>	<b>mRNA Format</b>
162a1	RBD subunit	uRNA (prime/boost)]
162b1	RBD subunit	modRNA (prime/boost)
162b2	2P-mutated full Spike protein	modRNA (prime/boost)
162b3	Membrane-anchored RBD subunit	modRNA (prime/boost)
162c2	2P-mutated full Spike protein	saRNA (single injection)

##### **b) Prophylactic Vaccine for the Prevention of Influenza**

We are collaborating with Pfizer to develop an influenza vaccine based on our mRNA drug classes. The product candidate, BNT161, will be designed to encode influenza virus antigens selected by the WHO in advance of a given flu season.

##### **c) Other Infectious Diseases**

We have a research collaboration with Penn, under which we have the exclusive option to develop and commercialize prophylactic mRNA immunotherapies for the treatment of up to 10 infectious disease indications. On September 20, 2019, Penn announced positive preclinical results of a vaccine product candidate using its mRNA technology. Penn reported that the immunization led to “mostly sterilizing immunity” from the virus. In addition to our collaboration with Penn, our infectious diseases portfolio also includes HIV, Tuberculosis vaccines (in collaboration with the Bill & Melinda Gates foundation) and additional 6 undisclosed programs.

## 6. Our Rare Disease Protein Replacement mRNA Product Candidates

We are collaborating with Genevant, in order to combine our mRNA technology with Genevant's LNP delivery technology, to create up to five mRNA protein replacement therapies for the treatment of rare diseases with high unmet medical needs. The first product candidate under the Genevant collaboration, BNT171, is being developed for Ornithine Transcarbamylase (OTC) Deficiency. Our mRNA replacement product candidate is associated with a favorable tolerability profile and good protein expression (in mice) and demonstrated phenotype rescue in a mouse disease model. Currently, we have put the programs under review in order to focus on other disease areas.

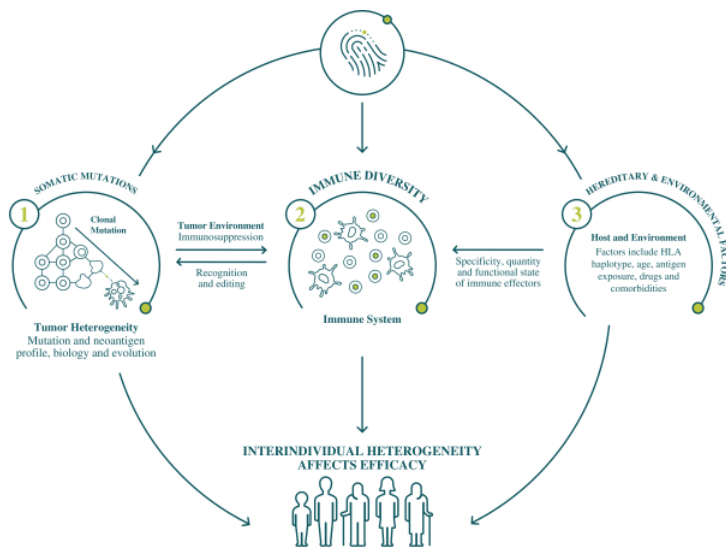
## III. Challenges and Opportunities of Cancer Therapies

Cancer results from an accumulation of abnormalities, known as somatic mutations, in the genome of cells over time leading to malignant transformation, combined with a failure by the immune system to detect and eradicate such transformed cells. Due to their random nature, the vast majority of these aberrations are unique to the individual patient.

As a consequence, heterogeneity is an intrinsic hallmark of cancer, posing a key challenge for cancer therapy:

- **Interindividual tumor heterogeneity.** Tumors, even within the same cancer type, differ at the molecular level. For example, two patients with the same type of cancer usually share less than five percent of their mutations. As a result, patients often respond very differently to the same drug.
- **Intratumor heterogeneity.** Within the same patient, cancer also evolves over time so that different tumor cell clones co-exist, in a manner known as clonal evolution. As a result, a patient's cancer may be intra-tumorally as well as inter-tumorally heterogeneous. Therapies might target only a subfraction of tumor cell clones. This can lead to immune escape and therapy failure.
- **Cancer evolution and immune escapes.** Cancer cells can adapt to therapeutic pressure, which results in treatment resistance. During immunotherapy, tumor cell clones may evolve that no longer express T cell recognized antigens or have defects in their antigen presentation machinery.
- **Tumor microenvironment.** Tumors induce various forms of immunosuppressive microenvironments that prevent T cells from proliferating and executing their anti-tumor effector function.
- **Host, environment and immune system.** The functional state of each patient's immune system is dependent on the patient's age, genetic makeup and environmental exposures. For example, the HLA haplotype, or the genetic makeup that encodes the major histocompatibility complex, is highly individual and decisive for which epitopes of an antigen are presented to T cells. Whereas a given tumor antigen might be a good target in one patient, a second patient might not be able to respond to it at all.

The graphic below depicts the interaction between three key factors influencing the patient unique tumor profile:



**Interindividual heterogeneity of patients.** The interaction between cancer and immune system is shaped by various host, tumor and environmental factors. The complex interplay of these sources of interpatient heterogeneity affects both the course of disease and the efficacy of immunotherapy.

Together, these factors make cancer an extremely complex and heterogeneous disease. As a consequence, in the majority of cancer types, many treated individuals do not benefit from highly potent approved therapies, and responses are often not durable. While these hallmarks of cancer are a challenge for cancer therapy, they also present opportunities for immunotherapy. These interconnected layers of complexity and variability require a deep understanding of an individual cancer and call for a patient-centric approach in order to find an optimal treatment.

#### IV. The BioNTech Approach

In oncology, we are focused on bringing cancer immunotherapy into the next generation. We believe that we can accomplish this by applying the following principles:

- **Exploiting the full potential of the immune system.** Our broad pipeline includes mRNA-based immune activators, antigen-targeting T cells and antibodies, and defined immunomodulators of various immune cell mechanisms. This portfolio is designed to mirror the evolution of the immune system to rely on multiple complementary pathways.
- **Broadening the universe of patients benefiting from cancer immunotherapy.** We discover and exploit novel targets and target combinations. Our aim is to extend the utility of immunotherapy to patient populations that are not currently amenable or do not benefit from the targets of current immunotherapies.
- **Improving the success rate.** We engineer and develop highly potent drug candidates designed to achieve precision for the specific target. We further augment activity and counteract resistance mechanisms by combining compounds with non-overlapping, synergistic mechanisms of action, such as combining our FixVac immunotherapy (CARVac) with our novel CAR-T therapies.

- Focusing on curative approaches.** The root cause of recurrence or for lack of tumor eradication is interindividual variability and cancer heterogeneity. Addressing this biological reality is one of the mandatory design aspects of the product candidates we develop. For example, each of our cancer immunotherapies incorporates multiple targets in order to account for this variability.

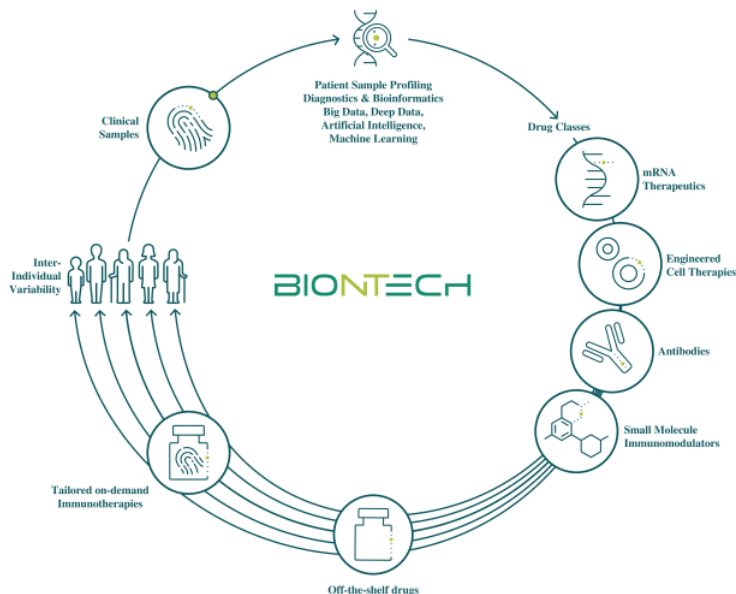
We have applied these four guiding principles to a broad suite of therapeutic platforms optimized for a distinct mode of action, high precision targeting, high potency and efficacy. We expect each platform to yield a pipeline of drug candidates for further development.

We believe this technology-agnostic range of platforms and product candidates positions us to remain at the forefront of the shift toward an individually tailored, patient-centric therapeutic approach in oncology.

Similarly, in infectious disease, we are deploying our full suite of technologies and immunotherapeutic understanding to develop mRNA vaccines against emerging infectious diseases, such as COVID-19, in a manner that is designed to be faster and more easily scalable, and with more flexible constructs, than traditional vaccine development.

**Patient-Centric Approach**

Our patient-centric approach starts with profiling and diagnostics by utilizing a target identification engine. This engine combines next generation sequencing, genomics, bioinformatics, machine learning and artificial intelligence to (a) identify gene targets of interest, (b) characterize the functional relevance of these targets (i.e. the ability to raise an immune response to or through a target) and (c) demonstrate their drugability. From our very beginning onwards, we have been developing the novel technologies needed to match the identified targets to the optimal individualized treatment approach.



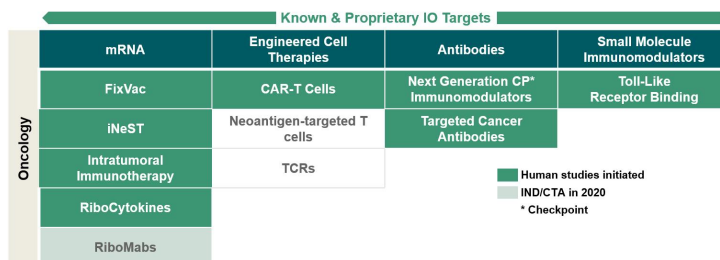
**Our patient-centric approach.** Utilizing patient profiling, diagnostics and bioinformatics, we select from our suite of drug classes to provide optimal individualized treatment. Our treatments include off-the-shelf drugs as well as highly tailored immunotherapies that are produced on-demand for the individual patient.

Utilizing this approach:

1. We develop and leverage our competencies in target discovery, biomarker science and computational medicine to thoroughly profile a patient's tumor sample and immune cells for the selection of suitable targets and treatments, and use this data to develop next-generation product candidates.
2. Each of our therapeutic platforms bundles innovations designed to deliver a distinct mode of action with high-precision targeting, high potency and efficacy. Each platform is being developed to provide a pipeline of drug candidates with complementary and potentially synergistic modes of action.
3. Our drug platforms are highly versatile and support the fast development of scalable manufacturing processes. We develop and establish highly digitalized and automated manufacturing technologies and quality controlled processes enabling fast delivery of customized therapies comprising off-the-shelf drugs, on-demand immunotherapies, and combinations thereof.

**Broad and Potentially Synergistic Suite of Platforms**

We believe the depth and breadth of our understanding of immune system and cancer biology allows us to create an extensive pipeline of specific and potentially efficacious product candidates. We are exploiting a comprehensive repertoire of known and proprietary therapeutically relevant immuno-oncology targets and are developing a diverse spectrum of immunotherapeutic approaches, as shown in the chart below.



We believe that harnessing complementary, potentially synergistic modes of action increases the likelihood of therapeutic success, reduces the risk of emergence of secondary resistance mechanisms, and also unlocks a larger potential market. Critically, this approach allows us to pursue a technology agnostic approach, providing the most appropriate therapeutic platform or a combination thereof for the intended patient and purpose.

For example, we believe our neoantigen immunotherapies are particularly well-suited to treat high mutation load cancers in the adjuvant setting to prevent the tumor from spreading or recurring following initial treatment, such as surgery. In this setting, tumor volumes tend to be low and there remains the potential for strong T cell responses since the patient's immune system has not been weakened by prior lines of treatment, and checkpoint inhibition alone often offers a poor risk-benefit profile or low response rate. Similarly, we believe our FixVac, CAR-T, neoantigen-targeted T cell and next-generation checkpoint immunomodulator platforms may have especially strong potential in lower mutation burden tumors such as ovarian or prostate cancers, which comprise a significant proportion of tumors and often also have a poor response to checkpoint inhibition. Likewise, we believe that monoclonal targeted cancer antibodies and CAR-T cell therapies are particularly well-suited for tumors that have defects in their antigen-presentation machinery.

We believe our breadth of our technology positions us to combine modes of action in a coordinated way to treat cancer in a more efficacious manner than current existing therapies. We further believe that our patient-centric approach and our broad, potentially synergistic portfolio of drug platforms place us at the forefront of the paradigm shift toward individualized immunotherapies.

Cancer segment	Patient Population	Challenge	Our Therapeutic Strategy
High mutational burden/ adjuvant stage cancers	Significant portion of cancer patients	Poor risk-benefit profile of checkpoint inhibitors	• <i>mRNA Neoantigen Immunotherapy</i> (iNeST)
Low mutational burden cancers	>60% of cancers	Poor response to checkpoint inhibitors	• <i>Shared Antigens</i> (FixVac, CAR-T cells, Antibodies)
"Immune desert" cancers	>40% of high-mutational cancers	Poor infiltration and activation of T-cells in TME <sup>1</sup>	• <i>mRNA Immunotherapy</i> • <i>Immunostimulatory Compounds</i> (intratumoral, RiboCytokines)
Cancers with MHC / B2M loss	20-30% of CPI-experienced advanced cancers	Failure of immune system to recognize tumor cells	• <i>Antibodies</i> • <i>CAR-Ts</i>
Refractory tumors	Patients with large tumors and multiple resistance mechanisms	Few treatment options	• <i>Engineered Cell Therapies</i> • <i>Combination Therapies</i>

<sup>1</sup>Tumor microenvironment

**Diversity of cancer patient populations, challenges and our therapeutic strategies.** We believe our diversified portfolio allows us to potentially address a large share of cancer patients. Abbreviations: B2M, beta-2 microglobulin, a component of MHC.

## V. Selection of Therapeutic Targets and Therapies

Immunotherapy targets can be categorized as *antigens* for targeted immunotherapy with antibody- or T cell-based effector mechanisms and *immunomodulatory targets* to be exploited to improve the anti-tumoral function of immune cells.

### A. Targeting Cancer Antigens

In order to address the broadest possible number of patients, our therapeutically targeted cancer antigen library comprises tumor associated antigens, viral neoantigens and mutant neoantigens:

#### 1. Tumor Associated Antigens

Tumor associated antigens, or TAAs, are cancer selective targets that typically have a highly restricted expression pattern in normal tissues but are frequently expressed in a wide range of human cancers. Over the last 15 years, we have built up a database of approximately 200 cancer-selective antigens, including proprietary disease targets that could be used as targets for immunotherapy-based approaches.

- Cancer-Germline and Cancer-Embryo-Fetal Antigens, which are normally expressed during embryonal development and silenced after birth or restricted to germline cells. These antigens are aberrantly expressed in a variety of human malignancies and are generally not expressed in healthy tissue, making them particularly suitable for our FixVac-, antibody- and CAR-T cell-based therapeutic approaches.
- Differentiation antigens, which are normally expressed in a highly tissue-specific manner in normal tissues (*e.g.*, on melanocytes or on prostate cells) but are also present in a high proportion of tumors derived from these tissues, are well-suited for therapeutic targeting with FixVac and antibody approaches.
- Tumor-associated carbohydrate antigens are carbohydrate-based cell surface tumor antigens generated by cancer cell-specific aberrant glycosylation that enable the development of antibody and CAR-T cell therapies.

#### 2. Viral Neoantigens

Viral oncoproteins, or viral neoantigens, are virus-derived proteins that drive the oncogenic transformation of infected cells by viruses that can cause cancer. Examples are the E6 and E7 oncoproteins from human papilloma virus, or HPV. Viral oncoproteins are commonly acknowledged as safe and promising targets for immunotherapy as they are (i)



absent from any non-infected tissue, (ii) highly immunogenic since they are not prone to central tolerance mechanisms and (iii) not subject to immune escape by gene silencing as they are crucial to maintaining the transformed state of the tumor cells. We leverage viral neoantigens as targets for our BNT113 FixVac program in HPV16+ head and neck cancer.

### **3. Mutant Neoantigens**

Somatic mutations, or mutations of non-germline cells, are a hallmark of cancer. Driver mutations promote the oncogenic process, whereas passenger mutations are considered as functionally irrelevant. Both types of mutations, however, can alter the sequence of proteins and create new epitopes which are processed and presented on specialized major histocompatibility complex, or MHC, molecules. Mutated epitopes that are recognized by T cells are called neoepitopes and the sequence-altered proteins they are derived from are neoantigens. They are promising targets for cancer immunotherapy as (i) activation of the immune system against such antigens is highly specific (they are only expressed on cancer cells) and (ii) mutant neoantigens are exempt from central tolerance and thus T cell affinity for neoantigens may be significantly superior. We utilize individualized mutant neoantigens as targets for our iNeST product candidates.

### **B. Immunomodulatory Targets**

The activity of immune cells can be controlled or manipulated by the targeting of receptors that control key biological processes in these cells, known as immunomodulation. Immunomodulatory targeting strategies include:

#### **1. Checkpoint Inhibition**

Checkpoint inhibition is a therapeutic approach by which T cell function is stimulated with mAbs that block their inhibitory receptors, which can be exploited by cancer cells to shut down T cell activity. Examples of checkpoint targets are PD-1, PD-L1, CTLA-4, TIGIT, LAG3 and many others. The concept is known as “releasing the brakes” and has been shown to be therapeutically effective in tumors with strong pre-existing immune cell infiltration. Our GEN1046 (BNT311) product candidate is a next-generation bispecific checkpoint immunomodulator, with one arm targeting PD-L1.

#### **2. Immunostimulation**

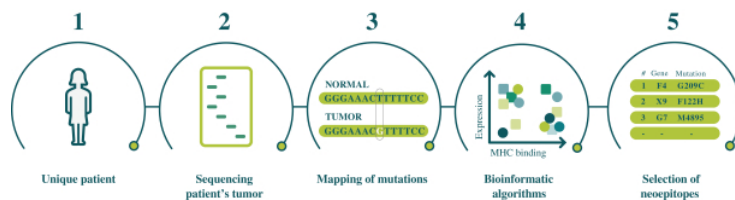
Immunostimulatory approaches are directed against receptors known to directly activate immune cells. Examples of these targets include co-stimulatory molecules such as CD40 and 4-1BB or cytokine receptors such as IL-2R, IL-7R and IL-12R. Immunostimulatory approaches provide a powerful opportunity to enhance immune activation, even in types of cancer that are not responsive to checkpoint inhibition due to lack of immune cell infiltration. However, this approach is often limited by a narrow therapeutic window associated with dose-limiting toxicity.

We believe that both concepts can be combined in a potentially synergistic and safe fashion by developing precisely engineered molecules, such as our BNT151 RiboCytokine program or GEN1042 (BNT312), our next-generation bispecific checkpoint immunomodulator targeting both CD40 and 4-1BB.

### **C. Our Computational Approach to Individualized Immunotherapy**

Bioinformatics are critical in the production of individualized therapies. We have accumulated a high level of experience in bioinformatic approaches to mutation detection, cancer genomics and immunotherapy through our ongoing research and preclinical studies and clinical trials.

Our validated patient-centric bioinformatic process, as illustrated below, allows the application of complex algorithms to the patient's data in the context of drug manufacturing. Our bioinformatics processes are robust and scalable, incorporating our experience handling genomic data in a high-throughput environment, as we target making on-demand production of individualized immunotherapies commercially viable.



**From Patient to Analysis.** Our bioinformatic process for the selection of neopeptides.

### 1. Sequencing

We sequence the patient's tumor and healthy tissue samples using NGS technology. Comparison of the patient's sequenced tumor and healthy samples provides us with the data from which we can identify targets for the design of individualized cancer immunotherapies. This is a multi-step process in which mutation detection and neoantigen prediction are particularly important.

### 2. Mutation Detection

Mutation detection, which defines which tumor-specific mutations are present in any cancer, is the starting point for defining targets for individualized immunotherapy. Determining mutations from NGS data with high precision and sensitivity is challenging because numerous factors can lead to false positives, which can mask mutations. Despite advances in the field, commonly used mutation detection algorithms still exhibit high false positive mutation detections.

### 3. Neopeptide Selection

Only a portion of mutated peptides (neopeptides) are suitable for raising an immune response *in vivo*. Our approach focuses on evoking responses involving both CD8+ T cells and CD4+ T cells. We do this by discerning the likelihood of presentation of the neopeptide to the T cell receptor as an MHC peptide complex using data from mRNA expression levels and MHC binding affinity predictions, among other factors. For example, in our first individualized neopeptide immunotherapy clinical study, all 13 stage III and IV melanoma patients selected for treatment developed a CD4+ and/or CD8+ T cell response, achieving an overall 60% immune response rate to predicted neopeptides.

Presentation of a neopeptide on an MHC molecule does not, however, guarantee recognition by T cells, and an integrated view combining several properties impacting immunogenicity is necessary. Our algorithms are continuously being improved and extended with data collections from various sources such as our past and current clinical studies as well as HLA data. By using machine learning approaches applied to these large datasets we aim to further improve prediction of overall presentation of neopeptides tailored to patients' specific HLA types. With our acquisition of Neon Therapeutics, Inc., or Neon, we further bolstered our neopeptide selection capabilities with the addition of Neon's RECON bioinformatics engine. RECON uses a number of inputs from each patient, including DNA sequences from samples of tumor and normal tissue, RNA sequences from tumor samples, and the patient's specific MHC allele profile. RECON processes data from these inputs using a proprietary combination of algorithms in order to produce a prioritized list of neoantigen-targeting peptides that can be manufactured for use in our product candidates.

## VI. Our mRNA Drug Class

### At a glance: mRNA as a Therapeutic Drug Class

- Natural molecule found universally within cells, with well-characterized properties.
- Suitable to encode for antibodies, antigens, cytokines and any other type of protein.
- Transient, with adaptable activity and half-life. Avoids genomic integration problems sometimes seen in gene therapy, potentially resulting in a better safety profile.

- Can be designed and optimized pharmacologically and immunologically, making it suitable for a broad range of applications.
- Fast manufacturability, making it a cost-effective and flexible therapeutic to produce.
- Our mRNA portfolio includes BNT162b2, our mRNA-based COVID-19 vaccine, which has received emergency or temporary use authorization or approval or been granted conditional marketing approval in over 65 countries

In the last decade mRNA has progressed into a promising new class of medicine, with the potential to treat a wide variety of diseases with high unmet medical needs. mRNA is a long, polymeric molecule, composed of four different building blocks called nucleotides. In mRNA, hundreds or thousands of these nucleotides are linked in a unique order to convey genetic information to cells, where it is used to express proteins with biological effects.

Considering that all mRNA is generated with four different building blocks, but with unique sequence order, all therapeutic mRNAs have highly similar compositions, while having the capacity to encode a variety of different proteins. These characteristics allow for rapid development of mRNA therapeutics that are broadly applicable for treatment of many diseases, including cancer, infectious diseases and rare diseases. Our mRNA pipeline addresses all of these therapeutic areas.

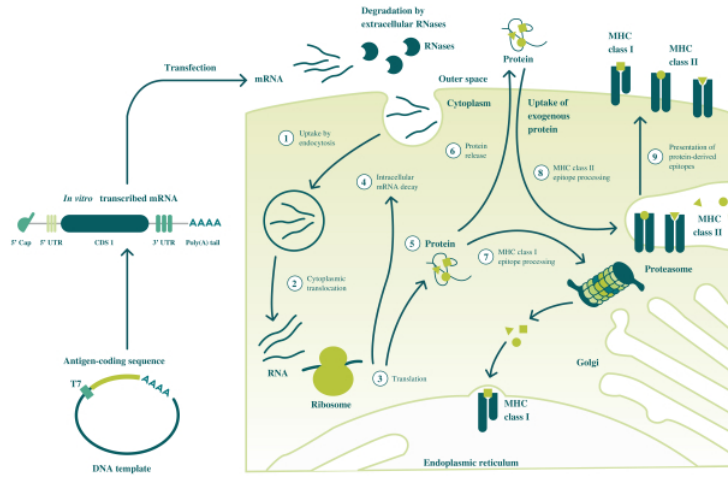
#### **A. General Principles of mRNA Pharmacology**

As a drug, manufactured mRNA provides instructions to a target cell to produce a desired therapeutic protein. An mRNA drug will temporarily change the status of the target cell where these instructions are translated into proteins. Based on the information encoded by the mRNA, the proteins will be either secreted or remain intracellular. The mRNA drug will eventually be degraded and eliminated from the body.

Our mRNA drugs are synthesized from a DNA template. With the exception of the 5' cap, the template determines all structural elements of the mRNA. The mRNA molecule comprises:

- an open reading frame, or ORF, which encodes for the protein of interest;
- untranslated regions, or UTRs, which flank the ORF; and
- the cap and the poly(A) tail, which are the two terminal structures of the linear mRNA, and are responsible for increased stability and translational efficiency of mRNA.

The mRNA drug needs to be appropriately formulated in order to protect it from breakdown by extracellular RNAses. The formulation is selected based on the intended application and route of delivery. After uptake into the target cell, the mRNA molecules are loaded into ribosomes, where translation into protein takes place. Subsequently, the mRNA is degraded by cellular mechanisms. In case of an immunotherapy application, the protein is degraded into immunogenic epitopes. These are loaded onto specialized molecules, namely MHC I or MHC II. These molecules present the epitopes to immune cells to provoke the desired immune response. In the case of other mRNA applications, the mRNA encodes proteins that are secreted from the cells, such as antibodies, and function extracellularly.

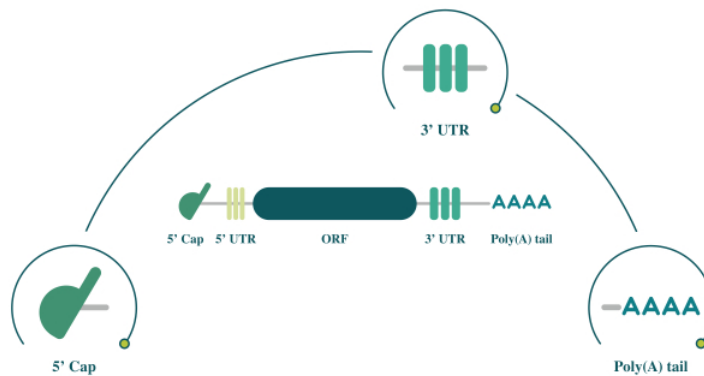


**General principles of mRNA pharmacology.** Step 1: mRNA is either delivered in a buffered solution as naked molecules or formulated as nano-particles to protect degradation by extracellular enzymes and is taken up by cells. Step 2: Subsequently, mRNA is released from endosomes into the cytoplasm. Step 3: mRNA is translated by the protein synthesis machinery of host cells. Step 4: Termination of translation by degradation of mRNA. Step 5: The translated protein product acts in the cell in which it has been generated. Step 6: Alternatively, the protein product is secreted and may act via autocrine, paracrine or systemic, body-wide mechanisms. Steps 7 and 8: For vaccine activity, mRNA encoded antigens are degraded into shorter fragments and loaded onto MHC class I and class II molecules. Step 9: Protein-derived epitopes can then be presented on the cell surface by both MHC class I and MHC class II molecules, enabling stimulation of CD8<sup>+</sup> and CD4<sup>+</sup> T cells.

The structural elements of the mRNA have an impact on its performance. This includes potential immunogenicity, efficacy of translation and stability of the molecule. We leverage our extensive experience to design, synthesize, manufacture and formulate our therapeutic mRNA, and adapt its composition to suit the desired application.

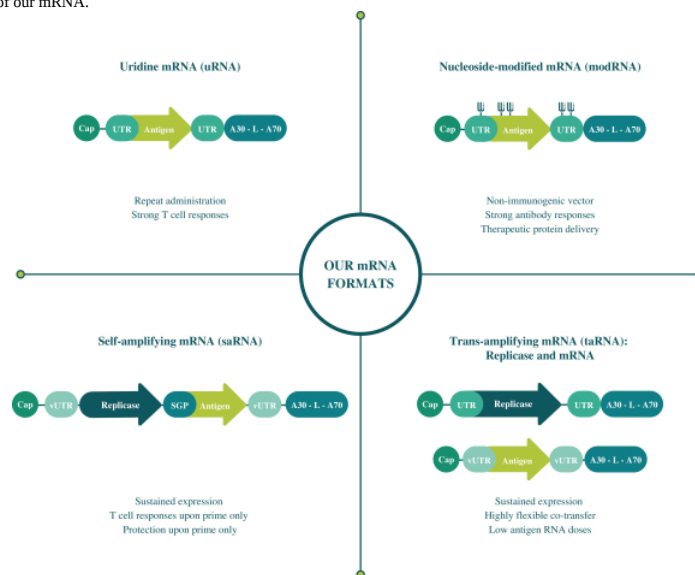
## B. Our mRNA Backbone Concepts and Technologies

Our mRNAs all contain basic structural elements, including the 5' cap, the untranslated regions and the poly(A) tail, in addition to a coding sequence, that are all encoded by our DNA template.



- The cap is added to the 5' end of the mRNA during its synthesis. Our studies have demonstrated that incorporation of a unique cap analogue into the mRNA helps to achieve superior translational performance by stabilizing the mRNA molecule and directing the immune response. This unique cap analogue is extremely useful for our immunotherapy approaches.
- The composition and structure of the 5' and 3' untranslated regions of the mRNA molecule are important determinants of the intracellular stability of mRNA. As a result of rigorous screening of different mRNA sequences, we identified specific UTRs that promote increased protein translation for long duration.
- We have performed extensive research on the structure of the poly(A) tail and the translational performance of mRNA and customized our template design accordingly.

The translational performance of mRNA can be increased by removing contaminating double-stranded RNA from the mRNA. We have extensive expertise in different mRNA purification procedures. We have also invented a novel mRNA purification method that greatly impacts translatability of our mRNA. Depending on the protein characteristics needed for treatment of a disease, we optimize the DNA template through a proprietary codon optimization process, changing the nucleotide sequence of the template without altering the amino acid composition of the encoded protein. We make further adjustments during mRNA production. We believe these fine tunings of the respective molecules are essential for the purpose-adapted performance of our mRNA.



**Our mRNA formats.** As shown above, we have developed four mRNA formats, each optimized for different therapeutic applications. Abbreviations: y, 1-methylpseudouridine; UTR, untranslated region.

Our mRNA formats include:

### 1. Optimized Uridine mRNA (uRNA)

The nucleotide sequence of mRNA determines the amino acid sequence of the protein. In addition, the nature of nucleosides used for production of mRNA drugs can also influence recognition of the molecule by the immune system. Presence of naturally occurring uridine (U) in our optimized uridine mRNA makes it immunogenic by activating immune sensors. We have further optimized our uridine mRNA for immunogenicity (augmented antigen presentation on MHC I and MHC II) and pharmacological activity (enhanced stability and translational efficiency). Immunogenicity of the mRNA is an added benefit when mRNA is used for immunotherapy applications, by acting as an immunotherapy adjuvant. This makes our therapeutics for iNeST and FixVac even more potent.

### 2. Nucleoside-modified mRNA (modRNA)

Immunogenic reaction against mRNA drugs needs to be avoided in applications where therapeutic proteins are produced, such as in our RiboMab and RiboCytokine platforms. We have profound expertise in incorporating naturally-occurring modified nucleosides into our therapeutic mRNAs. We have demonstrated that the presence of a variety of modified nucleosides in the manufactured mRNA suppresses its intrinsic immune activation, while leading to superior

protein production for long duration. Deimmunizing mRNA by incorporating modified nucleosides helps to avoid production of anti-drug antibodies and broaden the therapeutic application of these types of mRNA drugs. We believe this customization has resulted in therapeutic mRNA that is both potent and well tolerated.

### 3. Self-amplifying mRNA (saRNA)

Our self-amplifying mRNA, or saRNA, drugs use the concept of viral replication, while not being an infectious, disease-causing agent itself. saRNA resembles conventional mRNA encoding the protein of interest, but also encoding a polymerase, called replicase, that multiplies part of the mRNA within the target cell. During self-amplification inside the cell, a double-stranded RNA intermediate is generated, which is recognized by intracellular immune sensors. This makes saRNA a very potent activator of the immune system and therefore an excellent category of immunotherapy. As we have demonstrated, our saRNA ensures high levels of sustained antigen production with a small amount of initial mRNA input. Our scientific team has designed this mRNA technology to act as a potent tool for prophylactic vaccination, with the potential application in infectious diseases with high medical needs.

### 4. Trans-amplifying mRNA (taRNA)

We have also expanded on our self-amplifying mRNA capabilities, developing a novel mRNA amplification technology by separating the target mRNA to be amplified and the replicase encoding mRNA. This advancement broadens the spectrum of applications by making the development of therapeutic mRNAs even more flexible, as the replicase can amplify mRNA encoding of not only one protein, but several different ones. In the case of vaccines, this allows us to produce the replicase in advance for use with different vaccines. Our trans-amplifying mRNA is a proprietary mRNA format that is particularly well-suited for prophylactic vaccines to prevent infectious diseases.

### C. Our mRNA Delivery Formulation Technologies

We have deep and broad expertise in the targeted delivery of mRNA therapeutics. We are convinced that our development of suitable delivery formulations in conjunction with our own therapeutic mRNAs is a key competitive advantage.

We employ multiple mRNA delivery formulations, each designed for different functions and optimized for therapeutic product needs:

- **Lipoplex:** Our lipoplex formulation, or LPX, embeds the mRNA between a lipid bilayer, which is used for our FixVac and iNeST platforms. We use a proprietary size- and charge-based non-viral mRNA lipoplex that was developed to deliver mRNA to dendritic cells in lymphoid compartments such as the spleen for optimal antigen presentation and immune response activation.
- **LNPs:** For other applications, we encapsulate our mRNA in lipid nanoparticles, or LNPs. These formulations are suitable for our RiboMab, RiboCytokine and rare disease protein replacement platforms. Our LNP formulations can be adjusted according to our needs for delivery to particular target tissues, such as the liver in the case of our rare disease protein replacement platform.
- **Polyplexes:** Our portfolio also comprises polyplexes, which are being utilized in certain of our discovery programs, in which the mRNA is bound to a polymer and then forms nanoparticles.

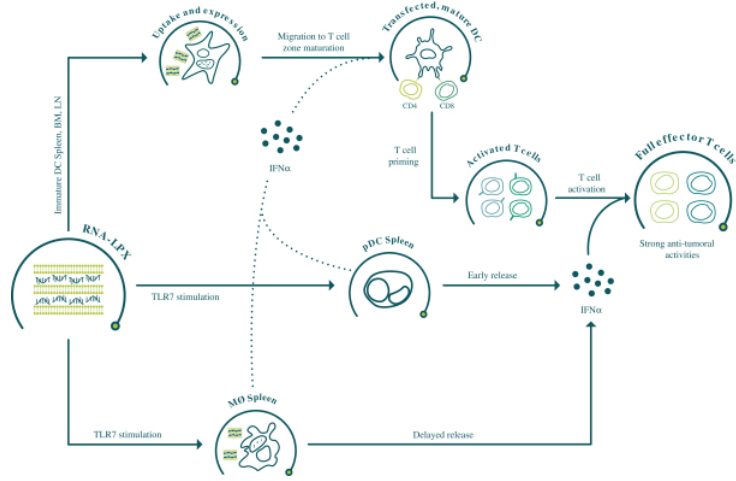
#### RNA-LPX Technology

#### At a glance: RNA-LPX Cancer Immunotherapy Technology

- Potential first-in-class clinical intravenous nano-particulate mRNA immunotherapy, allowing systemic delivery.
- Strong potency by systemic targeting to dendritic cells in lymphoid tissues.
- Universally applicable for all cancer antigens.
- Opportunity to deliver multiple antigens in parallel, enabling the induction of poly-specific T cell responses.
- Synchronized adjuvant effect mediated by toll-like receptor 7 (TLR7)-triggering and type-I interferon-driven innate and adaptive immune stimulation.
- Preclinical anti-tumoral activity demonstrated against multiple tumors.

- Unprecedented clinical immune responses against shared TAAs.
- Beneficial clinical activity demonstrated in advanced melanoma patients.

To advance from local to systemic dendritic cell, or DC, targeting, we developed an innovative liposome-based RNA-lipoplex formulation, RNA-LPX, that allows for intravenous administration of our mRNA cancer immunotherapies. We have demonstrated in the clinic that systemic DC targeting by mRNA cancer immunotherapies can result in potent activity at very low doses. Consequently, less material is required for treating high patient numbers, making manufacturing more cost-effective.



**Our RNA-LPX technology.** Our proprietary RNA-LPX formulation is designed to deliver vaccine mRNA precisely into DCs and macrophages in the spleen and other lymphoid compartments. The RNA-LPX has an inherent adjuvant function stimulating the release of cytokines such as IFN- $\alpha$  thereby promoting the activation of DCs and the induction of strong T cell responses. Abbreviations: BM, bone marrow; LN, lymph node; DC, dendritic cell; pDC, plasmacytoid dendritic cell; M $\phi$ , macrophage; IFN- $\alpha$ , interferon alpha.

RNA-LPX protects mRNA from degradation outside of the cell and mediates its efficient uptake and expression of encoded antigens in various dendritic cell populations. Our RNA-LPX technology is designed to target a wide variety of antigens and address cancer patients with all possible HLA haplotypes. Utilizing RNA-LPX, we can target fixed groups of known shared antigens with our FixVac platform and a whole new class of patient-specific neoantigen targets with our iNeST platform.

#### D. Our mRNA Platforms

We are developing multiple mRNA-based therapeutic platforms. These include FixVac, iNeST, mRNA-based intratumoral immunotherapy, RiboMabs and RiboCytokines in the oncology space. In addition, we have implemented mRNA platforms for the development of infectious disease vaccines and protein replacement therapies for rare diseases.



Importantly, each of these platforms enables the development of multiple pharmaceutical product candidates or programs.

	mRNA Platform	Drug Targets	mRNA Formats	Delivery Formulations
	7 mRNA platforms	Broad range of biological targets	4 types of mRNA	Multiple optimized formulations
Oncology	FixVac	Shared Antigens	uRNA	RNA-LPX
	iNeST	Neoepitopes	uRNA	RNA-LPX
	Intratumoral Immunotherapy	Immunomodulators	modRNA	Various formulations Intratumoral
	RiboMabs	mAb targets	modRNA	LNPs Intravenous delivery
	RiboCytokines	Cytokines	modRNA	Various LNP formulations
Other	Infectious Disease Vaccines	Pathogens	saRNA, taRNA, modRNA	Various LNPs for i.m. & s.c. delivery
	Rare Disease Protein Replacement Therapy	Diverse Proteins	modRNA	Liver targeted LNPs

uRNA, uridine mRNA, modRNA, nucleoside modified mRNA, saRNA, self-amplifying mRNA, taRNA, trans-amplifying mRNA.

**Our mRNA Platforms.** We have multiple mRNA-based platforms utilizing different mRNA formats and delivery formulations, directed at a range of biological targets in oncology and infectious and rare diseases.

### 1. Cancer Immunotherapies

Our goal is to develop safe, potent, efficacious and cost-effective cancer immunotherapies which stimulate and potentially expand tumor cell specific CD4+ and CD8+ T cells in cancer patients. Our cancer immunotherapy development integrates our competencies in mRNA backbone optimization, formulation development and immunological research.

#### a) FixVac

##### At a glance: Our FixVac Platform

- **Concept:** Cancer immunotherapies targeting shared antigens that we have identified to be frequently expressed across patients with a specific cancer type.
- **mRNA Format:** Optimized uridine mRNA providing superior immunogenicity.
- **mRNA Delivery Formulation:** Proprietary size- and charge-based RNA-LPX targeting dendritic cells (DCs).
- **Development Approach:** Worldwide rights; wholly owned.
- **Lead Candidate:** BNT111 for metastatic melanoma.

Our FixVac approach involves off-the-shelf mRNA immunotherapies targeting cancer cell-specific shared tumor associated antigens, or TAAs, for selected patient populations. Our FixVac product candidates target TAAs which are commonly expressed by a significant portion of patients in a given cancer type. We have developed a sophisticated target selection process which enables us to produce poly-specific FixVac immunotherapies that cover up to 95% of patients with a given cancer type. The use of off-the-shelf FixVac immunotherapies allows for large-batch manufacturing and prompt supply to patients with ready-to-use medication, ensuring a straight-forward cost- and time-efficient manufacturing process with favorable logistics.

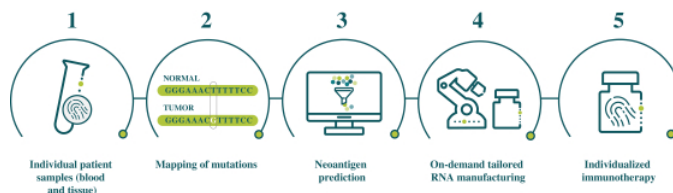
Besides targeting commonly expressed TAAs, our target selection strategy facilitates the identification of suitable viral oncoproteins for the treatment of virus-induced cancers like HPV+ head and neck cancer. Patient stratification, if needed, can easily be performed at the clinical site or a central lab using standard biotechnological methods, thereby reducing treatment costs. As the viral genome is comparatively small, encoding only for a few proteins, we believe our FixVac approach is ideally suited for the treatment of virus-induced cancers.

## b) Individualized Neoantigen Specific Immunotherapy (iNeST)

### At a glance: Our iNeST Platform

- **Concept:** Individualized cancer immunotherapy targeting neoantigens identified on a patient by patient basis and selected for immunogenicity.
- **mRNA Format:** Optimized uridine mRNA providing superior immunogenicity.
- **mRNA Delivery Formulation:** Proprietary size- and charge-based RNA-LPX targeting DCs.
- **Development Approach:** 50:50 cost share with Genentech.
- **Lead Candidate:** autogene cevumeran (BNT122) as a first-line melanoma therapy in combination with pembrolizumab.

We are a pioneer and global leader in developing fully individualized cancer immunotherapies. We have developed a first of its kind, on-demand manufacturing process to treat each individual patient based on the mutation profile of the patient's tumor. We are investigating this treatment approach in the clinic in collaboration with Genentech.



**Our iNeST process.** The figure above depicts our iNeST process for the on-demand production of individualized mRNA cancer immunotherapies.

Our iNeST process is summarized below:

- A blood sample and tumor biopsy is taken from the patient to obtain healthy cells and tumor tissue. We extract healthy cells from the patient's blood sample and tumor cells from the tumor sample. We use NGS to analyze genetic material (DNA and RNA) of these cells to identify which mutations are present in the cancer cells compared to healthy cells.
- We apply proprietary bioinformatic algorithms to identify tumor-specific mutations. The mutations within a cancer cell differ widely from patient to patient and form a unique signature for each tumor. This genomic information can be further utilized to analyze tumor heterogeneity and microenvironment as well as individual aspects of the immune system like the HLA type.
- Based on these bioinformatic algorithms, we then select mutations that are the most promising therapeutic targets. The specific traits of the patient's immune system, including HLA type, are key to the selection of the most appropriate targets. Picking multiple mutations increases the chance to induce potent T cell responses and reduces the risk that the tumor evades T cell attack over time. We account for heterogeneity of each tumor by preferentially selecting mutations that are expressed on all tumor cells. Importantly, the selected mutations are intended to ensure both CD4+ and CD8+ T cell induction.
- Following mutation selection, we design the structure for the iNeST product. The chosen mutations have to be arranged in a certain order and the DNA sequence of the mutations has to be optimized. This is important to ensure a robust production of the starting material, or DNA matrix, for the GMP manufacturing of the iNeST product.
- Next we produce the patient-specific iNeST product under GMP conditions and the iNeST product undergoes numerous different quality control tests.
- The iNeST product is transferred to the hospital and injected into the same patient by the physician.
- This process has been designed for the on-demand delivery of our iNeST products, and currently takes approximately six weeks.

We are currently developing iNeST therapeutics for the treatment of metastatic melanoma and multiple solid tumors.

### ***c) Intratumoral mRNA Immunotherapy***

#### ***At a glance: Our Intratumoral mRNA Platform***

- **Concept:** Immunomodulator-encoding mRNA injected directly into the tumor in order to avoid off-target toxicities.
- **mRNA Format:** Nucleoside-modified mRNA engineered for minimal immunogenicity in order to avoid immune detection and allow translation of the encoded cytokines to occur within the cells.
- **mRNA Delivery Formulation:** Various formulations, delivered by intratumoral injection.
- **Development Approach:** Co-development and co-commercialization, at our option, in collaboration with Sanofi.
- **Lead Candidate:** SAR441000 (BNT131) for advanced solid tumors as a monotherapy and in combination with cemiplimab.

In collaboration with Sanofi, we are leveraging our mRNA technology to develop intratumoral immunotherapies for the treatment of solid tumors. Intratumoral immunotherapy is designed to promote innate and adaptive immune responses against tumors, without toxicities related to systemic administration. Our intratumoral immunotherapy involves injection of cytokine-encoding mRNA directly into a tumor in order to alter the tumor microenvironment and promote greater T cell activity. This approach has been found in preclinical studies to boost cancer-specific immune responses locally, while also producing tumor responses in remote parts of the body due to the circulation of properly activated anti-tumor immune cells, known as an abscopal effect.

The first intratumoral immunotherapy product candidate arising from our collaboration, SAR441000 (BNT131), includes modified mRNA that encodes for the IL-15sushi, IL-12sc, GM-CSF and IFN- $\alpha$  cytokines. We and Sanofi published data from our Phase 1 trial of SAR441000 (BNT131) as a monotherapy and in combination with cemiplimab in advanced solid tumors in July 2020, in which no patient experienced a dose limiting toxicity and no grade 3, 4, or 5 adverse events related to study treatment were reported.

### **2. Infectious Disease Vaccines**

#### ***At a glance: Our Infectious Disease Vaccine Platform***

- **Concept:** mRNA-based vaccines targeting infectious disease pathogens.
- **mRNA Format:** Multiple.
- **mRNA Delivery Formulation:** LNPs.
- **Development Approach:** Collaborations with Pfizer and Fosun Pharma and exclusive option arrangement with Penn.
- **Commercial Product:** COVID-19 vaccine (COMIRNATY in the European Union and other locations where we have received marketing approval).
- **Lead Candidates:** Influenza vaccine candidate BNT161 and other vaccine candidate variants in our BNT162 development program.

Expanding beyond our research in oncology, we are leveraging our mRNA technologies to direct the immune system more effectively against infectious diseases. Our infectious disease vaccine candidates contain self-replicating or trans-replicating, modified mRNA-encoding antigens specific to a target pathogen, delivered in various LNP formulations in order to activate and direct T cells and B cells to fight the pathogen.

#### ***BNT162b2 COVID-19 vaccine and Other COVID-19 Vaccine Candidates***

Our COVID-19 vaccine, referred to as COMIRNATY in the European Union and other locations where we have received marketing approval, has received emergency or temporary use authorization or approval in over 65 countries.

We and Pfizer are also investigating other COVID-19 vaccine candidate variants in clinical trials as part of our BNT162 program.

### **Influenza Vaccine**

We are collaborating with Pfizer to develop an influenza vaccine using our mRNA-based immunotherapy technology. Current influenza vaccines consist of antigens from inactivated influenza viruses, recombinant influenza haemagglutinin, or HA, proteins or live attenuated influenza viruses and are available as trivalent (containing two influenza A strains and one influenza B strain) or quadrivalent (containing two influenza A strains and two influenza B strains) vaccines. Currently available influenza vaccines are produced in chicken eggs or cell culture and take about five to six months to produce. This requires the composition of the coming season's vaccine to be selected by the World Health Organization, or WHO, far in advance for the vaccine to be available on time, which reduces the reliability of that prediction.

We anticipate that our mRNA-based vaccines can be manufactured within three months from the time the recommendation is published, including cloning and production and therefore the WHO's review of the vaccine components can occur closer to the influenza season to obtain a more reliable prediction. In addition, the mRNA manufacturing process is designed to produce an HA vaccine antigen that matches the HA of circulating influenza strains, in contrast to egg- or cell-based processes which can introduce mutations in the HA amino acid sequence. The flexibility of the mRNA vaccine platform could allow for generation of vaccines against genetically drifted seasonal viruses or pandemic strains.

### **3. mRNA-based Protein Replacement Platform for Rare Diseases**

#### **At a glance: Our Protein Replacement Platform for Rare Diseases**

- **Concept:** Therapeutic proteins encoded by mRNA and produced in the patient as an alternative to recombinant protein replacement.
- **mRNA Format:** Nucleoside-modified mRNA, deimmunized to avoid immune activation in order to allow for translation of the therapeutic protein in the cells.
- **mRNA Delivery Formulation:** Liver-targeting LNPs.
- **Development Approach:** 50:50 cost and profit share with Genevant.

By incorporating modified nucleosides into our mRNA, we are able to reduce the immunogenicity of our product candidates, thereby allowing their use for therapeutic protein production. In addition, we utilize advanced mRNA delivery methods to protect the mRNA cargo *en route* to its target and promote its uptake into liver cells. Current protein-based replacement therapies were developed to treat rare diseases by administering recombinant proteins. Such therapies are limited to diseases where the missing protein function is extracellular. However, mRNA-based protein replacement therapy also has the potential to treat illnesses with intracellular protein defects, as long as the mRNA can be delivered into the affected cells.

Our mRNA-based protein replacement therapy features:

- **Nucleoside-modified mRNA.** Replacing uridines in mRNA with modified analogues is important to avoid immune activation that can provoke anti-drug antibody production and would limit efficacy of the treatment.
- **Liver targeted expression.** mRNA encoding therapeutic proteins are formulated into LNPs using in-licensed clinically-validated LNP delivery technology owned by Genevant. The mRNA-loaded LNPs are less than 100nm in size. When injected intravenously, these particles are selectively taken up by hepatocytes, the major cell component of the liver.

Our protein replacement technology is designed for the treatment of:

- Genetic disorders that manifest due to a missing or defective protein, where mRNA would need to be administered regularly for a lifetime.
- Acute diseases caused by transient depletion of a protein, such as a hormone, where treatment of such diseases with a single or a few doses of the encoding mRNA could be curative.

Therapeutic proteins encoded by the mRNA can either act intracellularly or be secreted and act extracellularly, in order to produce the desired therapeutic effect.

mRNA-based protein replacement technology has several advantages over recombinant proteins:

- **No need to develop a procedure for protein purification.** The development of recombinant proteins is a laborious and expensive procedure due to the requirement for a unique purification protocol for each protein. During mRNA-based protein replacement the protein is produced by the patient, which we believe avoids the need for purification and also accelerates drug development.
- **The protein has proper post-translational modification.** To function properly, most recombinant proteins need to be modified after synthesis. Proteins produced in patients from mRNA are more likely to obtain the correct modifications than recombinant proteins produced in cultured bacterial or mammalian cells.
- **Continuous *in vivo* supply of encoded protein.** Recombinant proteins, especially those with short half-lives, can be cleared from the body very quickly, thereby limiting therapeutic effect. During mRNA-based therapy, the encoded therapeutic protein is produced for a longer duration (*e.g.*, 10-14 days).
- **Production of intracellular proteins.** Recombinant proteins have limited intracellular therapeutic effects. In contrast, proteins encoded by mRNA can reach any cellular compartment and potentially help to cure diseases where the therapeutic protein needs to function in different subcellular locations, including the mitochondria, nucleus or cell membrane.

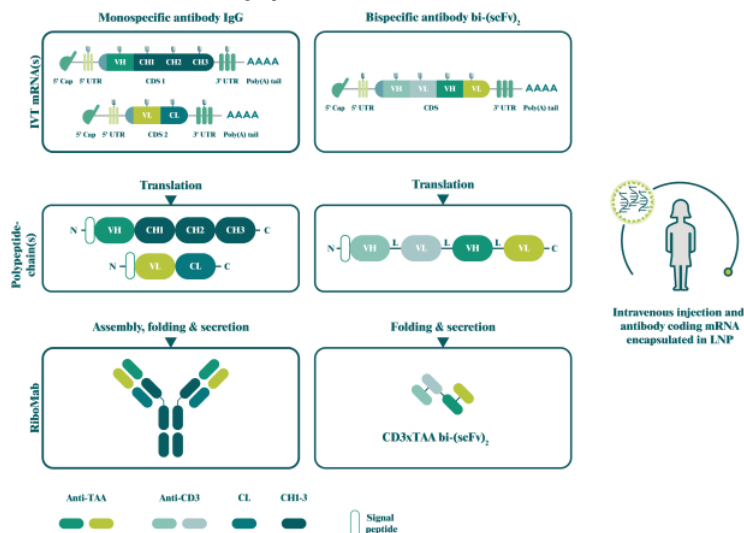
#### 4. RiboMabs

##### *At a glance: Our RiboMab Platform*

- **Concept:** Antibodies encoded by mRNA and produced in the patient as an alternative to recombinant antibodies.
- **mRNA Format:** Nucleoside-modified mRNA engineered for minimal immunogenicity in order to avoid immune detection and allow translation of the encoded antibodies to occur within the cells.
- **mRNA Delivery Formulation:** Various liver-targeting LNP formulations, delivered intravenously, to ensure systemic availability and prolonged production of the antibody *in vivo*.
- **Development Approach:** Worldwide rights; wholly owned.
- **Lead Candidate:** BNT141 in multiple solid tumors.

Our RiboMab product candidates are designed to encode secreted antibodies for expression *in vivo* by the patient's cells. We believe our RiboMab technology represents the next generation of antibody-based drugs. Antibody drugs are a leading class of biologics for the treatment of various diseases, but have a number of limitations. The development of antibodies is currently challenged by demanding and costly procedures of production, purification and formulation of a recombinant protein, which we believe hampers the rapid development and clinical testing of new drugs in this class. Recombinant protein antibodies require development of a cell line, establishment and adaptation of processes for production, purification and analytical testing. The whole process typically takes 18 to 30 months to optimize, scale-up and produce first clinical batches. Some of these antibodies are produced in low yields making them unsuitable for therapeutic application.

By contrast, mRNA not only involves a simpler and less expensive manufacturing process, but also is effective in much lower volumes than are required to produce similar effects using recombinant proteins. RiboMabs provide an antibody's mRNA sequence, and the body does the production work itself. This simplicity is designed to allow for both shorter development times and a greater diversity of druggable targets. For efficient RiboMab production, the encoding mRNA is encapsulated in LNPs that deliver the mRNA to the liver cells. For cancer treatment, we focus on tumor-associated antigens to keep adverse effects for the patients as low as possible. We believe we can integrate any antibody sequence in our RiboMab-encoding mRNA. We have demonstrated the feasibility of our RiboMab technology for a variety of antibody formats, such as full immunoglobulins (Ig), primarily IgG, or different bispecific antibody variants, all of which engage the patient's own immune cells to eradicate antigen-positive tumor cells.



**Our RiboMab technology.** The figure above depicts the structure of *in vitro* transcribed (IVT) IgG and bi-(scFv)<sub>2</sub> RiboMabs. IVP-mRNA encoding the therapeutic antibody is encapsulated in LNPs and injected intravenously into patients. The mRNA is delivered to the liver where it is translated into antibodies and secreted into the blood stream. Abbreviations: A100, poly adenosine tail; bi-(scFv)<sub>2</sub>, bispecific single chain variable fragment; C, C-terminus; CH, constant heavy domain; CL, constant light domain; IgG, immunoglobulin G; IVT, *in vitro* transcribed; L, linker; LNP, lipid nanoparticles; m1y, 1-methylpseudouridine; N, N-terminus; TAA, tumor-associated antigen; VH, variable heavy domain; VL, variable light domain; UTR, untranslated region.

We believe our broad portfolio of antibody formats will enable us to produce mRNAs encoding the appropriate antibody format for the individual patient's medical need and the desired treatment regimen (e.g., monotherapy or combination therapy).

## 5. RiboCytokines

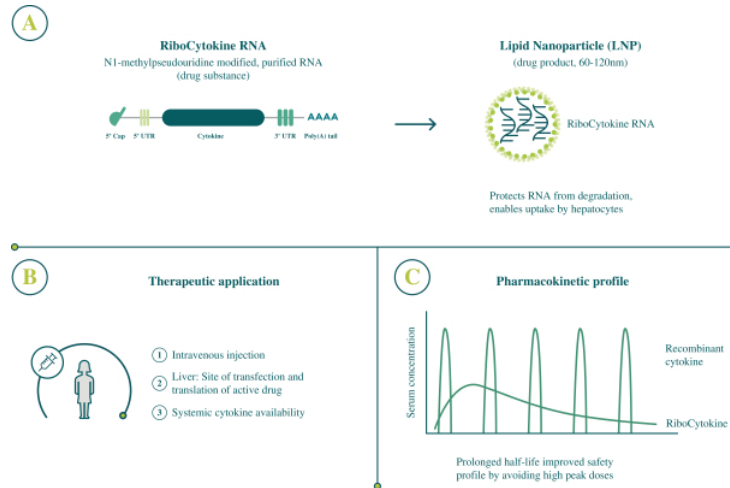
### At a glance: Our RiboCytokine Platform

- **Concept:** Cytokines encoded by mRNA and produced in the patient as an alternative to recombinant cytokines.
- **mRNA Format:** Nucleoside-modified mRNA engineered for minimal immunogenicity in order to avoid immune detection and allow translation of the encoded cytokines to occur within the cells.
- **mRNA Delivery Formulation:** Various liver-targeting LNP formulations, delivered intravenously, to ensure systemic availability and prolonged production of the cytokine *in vivo*.

- **Development Approach:** Worldwide rights; wholly owned.
- **Lead Candidate:** BNT151 in multiple advanced malignancies.

Our RiboCytokine product candidates utilize mRNA that encodes the desired cytokines for expression *in vivo* by the patient's cells. Cytokines represent a large group of relatively small proteins (<30 kDa) that regulate a variety of biological functions as they elicit signaling for immune and non-immune cells. In particular, cytokines play a pivotal role in orchestrating the initiation, execution and extinction of innate and adaptive immunity against pathogens as well as malignant cells. Due to their natural role as immunomodulators, recombinant cytokines are currently used for the treatment of a number of infectious, inflammatory, autoimmune and malignant diseases. One of the major challenges associated with the therapeutic use of cytokines relates to their short serum half-life and low bioavailability. This impedes therapeutic efficacy as it necessitates high and frequent dosing, which often results in dose-limiting toxicities.

We have developed a wholly owned, novel mRNA-based platform technology called RiboCytokines, designed to address the limitations of recombinantly expressed cytokines.



**Concept of our RiboCytokine technology.** The graphic above depicts our RiboCytokine technology, including mRNA formulated in LNPs and administered by injection, having a beneficial pharmacokinetic profile.

Our RiboCytokine platform allows for sustained delivery of the encoded cytokines with prolonged half-life, including through:

- **Usage of N1-methylpseudouridine modified mRNA.** N1-methylpseudouridine as a nucleoside analogue prevents the recognition of mRNA by TLRs, avoiding immune attack against the RiboCytokines.
- **Liver targeted expression.** RiboCytokines are formulated using clinically validated LNP delivery technology owned by Genevant. LNPs selectively target the liver resulting in high-level expression.

We believe that apart from a beneficial pharmacokinetic profile, our mRNA-based RiboCytokine technology has a number of additional advantages over other types of cytokine therapies:

- **Less immunogenic than recombinant cytokines.** Expression of self and foreign antigens in the liver is associated with immune tolerance due to a unique anti-inflammatory microenvironment. We expect

RiboCytokines to be less likely to trigger an immune response when compared to their recombinant counterparts.

- **Shorter development times and greater diversity.** The development of recombinant cytokines is a challenge due to demanding and costly CMC procedures of production, purification and formulation. The simplicity of our mRNA manufacturing allows for both shorter development times and a greater diversity of druggable targets.

We believe that our RiboCytokine technology is particularly well-suited to identify candidates for combination treatment with our proprietary CAR-T cell and cancer immunotherapies platforms.

## VII. Our Cell Therapies Drug Class

The tailored reprogramming of autologous T cells from cancer patients to recognize and attack their tumors has become a disruptive medical innovation. Retargeting of T cells can be achieved via introduction of tumor-specific receptors into patient-derived T cells. For that purpose, T cells are mostly engineered by retroviral gene transfer to express either T cell receptors, or TCRs, or chimeric antigen receptors, or CARs. Recently, CAR expressing T cells, or CAR-T cells, became the first engineered T cell therapy to obtain FDA approval for some B cell derived hematological malignancies. Additionally, with our Neon acquisition we recently acquired an adoptive T cell platform targeting patient-specific and shared neoantigens. This platform utilizes a proprietary *ex vivo* co-culture process, NEO-STIM, to prime, activate and expand autologous neoantigen-specific T cells specific either for a personal set of neoantigens for each patient or for a set of selected shared neoantigens.

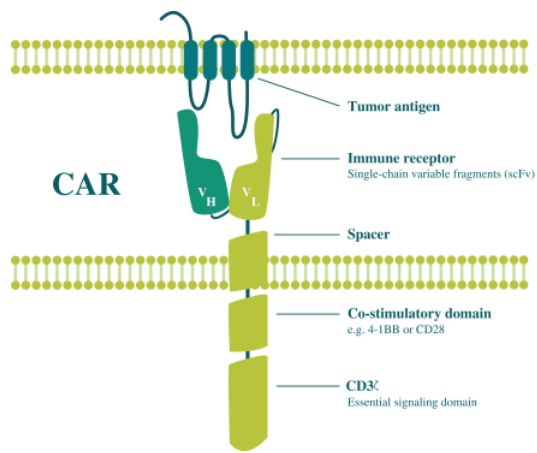
### A. CAR-T Cells

#### *At a glance: Our CAR-T Platform*

- **Concept:** Second-generation CAR-T therapy designed to overcome the shortcomings of CAR-T therapy in solid tumors.
- **Mechanism:** T cells with CARs engineered to target cancer-specific antigens, including novel antigens selected from our proprietary antigen library and administered with an mRNA-based immune booster, which we refer to as CARVac, to enhance CAR-T cell expansion and persistence.
- **Development Approach:** Worldwide rights; wholly owned.
- **Lead Candidate:** BNT211 for multiple solid tumors.

CARs are artificial receptors that consist of an antigen recognition domain derived from a tumor-specific antibody linked to intracellular T cell signaling domains. CARs redirect T cells to eradicate tumors through specific recognition of native surface proteins expressed on tumor cells in a non-MHC-restricted manner. Therefore, CAR-T cells can be used for the treatment of all individuals whose tumor expresses the respective target, independent of the individual's HLA genotype. CARs can be used for redirection of both CD4+ and CD8+ T cells.





**Second-generation CAR.** The figure above illustrates the basic structure of a second-generation CAR, such as those included in our BNT211 and BNT212 product candidates.

While CAR-T therapy has shown potent anti-tumor responses in patients with B cell malignancies, clinical efficacy in solid tumors so far is limited. The main hurdles for application of CAR-T therapies in solid tumors are:

- Lack of highly tumor-selective targets, which are needed for safe and effective tumor targeting; and
- Low anti-tumoral activity due to insufficient expansion of engineered T cells.

We are developing the next generation of engineered T cell therapies that:

- target novel and known tumor-specific antigens, including mutant neoantigens, and a broad spectrum of tumor-associated antigens expressed in a wide range of cancers; and
- leverage our proprietary CARVac technology for controlled *in vivo* stimulation, activation and expansion of engineered T cells.

The powerful characteristics of CAR-T cells, including their potential to eradicate targeted tumor cells in combination with their potentially life-long persistence in the host, require careful target selection. We believe the essential features of an ideal antigen for T cell-based immunotherapy are:

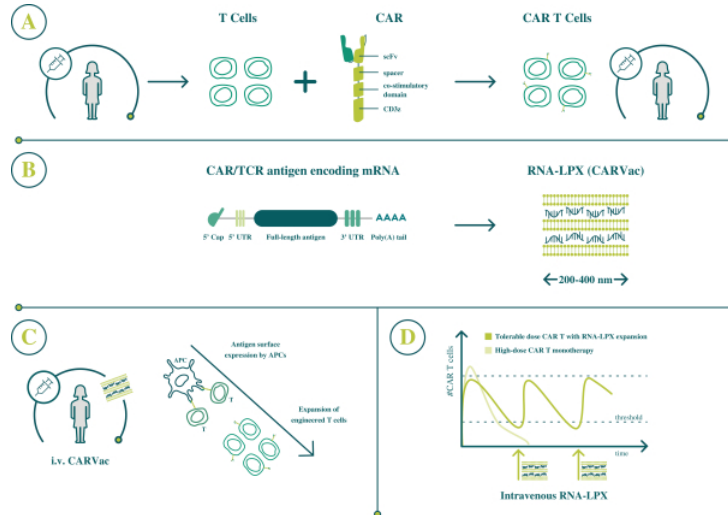
- Absence of expression from any toxicity-relevant non-malignant tissue, to prevent off-tumor/on-target toxicity; and
- Expression on the cell surface of tumor cells at sufficient levels to allow for recognition and lysis by CAR-T cells.

We are developing CAR-T programs targeting two different members of the Claudin family, namely CLDN6 and CLDN18.2. Claudins, or CLDNs, are central components of tight junctions that regulate epithelial-cell barrier function and polarity. Most of the CLDNs are broadly expressed, while CLDN6 and CLDN18.2 are exclusively expressed in different high medical need cancers. Disturbance and dysregulation of tight junction molecules is a frequent hallmark of cancer cells and often associated with malignant transformation and metastasis and, hence, disease progression.

### In-vivo expansion of engineered T cells using liposomally formulated mRNA

Besides targeting an ideal tumor-specific antigen, the frequency and the persistence of CAR-T cells in the respective patient is a critical factor determining antitumor efficacy. A positive correlation between clinical outcome and CAR-T cell engraftment and persistence has been shown in several CD19-targeting CAR-T trials. Both tend to be much more limited in the solid tumor setting, likely due to the lack of circulating antigen-presenting cells, or APCs, such as dendritic cells expressing the target CAR antigen.

To address this critical factor, we developed an approach for *in vivo* stimulation of CAR-T cells that relies on our proprietary FixVac technology for systemic mRNA delivery in combination with our CAR-T product candidates. Intravenous administration of a FixVac encoding for the tumor antigen induces expression of the desired target on antigen-presenting cells in secondary lymphoid tissues. FixVac treatment facilitates *in vivo* expansion of CAR-T cells in a dose-dependent manner. Moreover, repetitive administration of FixVac results in an improved CAR-T cell persistence as well as increased anti-tumor activity.



**Our CAR-T cell immunotherapies combined with CARVac-mediated *in vivo* expansion.** (A) Autologous T cells engineered to express a CAR are adoptively transferred into the patient. (B) Full-length CAR target-encoding mRNA is complexed with liposomes to form RNA-LPX lipoplexes (CARVac). (C) Intravenously administered CARVac selectively targets APCs in secondary lymphoid organs facilitating uptake, antigen expression and maturation of APCs. Exposure of CAR-T cells to their target results in CAR-T cell *in vivo* expansion. (D) CARVac can be administered repetitively to achieve controlled expansion and persistence of CAR-T cells within the therapeutic window.

### B. Neoantigen-targeting T Cells

#### At a glance: Our Neoantigen-targeting T Cell Platform

- **Concept:** Adoptive T cell therapies targeting personal or shared sets of cancer neoantigens.
- **Mechanism:** Autologous, neoantigen-specific T cells primed, activated and expanded utilizing a proprietary antigen-specific T cell induction protocol, NEO-STIM, to target either a personal set of neoantigens for each patient or a set of selected shared neoantigens.
- **Development Approach:** Worldwide rights.
- **Lead Candidate:** BNT221 for metastatic melanoma and other potential cancer indications.

Through our acquisition of Neon in 2020, we obtained a neoantigen-targeting T cell platform. This platform can be utilized to develop product candidates across several neoantigen-targeting non-engineered and engineered T cell therapies using two distinct approaches:

- An individualized approach enabling neoantigen-targeted therapies that are tailored for the individual profile of each patient's tumor.
- A shared neoantigen approach enabling neoantigen therapies that target prevalent neoantigens that are shared across subsets of patients or tumor types.

Our RECON bioinformatics engine is designed to predict the most therapeutically-relevant neoantigen targets associated with each patient's tumor. Effective prediction is critical because, although many mutations within a patient's tumor will lead to the production of a mutated protein, not all mutated proteins lead to suitable therapeutic neoantigen targets. RECON uses a number of inputs from each patient, including DNA sequences from samples of tumor and normal tissue, RNA sequences from tumor samples, and the patient's specific MHC allele profile. RECON processes data from these inputs using a proprietary combination of algorithms in order to produce a prioritized list of neoantigen-targeting peptides that can be manufactured for use in product candidates. After selection of the target neoantigens, our proprietary method for *ex vivo* T cell stimulation, which we call NEO-STIM, allows us to directly prime, activate and expand antigen-specific T cells.

### C. TCRs

The T cell receptor, or TCR, is part of a complex signaling machinery, which includes the TCR  $\alpha$  and  $\beta$  chains that are responsible for antigen recognition, the co-receptor CD4+ or CD8+ and the CD3 signal transduction complex. TCRs recognize antigens presented on the cell surface as small peptides loaded on the patients' HLA molecules. Those peptides are derived from proteins after intracellular degradation. In contrast to CARs that recognize solely native membrane proteins, the repertoire of suitable TCR target antigens include TAAs and mutant neoantigens.

#### *Our TCR Discovery and Validation Platform*

We have developed an integrated technology platform for the systematic identification of functional, fully human TCRs from single antigen-reactive T cells. This technology consists of a proprietary high-throughput approach for the fast retrieval, cloning and rapid validation of novel paired T cell receptor sequences. Our approach facilitates the isolation of tumor cell specific TCRs against multiple antigens and various HLA class I and II alleles.

We believe our TCR discovery technology has the potential to unlock an array of patient- and tumor-specific TCRs suitable for clinical use. We believe this technology has potential utility for:

- therapeutic TCR products encompassing single TCRs to target a specific antigen;
- a therapeutic TCR warehouse encompassing multiple TCRs to target one or more tumor antigens; or
- individualized T cell therapy involving on-demand identification and timely manufacturing of customized, engineered T cells with autologous TCRs against neoepitopes for adoptive transfer.

### VIII. Our Antibodies Drug Class

In the past decades, monoclonal antibodies, or mAbs, have transformed from scientific tools to powerful human therapeutics. As one of the fastest growing classes of drugs, to date, dozens of mAbs have been approved to treat a variety of diseases including cancer, inflammation, autoimmune diseases and others. In addition, identified antigen-binding domains are also fundamental elements for the construction of novel therapeutic formats and formulations, such as CAR-T cells, bispecific therapeutics and targeted nanoparticles.

We have developed and integrated multiple complementary antibody and antibody-mimetic protein technologies into our overall portfolio of treatment approaches.

## A. Our Next-generation Checkpoint Immunomodulators

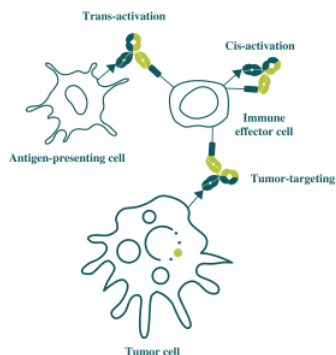
### *At a glance: Our Next-generation Checkpoint Immunomodulators*

- **Concept:** Bispecific antibodies for dual immunomodulation, initially targeting 4-1BB, an immune checkpoint that is expressed on T cells and NK cells and can enhance immune cell proliferation and activation, in combination with simultaneous checkpoint inhibition.
- **Mechanism:** Conditional activation of 4-1BB checkpoint only upon simultaneous binding of PD-L1 or CD40 (in the case of our initial candidates), potentially avoiding toxicities seen in prior attempts at 4-1BB agonism by localizing 4-1BB activation to the tumor environment.
- **Development Approach:** 50:50 cost and profit share with Genmab, combining our and Genmab's immunostimulatory antibodies and extensive immunology expertise with Genmab's DuoBody® bispecific antibody platform.
- **Lead Candidate:** GEN1046 (BNT311), our PD-L1x4-1BB product candidate for multiple solid tumors.

Following the success of immune checkpoint-blocking antibodies targeting CTLA-4, PD-1 or PD-L1 in cancer treatment, bispecific antibody approaches represent the next generation of emerging immunotherapies with the potential to further improve clinical efficacy. In addition to bispecific T cell engager formats, which redirect T-cell cytotoxicity to malignant cells, bispecific antibodies can be formatted as tumor-targeted immunomodulators and dual immunomodulators. Tumor-targeted immunomodulators direct potent immune costimulation to the tumor-infiltrating immune cells, whereas dual immunomodulators simultaneously address two immunomodulating targets, resulting in blockade of inhibitory targets, depletion of suppressive cells or activation of immune effector cells.

We are developing, in collaboration with Genmab, bispecific antibodies that function as tumor-targeted and dual immunomodulators, applying Genmab's proprietary DuoBody® technology in combination with our joint target identification and product concept expertise. These next-generation checkpoint immunomodulators are thought to induce beneficial co-stimulation, promoting specific T cell activation, survival, proliferation and T cell effector functions. Our collaboration encompasses three potential classes of immunotherapeutic bispecific antibodies:

- Tumor-targeted DuoBody® molecules are bispecific antibodies targeting a tumor-specific antigen expressed by the malignant cell, and an immunomodulatory receptor expressed by tumor-infiltrating immune cells. This is expected to induce powerful activation of tumor-specific effector immune cells with reduced risk of immune-related adverse events.
- Cis-activating DuoBody® molecules are bispecific antibodies that bind two distinct immunomodulating targets presented on the same cell. These targets are specifically expressed on activated immune cells with the rationale to boost existing immune responses by additive or synergistic effects of dual immunomodulation.
- Trans-activating DuoBody® molecules are bispecific antibodies that bind two distinct immunomodulating targets expressed on two separate cell subsets. By simultaneously targeting, for example, effector immune cells and antigen-presenting cells, these compounds are thought to amplify the immune cell priming process and augment subsequent effector responses.



**Next-generation checkpoint immunomodulators.** Our collaboration with Genmab potentially includes bispecific antibodies from three different classes: trans-activating, cis-activating and tumor-targeting antibodies.

## IX. Our Small Molecule Immunomodulator Drug Class

### *At a glance: Our Small Molecule Immunomodulators*

- **Concept:** Small molecule therapies, with a specific focus on TLRs, that can be used synergistically with other cancer therapeutics, including other product candidates in our portfolio.
- **Development Approach:** Worldwide rights; wholly owned.
- **Lead Candidate:** BNT411, our TLR7 agonist product candidate intended as a monotherapy or in combination with chemotherapy and/or checkpoint inhibitors.

Small molecule cancer therapeutics can be used to regulate cancer growth, halt blood vessel formation in tumors, deliver toxins to cancer cells and mark cancer cells for destruction by the immune system. Unlike larger antibody-based cancer therapies, small molecule compounds are often developed for targets located within cells since they can enter the cells more easily as a result of their physical properties and low molecular weight. Small molecules also often have other intrinsic benefits including relative ease and cost of production compared to larger compounds, as well as more frequently having the potential for oral administration to patients. They can also often be used synergistically in combination with other therapeutics such as mRNA, checkpoint inhibitors, radiation therapy and chemotherapy.

Our immunomodulatory small molecule product class focuses on a range of endosomal and intracellular targets that are known to stimulate the activity of a wide range of immune cells. We have a particular emphasis on TLRs, a family of pattern recognition receptors that function as primary sensors of the innate immune system to recognize pathogens. We believe TLRs represent a promising target class for cancer immunotherapy, particularly for inflammatory re-programming of the tumor microenvironment. In many cancers, tumors are protected by an anti-inflammatory environment, which reduces the ability of the immune system to attack the cancer cells. TLR7 agonists are able to initiate a direct cellular immune response, for example, by activating immature dendritic cells, cytotoxic T cells and NK cells, as well as stimulating the release of signal molecules such as cytokines and chemokines including IFN- $\alpha$  and IP-10, which can be directed against tumor cells. The activation of the innate and adaptive immune system and the release of cytokines and chemokines, for instance by our small molecule TLR7 agonist, results in the potent stimulation of antigen-specific T cells, B cells and innate immune cells such as NK cells and macrophages.

Our initial focus is on small molecule product candidates that activate the innate and adaptive immune system via TLR7 and are designed to be used in combination with chemotherapeutics as well as checkpoint inhibitors.

## **X. Sales, Marketing and Distribution**

Our commercial organization focuses on supporting sales of our COVID-19 vaccine in Germany and certain markets where approved or authorized. Our sales and marketing organizations are responsible for promoting our products to health care providers and providing information to stakeholders, including governmental organizations, in the countries where we have authorization to sell the vaccine. Our commercial organization is also responsible for preparing and obtaining reimbursement from third-party payors, including governmental organizations, for our COVID-19 vaccine and will have the same responsibilities for our clinical-stage oncology product candidates, if approved.

Our German commercial team is comprised of a small number of individuals to support commercialization of our COVID-19 vaccine. We focus our marketing and sales efforts in Germany on all physicians and health care professionals involved in the vaccination efforts against COVID-19. If and when we receive full marketing authorization for our COVID-19 vaccine, we will market our products through personal interactions with physicians and allied health care professionals. Our government and public affairs group advocates for policies that promote life sciences innovation and increase awareness of the diseases on which we are focusing, with state and federal legislatures, government agencies, public health officials and other policy-makers.

The commercialization models in the countries where we have the rights to commercialize are adjusted based on the respective commercialization agreements with our collaborators as well as the nature of the supply agreements with the governments for our COVID-19 vaccine.

## **XI. Manufacturing**

We are building a fully integrated biotechnology company, with operations spanning from research through clinical development, and manufacturing through sales and marketing. We operate four GMP-certified manufacturing facilities in Germany, where we manufacture mRNA therapeutics and engineered cell therapies for our own pipeline and for external customers, including a state-of-the-art, multi-platform, GMP-certified manufacturing facility located in a life science industrial park in Marburg, Germany, which we acquired in October 2020 from Novartis AG to increase manufacturing capacity of our COVID-19 vaccine for commercial supply commencing in 2021. We also operate a fifth facility in Germany where we manufacture custom peptides to support our extensive immunomonitoring activities within our development programs. Our subsidiary BioNTech Innovative Manufacturing Services GmbH, or BioNTech IMFS, has been manufacturing GMP-certified cellular products since 1999. It was granted its first GMP license for manufacturing mRNA in 2011 and has been manufacturing individualized mRNA products since 2014.

We have expanded our capability to produce and supply drug products to support clinical development of our, and our collaborators', product candidates. To date, we have manufactured about 1000 drug substance batches in our manufacturing facilities.

Our approach has been to proactively build capacity in anticipation of demand from internal research and development, as well as from our collaborators. We have done so by continuing to make significant investments in manufacturing infrastructure and increasingly expanding our capacity to manufacture mRNA, viral vectors, cellular products and peptides. We believe the development and optimization of our manufacturing processes in parallel to drug development is crucial to our success. We have also collaborated with Siemens to develop a process for a fully-automated, on-demand production of mRNA therapies.

### ***Our Manufacturing Operations***

**COVID-19 Vaccine.** Our recently acquired manufacturing site in Marburg was approved by the EMA for manufacturing of the COVID-19 drug product in March 2021. This approval makes it one of the largest mRNA manufacturing sites worldwide alongside two of our existing GMP facilities, which currently produce the COVID-19 vaccine candidates for clinical trials, and it will have an annual production capacity of up to one billion doses of our COVID-19 vaccine, once fully operational. We also expect that the first vaccines manufactured at the Marburg site to be delivered in the second half of April 2021. We will rely on a network of sub-contractors to provide drug substance, drug conjugate, drug product, and fill and finish services to enable production. While we have already signed orders for 1.4 billion doses of the vaccine for 2021 based on existing supply agreements with governments worldwide, and discussions for additional dose commitments are ongoing, our manufacturing capacity target is 2.5 billion doses in total by the end of 2021. Additionally, as of March 23, 2021 we have shipped 200 million doses of our COVID-19 vaccine globally. This estimate is based on the six BioNTech and Pfizer manufacturing sites producing the vaccine, the updated label permitting six doses per

vial and continuous process improvements and expansion at our current facilities. It is further contingent upon us contracting with more suppliers and external contract manufacturers to expand LNP and fill and finish capacity.

The Marburg site contains approximately 100,000 square feet of laboratory and office space, including 50,000 square feet of GMP facilities and currently employs approximately 400 people. We plan to manufacture additional therapeutic and vaccine drug candidates at the plant, such as other mRNA vaccine, antibody, and cell and gene therapy product candidates to support the development of our product pipeline. The site is also fully equipped to hold cell culture labs and produce viral vectors, with further potential for long-term growth and expansion.

**mRNA.** We believe scaling up manufacturing for mRNA can best be executed as part of a proprietary manufacturing approach, not as part of an outsourcing strategy. We believe this approach allows us to maintain control of our proprietary processes and gives us the flexibility we need for scheduling batch production for our drug substances to match our development plans as they evolve. Our mRNA manufacturing is currently conducted at our in-house BioNTech IMFS facility and our BioNTech East Wing facility, and will also be conducted at our Marburg facility. The East Wing facility is dedicated to iNeST and bulk mRNA manufacturing. Our mRNA manufacturing process involves standardized production of all mRNA constructs and minimal restrictions in construct length. We have the capacity to undertake sterile filtration and final filling in up to 1,200 vials of various sizes. Batch sizes range from a few milligrams for individualized applications (*i.e.*, iNeST) to 10g for standard mRNA applications (*i.e.*, FixVac, intratumoral immunotherapies and infectious diseases, *e.g.*, COVID-19), with batch sizes of up to 10g currently possible.

To date, we have produced more than 500 batches of mRNA drug substance to support our studies. We currently have infrastructure capable of producing more than 100 batches of mRNA drug substance and formulated drug product per month with a turnaround time of about 30 to 40 days from sequence identification to released product. We believe we currently have the capacity to supply needs of our product candidates in clinical trials up to registration.

In recent years, we have successfully decreased the time required to deliver individualized immunotherapy to patients. In 2014, it took us over three months to manually manufacture and deliver individualized immunotherapies to patients. Since December 2017, with the implementation of semiautomatic GMP manufacturing in collaboration with Siemens, we have been consistently manufacturing and delivering individualized immunotherapies in under six weeks. This advancement represents significant progress toward our target commercial manufacturing turnaround time of less than 28 days. We believe this is achievable, and we plan to continue to develop additional process improvements, which we expect will further reduce our turnaround times as we progress through clinical development.

**Cell Therapy Products.** We have end-to-end capabilities and over 20 years of experience in cell therapy manufacturing. Our manufacturing process for cellular products involves the isolation of primary human cells and subpopulations, including CD34+ and CD3+ cells. We engage in the culturing, expansion and genetic modification of primary human cells as well as mammalian cell lines. Our processes include vector production for transfection of cells with CARs, cell banking and cryopreservation.

We have set up a broad range of quality control assays for the characterization of cell therapy products that allow us to certify the manufactured drug products in a short time. We are a leader in the production of gamma retroviral vectors. To date, we have produced more than 50 different cell therapy products.

**Peptides.** Our custom peptide synthesis business has developed unique technologies to produce several million peptides during the past three years to support our growing clinical pipeline. These include fast small-scale manufacturing of peptides for target and epitope discovery as well as for neoepitope characterization and production of high content arrays. It is important to synthesize highly purified peptides in order to avoid false positives in immunomonitoring in our mRNA immunotherapy trials. We also use these peptides as starting material in our engineered cell therapies. We have developed know-how to produce highly complex and purified peptide pools that consist of overlapping peptides spanning entire antigens or neoepitopes. We plan to establish a new production facility, which will roughly double our current capacity.

#### **Our Manufacturing Facilities**

In addition to the recently acquired Marburg site, we operate four other manufacturing and packaging facilities in Germany. In these facilities, we manufacture and package individualized mRNA, bulk mRNA, retroviral vectors, cellular products and peptides. In Mainz, we are currently constructing another facility for iNeST manufacturing at a commercial scale, which is planned to start manufacturing in 2022 and will supply markets mainly in Europe and the United States.

*BioNTech IMFS.* Our manufacturing operations for retroviral vectors, cell therapy products and mRNA are housed in our wholly owned subsidiary, BioNTech IMFS. Founded in 1997, BioNTech IMFS specializes in services for innovative therapeutic approaches. In 2009, BioNTech IMFS became our wholly owned subsidiary, giving us access to synergistic platforms and complementary expertise for development, testing and manufacturing services. BioNTech IMFS and its predecessors have had GMP-certified cell and gene therapy manufacturing capabilities since 1999, and obtained GMP manufacturing authorization for mRNA production in 2011. In 2017, BioNTech IMFS began automated manufacturing of the iNeST product candidate and entered into its first commercial supply contract for retroviral vectors. Located near Mainz, the BioNTech IMFS facility occupies over 30,000 square feet. Two hundred and twenty staff members are employed at this facility, with collective expertise in molecular biology, cell biology and virology.

*BioNTech iNeST Clinical Manufacturing (East Wing).* We dedicate our GMP-certified manufacturing facility at our headquarters in Mainz, Germany to the production of iNeST immunotherapies. In 2015, our wholly owned subsidiary, BioNTech RNA Pharmaceuticals GmbH, or BioNTech RNA, and Siemens announced a collaboration for developing an automated, paperless and digitalized production site for individualized mRNA. We obtained our GMP manufacturing authorization for iNeST production at our East Wing facility in June 2018 and released our first drug product there the following month.

This facility contains approximately 17,000 square feet of laboratory and office space, including 4,300 square feet of GMP facilities. About 200 staff members are employed at this facility and operate it seven days per week. In its first year of operation the facility manufactured and released more than 250 batches of mRNA and has, since inception, manufactured and released more than 450 batches of mRNA.

*BioNTech Clinical Manufacturing.* Our GMP-certified manufacturing facility in Kupferbergterrasse, Mainz, Germany is authorized to conduct secondary packing, labeling, storage and batch release of primary packed investigational medicinal products. This facility contains approximately 11,500 square feet of laboratory and office space, including 1,250 square feet of GMP facilities.

*JPT.* JPT, our peptide manufacturing facility, was established in 2004 and became a wholly owned subsidiary of BioNTech in 2008. JPT is located in Berlin, Germany and occupies over 16,000 square feet of clean rooms, laboratory and office space.

#### **Other Certifications**

BioNTech Diagnostics has a quality management system that is certified according to ISO 13485:2016 and JPT maintains a ISO 9001:2015 certified Quality Management System to allow production of European CE marked companion diagnostics.

#### **Quality Assurance**

We have implemented and maintain several Quality Assurance systems. BioNTech IMFS, BioNTech Clinical Manufacturing and BioNTech iNeST Clinical Manufacturing have implemented GMP-certified quality assurance systems. BioNTech Diagnostics has a quality management system that is certified according to ISO 13485:2016 and JPT maintains a ISO 9001:2015 certified Quality Management System.

#### **XII. Third-Party Collaborations**

We have forged productive collaborations with pharmaceutical companies and academic research institutions with area expertise and resources in an effort to advance and accelerate our discovery and development programs in oncology, and also to leverage our drug classes into additional disease indications while minimizing our incremental costs.

Our collaborations include:

- Pfizer for our COVID-19 and influenza vaccine programs, which leverage technology from our infectious disease mRNA-based platform;
- Fosun Pharma for our COVID-19 vaccine program;
- Genentech for our iNeST platform in our mRNA drug class;
- Sanofi for our intratumoral therapy platform in our mRNA drug class;



- Genmab for our next-generation checkpoint immunomodulator platform in our antibodies drug class; and
- Genevant for our rare disease protein replacement therapy platform in our mRNA drug class.

We either wholly own or retain significant rights to all of our clinical stage programs, either in the form of a global share of profit and co-commercialization rights with our collaborators in certain markets or significant royalties and milestones. We plan to continue to identify potential collaborators who can contribute meaningful resources and insights to our programs and allow us to more rapidly expand our impact to broader patient populations.

#### ***Pfizer-COVID-19 Collaboration***

On April 9, 2020, effective as of March 17, 2020, we entered into a Collaboration Agreement with Pfizer for the research and development of immunogenic compositions comprising RNA encoding a SARS-CoV-2 polypeptide or fragment thereof for prophylaxis against SARS-CoV-2 in humans, which we refer to as the Pfizer Corona Field. On January 29, 2021, effective as of March 17, 2020, we entered into an amended and restated Collaboration Agreement with Pfizer for the research, development and commercialization of immunogenic compositions comprising RNA in the Pfizer Corona Field, which we refer to as the Pfizer Agreement.

We and Pfizer agreed to collaborate on research and development in the Pfizer Corona Field worldwide (excluding the Fosun Territory) which we refer to as the Pfizer Territory. The details of such activities are set forth in a research and development plan that is governed by a joint steering committee. Each party bears its own personnel and capital expenditures costs, but the parties will share the costs of all other agreed development activities (including the costs of manufacturing material for use in clinical trials) evenly. Each party will, in good faith, seek funding from government funds, non-governmental organizations and other third-party organizations to support their research and development activities. Under the Pfizer Agreement, Pfizer will lead clinical development of and seek regulatory approval for any candidates or products in the United States and we will lead clinical development of and seek regulatory approval for any candidates or products in the European Union, and we will agree on a strategy for all other countries.

BioNTech can solely commercialize the vaccine in Germany and Turkey, as well as specified developing countries (collectively referred to as the BioNTech Territory) for so long as we or a third-party funding organization is conducting vaccine commercialization in such countries, and subject to any future agreement with the third-party funding organization. We have the option to opt-out of commercializing the vaccine in Germany and/or Turkey, whereupon such countries will become part of the Pfizer Territory.

Pfizer has the right to commercialize any approved vaccine (such as our COVID-19 vaccine) in the rest of the Pfizer Territory. On a country-by-country basis in relation to the United Arab Emirates and certain countries of southeast Asia, if we obtain funding from a third-party government, non-governmental organization or other organization that obligates us to commercialize an approved vaccine in such country, we are obligated to request from Pfizer in writing a decision as to whether Pfizer wishes to commercialize such vaccine in such country in accordance with the requirements agreed with the third-party funder. If Pfizer elects not to commercialize the vaccine in such country, then such country shall become a part of the BioNTech Territory.

If our Collaboration Agreement with Fosun expires or is otherwise terminated for any reason, as between us and any international pharmaceutical group headquartered outside of China, we granted Pfizer a right of first negotiation to expand the Pfizer Territory to include the Fosun Territory. See "Fosun-COVID-19 Collaboration" below for more information on the Fosun Agreement.

We and Pfizer will share responsibilities for manufacturing and supplying the approved vaccine. If there is insufficient supply to satisfy the entire demand for a vaccine in the Pfizer Territory, we and Pfizer have agreed to determine by mutual consent the allocation of supplies on a fair and equitable basis, subject also to any applicable law, export controls, any government supply obligations, or supply obligations included in any agreement reached with a third-party funding organization.

Under the Pfizer Agreement, we granted Pfizer an exclusive, sublicensable license in the Pfizer Territory under certain of our intellectual property, including our patents and know-how, relating to uridine RNA, modified RNA and replicons in the Pfizer Corona Field as well as certain intellectual property in-licensed by us from third parties, to use, research, develop, manufacture, commercialize and otherwise exploit candidates and products selected under the Pfizer Agreement. We undertake to maintain in full effect all intellectual property licenses held by us at the time we entered into the Pfizer Agreement and not to modify or amend any such license in a manner that would adversely affect any of the rights

granted to Pfizer under the Pfizer Agreement. We are obligated to notify Pfizer of any breach of our current licenses and may be obligated to take steps to maintain Pfizer's access to any intellectual property licensed under such licenses.

During the term of the Pfizer Agreement and a certain period thereafter, we and Pfizer have committed not to research, develop, manufacture, commercialize or otherwise exploit immunogenic compositions comprising RNA in the Pfizer Corona Field, or exploit vaccine candidates or products developed under the agreement for any use, other than pursuant to the Pfizer Agreement, provided, however, that Pfizer shall have the right to work as a contract manufacturer for a third party and Pfizer shall not be precluded from acquiring a third party, or being acquired by a third party, that at the time of acquisition is active in the development or commercialization of an immunogenic composition comprising mRNA in the Pfizer Corona Field.

On April 9, 2020, Pfizer also subscribed for \$113 million of our ordinary shares under a separate investment agreement. In addition, under the Pfizer Agreement, Pfizer made an upfront payment of \$72 million and agreed to make potential payments of up to \$563 million upon the achievement of specified regulatory and commercial milestones. We and Pfizer agreed to share development costs equally. We and Pfizer will share the cost of and profits from commercializing a vaccine evenly. The Pfizer Agreement continues for so long as either at least a vaccine is being developed for use in the Pfizer Territory or a vaccine is being commercialized anywhere in the Pfizer Territory. In addition to termination rights granted to each party in the case of the other party's uncured material breach, Pfizer may terminate the agreement (i) upon our insolvency or (ii) on a country-by-country basis or in its entirety for convenience upon one (1) year's prior written notice provided that any such termination shall not become effective less than two (2) years from the first commercial sale of an approved vaccine.

#### ***Fosun-COVID-19 Collaboration***

On March 13, 2020, we entered into a Development and License Agreement with Shanghai Fosun Pharmaceutical Industrial Development, Co., Ltd, or Fosun Pharma, for the development and commercialization in mainland China, Hong Kong SAR, Macau Special Administrative Regions and in Taiwan, or the Fosun Territory, of immunogenic compositions generated by BioNTech and comprising uridine RNA, modified RNA and/or replicon technology for prophylaxis against SARS-CoV-2 in humans. We refer to this agreement as the Fosun Agreement.

The details of the development activities to be undertaken by Fosun Pharma are to be set forth in a development plan that is overseen by a joint steering committee. Fosun Pharma's development activities are to be undertaken at its own cost and expense. Fosun Pharma has the sole responsibility to prepare, obtain and maintain regulatory approvals for the vaccine candidates in the Fosun Territory. We agreed to give Fosun Pharma reasonable assistance with the regulatory aspects of these activities.

Fosun Pharma has the sole responsibility, authority and control of the commercialization of a vaccine candidate in the Fosun Territory, but must use commercially reasonable efforts to do so in accordance with an agreed commercialization plan, including by launching a vaccine product in the Fosun Territory within three months after receiving marketing approval for it, provided sufficient quantities of the vaccine have been delivered.

We retain the sole right to manufacture (or have manufactured) and supply any vaccine candidates and products for development purposes and commercial sale in the Fosun Territory. We agreed to manufacture and supply all quantities of vaccine from a GMP-certified RNA manufacturing facility. As compensation for supply of the vaccine Fosun Pharma will reimburse us our manufacturing costs plus an administrative fee that is between 10 and 19 percent.

Under the Fosun Agreement, we granted Fosun Pharma an exclusive license under certain of our owned or in-licensed intellectual property, including our patents relating to replicons, uridine RNA and modified RNA and other mRNA technology or a vaccine to use, develop, commercialize and otherwise exploit the vaccine candidates in the Fosun Territory. In the event of any failure of the development of a vaccine, we agreed to grant Fosun Pharma a right of first negotiation on a separate competent vaccine for the prophylaxis of COVID-19 in the Fosun Territory.

In consideration of the rights granted to Fosun Pharma under the Fosun Agreement, Fosun Pharma subscribed for \$50 million of our ordinary shares under a separate investment agreement. In addition, under the Fosun Agreement, Fosun Pharma made an upfront payment of \$1 million and agreed to potential payments of up to \$14 million upon the achievement of specified development and regulatory milestones and up to \$70 million upon the achievement of specified sales milestones. Fosun Pharma further agreed to pay us a royalty rate that is between 30 and 39 percent of its profits on net sales of a vaccine product, if approved, for a period of 15 years from launch of that vaccine in the Fosun Territory.

The Fosun Agreement ends upon expiration of the royalty term. Fosun Pharma may elect to continue to pay royalties and extend the agreement and its rights thereunder. In addition to termination rights granted to each party in the case of the other party's uncured material breach or insolvency, Fosun Pharma may terminate the agreement, in whole, for convenience and with or without reason at any time upon 180 days' prior written notice. If the agreement is terminated by Fosun Pharma for cause, the licenses to Fosun Pharma survive, we will manufacture and deliver the vaccine candidate or product for one year and we will grant a non-exclusive license to a reasonably acceptable contract manufacturing organization for manufacturing of the vaccine candidate or product thereafter for development and commercialization by Fosun Pharma in the Fosun Territory.

During the term of the Fosun Agreement, we have committed not to, and not to license the licensed intellectual property to any third party to, develop or commercialize the same vaccine candidate or vaccine in the Fosun Territory.

#### **Genentech-iNeST Collaboration**

##### *Collaboration Agreement*

On September 20, 2016, we and BioNTech RNA entered into a Collaboration Agreement with Genentech and F. Hoffman-La Roche Ltd, which, as amended on June 1, 2018 and December 6, 2019, we refer to as the Genentech Collaboration Agreement, to jointly research, develop, manufacture and commercialize certain pharmaceutical products that comprise neoepitope RNAs, or the Genentech Collaboration Products, which include our iNeST development candidates, for any use worldwide. Under the Genentech Collaboration Agreement, we and Genentech agreed to perform joint research under a research plan to further improve our technology platform for the manufacturing of Genentech Collaboration Products. Under the terms of the Genentech Collaboration Agreement, Genentech paid us \$310 million in upfront and near-term milestone payments.

We and Genentech must use commercially reasonable efforts to jointly develop one or more Genentech Collaboration Products in accordance with an agreed global development plan, with the costs of such development to be shared equally. We will continue certain clinical studies that were initiated prior to the execution of the Genentech Collaboration Agreement at our sole expense, and any future material changes in the operation of such clinical studies require Genentech's approval. Genentech may access and use any data generated in these ongoing clinical studies.

In addition to the clinical studies included in the global development plan, we may propose certain additional clinical studies for indications not included in the global development plan, and if the joint development committee formed by the parties does not elect to include the proposed studies in the global development plan, then we may conduct the study at our sole expense under certain conditions, and subject to certain restrictions. Genentech has the option to select any candidate in such studies for potential further joint development and/or commercialization by Genentech as a Genentech Collaboration Product. In the case that Genentech wishes to pursue the clinical development of a Genentech Collaboration Product in an indication that we are not interested in pursuing, then under certain conditions, we may opt out of the co-funding of such development and Genentech may continue do so at its own costs, except that we are obligated to repay Genentech's development costs in the event that such product subsequently receives regulatory approval.

Genentech has the sole right to commercialize the Genentech Collaboration Products on a worldwide basis, with all profits and losses from such commercialization to be split equally with us. If we exercise our right to opt out of sharing equally in future development costs for any Genentech Collaboration Products, then we will no longer split all such profits and losses for such Genentech Collaboration Products equally with Genentech and will instead receive a royalty on annual worldwide net sales of such Genentech Collaboration Products that are covered by a valid claim included in certain of our patents and certain joint patents that arise out of the collaboration. Furthermore, for certain Genentech Collaboration Products for which we share co-promotion rights with Genentech, we have the option to assume a percentage to be determined of the total sales force in the United States and certain other countries, including Germany and other major European markets. In addition, under certain regulatory and other circumstances, we have the right to independently commercialize Genentech Collaboration Products in indications that the joint development committee declines to pursue and that Genentech does not subsequently elect to commercialize, provided that we market such Genentech Collaboration Products under a separate brand and trademark that is approved by the joint commercialization committee established by the parties as not confusingly similar to the Genentech Collaboration Products being commercialized by Genentech. Our ability to research, develop, co-promote and/or independently commercialize Genentech Collaboration Products may be terminated or limited in the event we undergo a change of control.

We granted to Genentech an exclusive license under certain of our intellectual property, and our interest in any jointly-owned intellectual property developed under this agreement, to research, develop, make, sell and import any

pharmaceutical products that comprise neoepitope RNA. Genentech granted to us an exclusive, non-transferable, sublicensable licenses under certain Genentech intellectual property, our intellectual property exclusively licensed to Genentech, and their interest in any jointly-owned intellectual property developed under this agreement for the performance of our ongoing clinical studies and the exercise of our rights and obligations under the Genentech Collaboration Agreement.

Until the first marketing approval for a Genentech Collaboration Product, we have granted Genentech the first right to negotiate an exclusive license to develop, manufacture and commercialize combination therapies involving pharmaceutical products based on neoepitope RNA and pharmaceutical products based on non-neoepitope RNA for the treatment of cancer in humans.

The Genentech Collaboration Agreement will remain in effect so as long as Genentech Collaboration Products are in development or commercialization, or until the date of the expiration of the last royalty term if BioNTech has exercised its option to opt-out of joint development of Genentech Collaboration Products. If the agreement expires, the licenses granted to Genentech become fully-paid up, royalty-free and irrevocable. Genentech may terminate the Collaboration Agreement if we fail to achieve certain milestone targets or at any time for convenience with or without reason upon 60 days' prior written notice. In the event of any such termination, all rights to the development and commercialization of Genentech Collaboration Products developed under the collaboration would revert to us and Genentech would grant us licenses under its intellectual property to further develop and commercialize Genentech Collaboration Products. We would be required to pay certain royalties to Genentech for such license(s). In addition, either party may terminate the agreement upon the other party's uncured material breach or insolvency.

#### *Manufacturing Development and Supply Agreement*

Concurrent with the Genentech Collaboration Agreement, we and BioNTech RNA entered into a Manufacturing Development and Supply Agreement with Genentech and F. Hoffman-La Roche Ltd, or the Genentech Manufacturing Agreement, which governs the manufacturing, related manufacturing development activities and supply of Genentech Collaboration Products. Pursuant to the Genentech Manufacturing Agreement, we are responsible for clinical manufacturing and supply, for developing and implementing manufacturing processes (including pursuant to specified target turnaround times), and for constructing, commissioning, qualifying and obtaining permits for the clinical facilities. We are permitted to subcontract certain steps in the clinical manufacturing process to our affiliate, BioNTech IMFS.

In addition, we are responsible for developing the commercial manufacturing process, which requires more stringent turnaround times than the clinical manufacturing process. Genentech will generally be responsible for conducting commercial manufacturing. We are obligated to use commercially reasonable efforts to achieve certain predetermined clinical manufacturing capacity commitments.

Under the Genentech Manufacturing Agreement, we and Genentech will jointly develop a manufacturing network plan detailing the location, capacity, scale-out, associated timing and other appropriate details of the commercial manufacturing facilities. We may participate in commercial manufacturing through our right to include as part of the commercial manufacturing network one of our own facilities in the European Union or the United States and one of our own facilities in another region to be agreed upon with Genentech (provided that in each region our facility is not the first facility to be included in the commercial manufacturing network).

#### *Sanofi-Intratumoral Therapy Collaboration*

On November 2, 2015, BioNTech RNA entered into a Collaboration and License Agreement with Sanofi, which we refer to as the Sanofi Agreement. Pursuant to the Sanofi Agreement, we and Sanofi will collaborate on intratumorally administered mRNA-based therapeutics for the treatment of solid tumors in humans.

The Sanofi Agreement contemplates: (i) research, (ii) development and commercialization and (iii) possible co-development and co-commercialization activities with us.

During the research phase, the parties seek to identify, characterize and validate up to five "mixtures" of two or more mRNAs encoding different proteins administered together in the same solution. Sanofi at its sole discretion may select up to five mixtures created under the research plan for further development and commercialization, which we refer to as Sanofi Collaboration Products.

After selection of a Sanofi Collaboration Product, Sanofi would be responsible for all development and commercialization activities involving that product. We have the option, by payment of an exercise fee, to co-develop and

co-commercialize up to two Sanofi Collaboration Products primarily in the United States and in some European countries, including the United Kingdom, France, Germany, Italy and Spain. If we exercise such an option, the costs for co-development and co-commercialization of the chosen Sanofi Collaboration Products would be allocated between the parties. In turn, Sanofi has an option to co-develop and co-commercialize certain mixtures developed by us or with third parties that contain a certain amount of the mRNAs of a Sanofi Collaboration Product.

In March 2018, Sanofi selected the first Sanofi Collaboration Product for further development and commercialization and we exercised our option for co-development and co-commercialization of the Sanofi Collaboration Product. Effective as of March 2018, the parties entered into a separate development agreement for the co-development of this Sanofi Collaboration Product.

Under the Sanofi Agreement, Sanofi has paid upfront and near-term milestone payments of approximately €60 million. We are entitled to receive up to approximately €260 million per product upon achievement of certain development, regulatory and commercial milestones. If commercialized successfully, we would also be eligible for mid-single digit to very low double-digit tiered royalties on net sales on a country-by-country and product-by-product basis until the later of (i) expiration of the last relevant patent covering such product in such country, (ii) 10 years following first commercial sale of such product in such country, (iii) expiration of regulatory data exclusivity for such product in such country and (iv) the market entry of a generic biological product with a certain market share in relation to such product in such country.

The Sanofi Agreement will remain effective until the last-to-expire royalty term (or, when a co-development option has been exercised, the completion of all co-development and co-commercialization activities). The parties may terminate the Sanofi Agreement in its entirety or terminate certain co-development activities for convenience, with or without cause.

The Sanofi Agreement provides that we may not engage in certain research and development activities relating to the intratumoral injection of mRNAs.

***Genmab-Next-generation Immunomodulator Collaboration***

On May 19, 2015, we entered into a License and Collaboration Agreement with Genmab (together with all amendments and side letters thereto, collectively referred to as the Genmab Agreement) to jointly research, develop and commercialize polypeptide-based bispecific antibodies against certain target combinations for the treatment of cancer in humans worldwide, or the Genmab Agreement Field, using certain Genmab technology. In connection with our entry into the Genmab Agreement, Genmab paid us an upfront fee of \$10 million.

Under the Genmab Agreement, we and Genmab must use commercially reasonable efforts to research and develop clinical candidates, including our next-generation checkpoint immunomodulators, with costs split equally during the research and evaluation phase. Our joint activities in this phase are governed by a research plan, which is subject to annual review and updates, and which specifies the clinical candidates to be developed. This research and evaluation phase is currently set to expire on May 19, 2022, but has in the past been extended.

During the research and evaluation phase, we and Genmab may propose clinical candidates for consideration by a joint research committee for further preclinical and clinical development. If a party, through the joint research committee, indicates that it is not interested in further development and commercialization of any clinical candidate, the other party may continue development and commercialization of such products on a unilateral basis, at its sole expense. The party that continues such development and commercialization is obligated to pay the other party certain development, regulatory and sales milestone payments and royalties on net sales of the applicable Unilateral Products. During either party's development and commercialization of a Unilateral Product, the other party must not develop or commercialize any bispecific antibody targeting the same target combination of such Genmab Unilateral Product if such bispecific antibody was generated as part of the collaboration under this agreement.

We and Genmab must use commercially reasonable efforts to develop candidates selected by the joint research committee, or the Genmab Collaboration Products, through preclinical and clinical development. In addition, the joint research committee may select an additional candidate, or the Genmab Back-up Candidate, as a back-up for each Genmab Collaboration Product and may decide at any time to replace the Genmab Collaboration Product with its Genmab Back-up Candidate. The preclinical and clinical development of the Genmab Collaboration Products would be performed pursuant to a development plan to be agreed upon by us and Genmab, with costs to be split equally. The joint steering committee may designate a third party as a manufacturer of a Genmab Collaboration Product or of any of its components.

We and Genmab must use commercially reasonable efforts to jointly commercialize all Genmab Collaboration Products and share equally all expenses and profits arising from such commercialization. We and Genmab, on a product-by-product basis and at least 12 months prior to the anticipated start of a pivotal clinical trial for a Genmab Collaboration Product, will jointly designate between the two of us a lead party responsible for establishing the distribution and marketing operations in each geographical region. Each party would be entitled to equally co-promote the products pursuant to a separately negotiated global commercialization agreement that the parties agree to negotiate.

Unless otherwise agreed by the joint steering committee established under the agreement, Genmab is responsible for all regulatory actions and shall own all regulatory approvals obtained for the Genmab Collaboration Products. Genmab is obligated to provide regular updates to us on regulatory activities.

Each party grants to the other party a worldwide, co-exclusive, sublicensable, royalty-free license under certain of such first party's intellectual property, including certain patents and know-how, to perform the research under this agreement and to research, develop, make, import, use and sell Genmab Collaboration Products in the Genmab Agreement Field pursuant to the terms of the Genmab Agreement. These licenses shall continue on a country-by-country and product-by-product basis for as long as development or commercialization activities are contemplated under the Genmab Agreement.

During the research and evaluation phase prior to the selection of a Genmab Collaboration Product, neither we nor Genmab may engage in any research and development activity in the Genmab Agreement Field relating to the development of any bispecific antibody which targets any combination that is the subject of our joint research plan. During the preclinical and clinical development phase for any Genmab Collaboration Product, engagement in research and development activities in the Genmab Agreement Field unilaterally by a party relating to a Genmab Collaboration Product or its Genmab Back-up Candidate or any bispecific antibody which targets the same target combination for which such Genmab Collaboration Product or Genmab Back-up Candidate has been developed would require the other party's prior written consent.

Each party has the right to discontinue its participation in the further development and commercialization of a Genmab Collaboration Product at two points: (i) when an IND submission package has been agreed upon by the parties and (ii) when the draft clinical trial report from the first Phase 1/2 clinical trial becomes available. The party that wishes to opt out of such further development and commercialization may choose to permit the other party to continue the development and commercialization of the Genmab Collaboration Product or divest its interest in such Genmab Collaboration Product. If the opt-out party permits continued development and commercialization, the other party may elect to pursue development and commercialization of such Genmab Collaboration Product alone as a Unilateral Product, at its sole cost and subject to pre-defined milestone and royalty payments and certain additional pre-defined terms. If the other party wishes to not pursue such continued development and commercialization on such pre-defined payment and additional terms, then the parties will jointly divest their interest in such Genmab Collaboration Product to a third party, and if such divestiture fails, the parties will cease all development and commercialization of such Genmab Collaboration Product. Alternatively, if the opt-out party seeks to unilaterally divest its interest in the applicable Genmab Collaboration Product, the other party has the right of first exclusive negotiation to obtain exclusive, worldwide rights to develop and commercialize such Genmab Collaboration Product. If such unilateral divestiture fails after the other party's exercise of its right of first exclusive negotiation, the opt-out party may either continue development and commercialization of such Genmab Collaboration Product or offer the other party to continue such development and commercialization on such pre-defined payment and additional terms as set forth above.

The Genmab Agreement will remain in effect until the later of (i) the expiration of the last-to-expire royalty term for any Unilateral Product and (ii) the time when no Genmab Collaboration Products are being developed or commercialized under this agreement. Either party may terminate the agreement in its entirety or on a product-by-product basis with immediate effect upon the other party's uncured material breach or insolvency.

#### ***Pfizer-Influenza Collaboration***

On July 20, 2018, we and BioNTech RNA entered into a Research Collaboration and License Agreement with Pfizer, or the Pfizer Influenza Agreement, for the research, development and Pfizer's commercialization of immunogenic compositions comprising modified RNA and/or replicon technology for prophylaxis against influenza in humans, which we refer to as the Pfizer Influenza Agreement Field.

We and Pfizer agreed to collaborate on the research in the Pfizer Influenza Agreement Field for an initial period of three years. The details of such research were set forth in a research plan that is governed by a joint steering committee, with Pfizer holding the final decision-making right. Each party will bear its own costs under the research plan. The research term will be extended automatically by a reasonable amount of time if the activities or deliverables under the research plan are delayed due to our material breach of our research obligations under the research plan. In addition, Pfizer may unilaterally extend the research term by up to a year by making an additional payment to us.

After the research term expires, Pfizer has the sole responsibility, authority and control of the development, manufacturing and commercialization of all candidates and products. Pfizer undertakes to use commercially reasonable efforts to seek regulatory approval for one product in the United States and in two countries out of France, Germany, Italy, Spain, the United Kingdom and Japan, and to commercialize such product in such countries where such product has received regulatory approval.

Under the Pfizer Influenza Agreement, we grant to Pfizer an exclusive, worldwide, sublicensable license under certain of our intellectual property, including our patents and know-how, relating to replicons and modified RNA in the Pfizer Influenza Agreement Field as well as certain intellectual property in-licensed by us from third parties, to use, research, develop, manufacture, commercialize and otherwise exploit candidates and products selected under the Pfizer Influenza Agreement. We also grant to Pfizer a non-exclusive, royalty-free, sublicensable license under all intellectual property controlled by us or our affiliates to use, develop, manufacture, commercialize and otherwise exploit candidates and products selected under the Pfizer Influenza Agreement in the Pfizer Influenza Agreement Field. We undertake to maintain in full effect all intellectual property licenses held by us at the time we entered into the agreement and to not modify or amend any such license in a manner that would adversely affect any of the rights granted to Pfizer under the Pfizer Influenza Agreement. We are obligated to notify Pfizer of any breach of our current licenses and may be obligated to take steps to maintain Pfizer's access to any intellectual property licensed under such licenses.

We also granted Pfizer a right of first negotiation to acquire an exclusive worldwide license under certain intellectual property controlled by us for Pfizer to develop, manufacture and commercialize immunogenic products comprising RNA for prophylaxis against respiratory syncytial virus or human cytomegalovirus. The right of first negotiation may be exercised until the end of the research term.

In consideration of the rights granted to Pfizer under the agreement, Pfizer subscribed to shares in BioNTech AG under a separate investment agreement. In addition, under the Pfizer Influenza Agreement, Pfizer made an upfront payment of \$50 million and agreed to potential payments of up to \$325 million upon the achievement of specified development, regulatory and commercial milestones. Pfizer further agreed to a mid-single digit to very low double-digit tiered royalty on net sales if a product is commercialized. Royalties are subject to stacking provisions. The obligation of Pfizer to pay royalties ends, on a country-by-country and a product-by-product, basis upon the later of (i) the expiration of the last valid licensed patent right covering such product category in such country, (ii) 10 years after the first commercial sale of a product of such product category in such country and (iii) the lapse of regulatory data exclusivity for the first product in such product category in such country. There are only two product categories: one for modified RNA and a second for replicon products.

During the term of the Pfizer Influenza Agreement, we have committed not to research, develop, manufacture, commercialize or otherwise exploit immunogenic compositions comprising RNA in the Pfizer Influenza Agreement Field other than pursuant to the Pfizer Influenza Agreement.

The Pfizer Influenza Agreement ends on a country-by-country basis upon expiration of the last royalty term for any product in that country. Thereafter, the licenses granted to Pfizer with respect to such product in such country will convert into a perpetual, exclusive, fully paid-up and royalty-free license. In addition to termination rights granted to each party in the case of the other party's uncured material breach, Pfizer may terminate the agreement, in whole or in part, for convenience and with or without reason at any time upon 60 days' prior written notice. In addition, Pfizer is entitled to terminate the agreement and initiate a technology transfer of certain intellectual property if one of its key competitors acquires control over us.

#### ***Genevant-Rare Disease Protein Replacement Therapy Strategic Collaboration***

In July 2018, our wholly owned subsidiary BioNTech RNA Pharmaceuticals GmbH, or BioNTech RNA, entered into a license and co-development agreement with Genevant Sciences GmbH, or Genevant for the joint development of certain

pharmaceutical products and the licensing of specified rights to Genevant's lipid nanoparticle delivery technology to BioNTech RNA. We refer to this agreement as the Genevant Agreement.

Under the Genevant Agreement, BioNTech RNA and Genevant have agreed to collaborate to develop pharmaceutical products that contain any of five mRNA payloads created by BioNTech RNA encapsulated within a Genevant (or, if the parties agree, a third party) LNP, or the Co-Development Products, for the treatment, prevention and diagnosis of liver diseases, excluding any oncology diseases, or the Co-Development Field. Each party granted to the other party a worldwide, co-exclusive license or sublicense, with limited sublicensing rights, under certain of its patents and know-how to research, develop, make, have made, use, distribute, sell, offer for sale, have sold, import, export and otherwise commercialize the Co-Development Products in the Co-Development Field as provided in development and commercialization plans approved by a joint steering committee and subject to certain restrictions under the Genevant Agreement.

In addition, BioNTech RNA obtained an exclusive, worldwide, royalty-bearing license or sublicense under Genevant's LNP delivery technology to research, develop, make, have made, use, distribute, sell, offer for sale, have sold, import, export and otherwise commercialize pharmaceutical products containing BioNTech mRNA payloads encapsulated within an LNP, or the BioNTech Products, for the treatment, prevention and diagnosis of illnesses in the field of oncology, or the BioNTech Field.

Each party retained certain rights to practice its intellectual property for all purposes outside of the Co-Development Field or in the Co-Development Field with any product that is not a Co-Development Product, subject to the next sentence as to BioNTech. During the term of the Genevant Agreement for each Co-Development Product or BioNTech Product, BioNTech RNA has agreed not to conduct or enable any clinical development, promotion or commercialization of any product involving the use of LNP with the BioNTech mRNA payload contained in the Co-Development Product or BioNTech Product other than in collaboration with Genevant pursuant to the Genevant Agreement. Genevant has also retained rights to practice its intellectual property for all purposes outside the BioNTech Field, or in the BioNTech Field with any product that is not a BioNTech Product.

The parties are jointly responsible for the development of, and must use commercially reasonable efforts to develop, the Co-Development Products in accordance with a development plan approved by a joint steering committee. Genevant is responsible for the preclinical, clinical and commercial manufacture of the Co-Development Products, and BioNTech RNA is obligated to supply the mRNA payloads for use in manufactured Co-Development Products. The parties share equally all costs for the development of Co-Development Products as well as any profits and losses. For each Co-Development Product, one or the other party will take the lead responsibility for commercialization of the Co-Development Product in the Co-Development Field. Each party must use commercially reasonable efforts to perform the commercialization activities allocated to it in a commercialization plan approved by a joint steering committee.

Each party may opt-out of the co-development of any Co-Development Product with 90 days' prior notice at any time after the filing of an IND or equivalent for the Co-Development Product. In such event, the other party may continue the development of the Co-Development Product on its own, at its sole cost and expense apart from specified obligations to support manufacturing and any ongoing clinical studies, but has to pay to the party that opted out pre-defined regulatory and sales milestones for the Co-Development Product of up to a low nine figure U.S. dollar amount in the aggregate and tiered low to mid-single digit percentage royalties on aggregate net sales of the Co-Development Product. In the event that a party opts out of the co-development of any Co-Development Product, the license granted by the party opting out to the other party shall become exclusive licenses, even as to the opting out party.

BioNTech RNA is solely responsible for the development and commercialization of the BioNTech Products, including the performance of preclinical and clinical trials, all regulatory activities, and marketing and sales, and bears all related costs. BioNTech RNA must use commercially reasonable efforts to develop and obtain regulatory approval for BioNTech Products in the BioNTech Field in the United States, Germany, United Kingdom, France, Spain and Italy. Genevant is responsible for the manufacturing of the BioNTech Products, and the details of such manufacturing are to be agreed in a separate manufacturing and supply agreement. BioNTech RNA is obligated to pay regulatory and sales milestone payments on each BioNTech Product, and royalties based on aggregate net sales of all BioNTech Products, to Genevant.

The Genevant Agreement continues until later of (i) the expiration of the last-to-expire royalty term for any BioNTech Product worldwide and (ii) the date on which all Co-Development Products cease being developed or commercialized. BioNTech RNA may terminate the agreement for convenience with respect to one or more BioNTech



Products at any time with 90 or 180 days' prior notice, depending on whether regulatory approval has been granted. The Genevant Agreement grants each party termination rights: if the other party challenges the validity, enforceability or scope of any patents licensed to it under the Genevant Agreement; for uncured material breaches of the other party; for the other party's insolvency; or if the other party undergoes a change of control through which it is controlled by a competitor, if specified by the parties at the time of the Genevant Agreement, before the earlier of July 4, 2021 or when the other party undergoes an initial public offering.

Under certain scenarios, if BioNTech RNA terminates the Genevant Agreement with respect to a particular BioNTech Product, before granting a license to a third party for the BioNTech mRNA payload included in the BioNTech Product, Genevant has the right of negotiation with BioNTech. Under certain scenarios, if Genevant terminates the Genevant Agreement, Genevant keeps all licenses and have certain rights, but not the obligation, to continue the development and commercialization of Co-Development Products, and BioNTech RNA has certain obligations to provide assistance, documentation, and certain know-how and inventions to enable Genevant's continued development and commercialization of Co-Development Products.

### **XIII. Government Regulation**

Government authorities in the United States, at the federal, state and local levels, and in the European Union and other countries and jurisdictions, extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, packaging, storage, record-keeping, labeling, advertising, promotion, distribution, marketing, post-approval monitoring and reporting and import and export of pharmaceutical products, including biological products. In addition, some jurisdictions regulate the pricing of pharmaceutical products. The processes for obtaining marketing approvals in the United States and in foreign countries and jurisdictions, along with subsequent compliance with applicable statutes and regulations and other requirements of regulatory authorities, require the expenditure of substantial time and financial resources.

#### ***Regulation and Procedures Governing Approval of Drug and Biological Products in the United States***

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or the FDCA, and its implementing regulations and biologics under the FDCA, the Public Health Service Act, or the PHSA, and their implementing regulations. Both drugs and biologics are subject to other federal, state and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with applicable federal, state and local statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or following approval may subject a sponsor to administrative or judicial sanctions. These sanctions could include, among other actions, the FDA's refusal to approve pending applications, withdrawal of an approval, license revocation, clinical hold, untitled or warning letters, voluntary or mandatory product recalls, market withdrawals, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement and civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

A sponsor seeking approval to market and distribute a new drug or biological product in the United States generally must satisfactorily complete each of the following steps:

- preclinical laboratory tests, animal studies and formulation studies all performed in accordance with applicable regulations, including the FDA's good laboratory practices, or GLP, regulations;
- submission to the FDA of an IND application for human clinical testing, which must become effective before human clinical trials may begin;
- approval by the IRB representing each clinical site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials to establish the safety, potency and purity of the product candidate for each proposed indication, in accordance applicable regulations, including with GCP, regulations;
- preparation and submission to the FDA of a NDA for a drug product, or a BLA for a biological product requesting marketing approval for one or more proposed indications, including submission of detailed information on the manufacture and composition of the product in clinical development, evidence of safety, purity and potency from preclinical testing and clinical trials, and proposed labeling;
- review of the product by an FDA advisory committee, if applicable;

- satisfactory completion of one or more FDA inspections of the manufacturing facility or facilities, including those of third parties, at which the product, or components thereof, are produced to assess compliance with current GMP requirements and to assure that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality and purity;
- satisfactory completion of any FDA audits of the clinical study sites to assure compliance with GCPs, and the integrity of clinical data in support of the NDA or BLA;
- payment of user fees and securing FDA approval of the NDA or BLA; and
- compliance with any post-approval requirements, including the potential requirement to implement a REMS and to conduct any post-approval studies required by the FDA.

The preclinical and clinical testing and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for our investigational medicines and any future investigational medicines will be granted on a timely basis, or at all.

#### *Preclinical Studies and Investigational New Drug Application*

Before testing any drug or biological product candidate in humans, the product candidate must undergo preclinical testing. Preclinical tests include laboratory evaluations of product chemistry, formulation and stability, as well as animal studies to evaluate the potential for activity and toxicity. The conduct of the preclinical tests and formulation of the compounds for testing must comply with federal regulations and requirements. The results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, are submitted to the FDA as part of an IND application. The IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions about the product or conduct of the proposed clinical trial, including concerns that patients will be exposed to unreasonable health risks, and places the trial on a clinical hold. In that case, the IND sponsor and the FDA must resolve any outstanding FDA concerns before the clinical trial can begin.

As a result, submission of the IND may result in the FDA not allowing the trial to commence or not be conducted on the terms originally specified by the sponsor in the IND. If the FDA raises concerns or questions either during this initial 30-day period, or at any time during the IND process, it may choose to impose a partial or complete clinical hold. If the FDA imposes a clinical hold, trials may not recommence without FDA authorization and then only under terms authorized by the FDA. A clinical hold issued by the FDA may therefore delay either a proposed clinical study or cause suspension of an ongoing study, until all outstanding concerns have been adequately addressed and the FDA has notified the company that investigation may proceed. This could cause significant difficulties in completing planned clinical trials in a timely manner.

The FDA may impose clinical holds on a biological product candidate at any time before or during clinical trials due to safety concerns or non-compliance.

#### *Human Clinical Trials in Support of an NDA or a BLA*

Clinical trials involve the administration of the investigational product candidate to healthy volunteers or patients with the disease to be treated under the supervision of qualified principal investigators, generally physicians not employed by or under the trial sponsor's control, in accordance with GCP requirements, which include the requirement that all patients provide their informed consent for their participation. Clinical trials are conducted under study protocols detailing, among other things, the objectives of the study, inclusion and exclusion criteria, the parameters to be used in monitoring safety, dosing procedures and the effectiveness criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND.

A sponsor who wishes to conduct a clinical trial outside the United States may, but need not, obtain FDA authorization to conduct the clinical trial under an IND. If a foreign clinical trial is not conducted under an IND, the sponsor may submit data from the clinical trial to the FDA in support of the NDA or BLA so long as the clinical trial is well-designed and well-conducted in accordance with GCP, including review and approval by an independent ethics committee, and the FDA is able to validate the study data through an onsite inspection, if necessary.

Further, each clinical trial must be reviewed and approved by an IRB either centrally or individually at each institution at which the clinical trial will be conducted. The IRB will consider, among other things, clinical trial design, patient informed consent, ethical factors and the safety of patients. An IRB must operate in compliance with FDA

regulations. The FDA, IRB, or the clinical trial sponsor may suspend or discontinue a clinical trial at any time for various reasons, including a finding that the clinical trial is not being conducted in accordance with FDA requirements or that the patients are being exposed to an unacceptable health risk. Clinical testing also must satisfy extensive GCP rules and the requirements for informed consent. The IRB also approves the form and content of the informed consent that must be signed by each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee, or DSMB. This group may recommend continuation of the study as planned, changes in study conduct, or cessation of the study at designated check points based on access to certain data from the study.

Clinical trials typically are conducted in three sequential phases, but the phases may overlap or be combined. Additional studies may be required after approval.

- Phase 1 clinical trials (or Phase 1) are initially conducted in a limited population to test the product candidate for safety, including adverse effects, dose tolerance, absorption, metabolism, distribution, excretion and pharmacodynamics in healthy humans or, on occasion, in patients, such as in the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers.
- Phase 2 clinical trials (or Phase 2) are generally conducted in a limited patient population to identify possible adverse effects and safety risks, preliminarily evaluate the efficacy of the product candidate for specific targeted indications and determine dose tolerance and optimal dosage. Multiple Phase 2 clinical trials may be conducted by the sponsor to obtain information prior to beginning larger Phase 3 clinical trials. When a drug is intended to treat life-threatening or severely debilitating illnesses, the FDA may accept well-controlled Phase 2 clinical trials as adequate to provide sufficient data on the drug's safety and effectiveness to support a decision on its approvability for marketing, in which case Phase 3 clinical trials would not be required.
- Phase 3 clinical trials (or Phase 3) proceed if the Phase 2 clinical trials demonstrate that a certain dose or dose range of the product candidate is potentially effective and has an acceptable safety profile. Phase 3 clinical trials are undertaken within an expanded patient population, often at geographically dispersed clinical trial sites, to gather additional information about safety and effectiveness necessary to evaluate the overall benefit-risk relationship of the product and to provide an adequate basis for product labeling.

In some cases, the FDA may approve an NDA or a BLA for a product candidate but require the sponsor to conduct additional clinical trials to further assess the product candidate's safety and effectiveness after approval. Such post-approval trials are typically referred to as Phase 4 clinical trials (or Phase 4). These studies may be used to gain additional experience from the treatment of patients in the intended therapeutic indication and to document a clinical benefit in the case of biologics approved under accelerated approval regulations. If the FDA approves a product while a company has ongoing clinical trials that were not necessary for approval, a company may be able to use the data from these clinical trials to meet all or part of any Phase 4 clinical trial requirement or to request a change in the product labeling. Failure to exhibit due diligence with regard to conducting required Phase 4 clinical trials could result in withdrawal of approval for products.

During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data and clinical trial investigators. Annual progress reports detailing the results of the clinical trials must be submitted to the FDA. Written IND safety reports must be promptly submitted to the FDA and the investigators for serious and unexpected adverse events, any findings from other trials, tests in laboratory animals or *in vitro* testing that suggest a significant risk for patients, or any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must submit an IND safety report within 15 calendar days after the sponsor determines that the information qualifies for reporting. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within seven calendar days after the sponsor's initial receipt of the information. The FDA or the sponsor or its DSMB may suspend a clinical trial at any time on various grounds, including a finding that the patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the new drug candidate or biological product candidate has been associated with unexpected serious harm to patients.

There are also requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries. Sponsors of clinical trials of FDA-regulated products, including biologics, are required to register and disclose certain clinical trial information, which is publicly available at [www.clinicaltrials.gov](http://www.clinicaltrials.gov). Information related to the

product, patient population, phase of investigation, trial sites and investigators, and other aspects of the clinical trial is then made public as part of the registration. Sponsors are also obligated to discuss the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed until the new product or new indication being studied has been approved.

#### *Compliance with GMP Requirements*

Before approving an NDA or a BLA, the FDA typically will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in full compliance with GMP requirements and adequate to assure consistent production of the product within required specifications. Among other things, the sponsor must develop methods for testing the identity, strength, quality, potency and purity of the final drug or biological product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the drug or biological product does not undergo unacceptable deterioration over its shelf life. In particular, the PHSa emphasizes the importance of manufacturing control for products like biologics whose attributes cannot be precisely defined.

Manufacturers and others involved in the manufacture and distribution of drugs and biological products must also register their establishments with the FDA and certain state agencies. Both domestic and foreign manufacturing establishments must register and provide additional information to the FDA upon their initial participation in the manufacturing process.

The manufacturing facilities may be subject to periodic unannounced inspections by government authorities to ensure compliance with GMPs and other laws. Manufacturers may have to provide, on request, electronic or physical records regarding their establishments. Delaying, denying, limiting or refusing inspection by the FDA may lead to a product being deemed to be adulterated.

#### *Review and Approval of an NDA or a BLA*

The results of product candidate development, preclinical testing and clinical trials, including negative or ambiguous results as well as positive findings, are submitted to the FDA as part of an NDA or a BLA requesting a license to market the product. These applications must contain extensive manufacturing information and detailed information on the composition of the product and proposed labeling. The FDA adjusts the Prescription Drug User Fee Act, or PDUFA, user fees on an annual basis. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on NDAs or BLAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

The FDA has 60 days after submission of the application to conduct an initial review to determine whether the NDA or BLA is sufficient to accept for filing based on the agency's threshold determination that it is substantially complete so as to permit substantive review. Once the submission has been accepted for filing, the FDA begins an in-depth review of the application. Under the goals and policies agreed to by the FDA under PDUFA, the FDA aims to complete its initial review of a standard application and respond to the sponsor within ten months of the 60-day filing date, and for a priority review application within six months. The FDA does not always meet its PDUFA goal dates for standard and priority NDA or BLA applications, and its review goals are subject to change from time to time. The review process may often be significantly extended by FDA requests for additional information or clarification. The review process and the PDUFA goal date may also be extended by three months if the FDA requests or if the sponsor otherwise provides additional information or clarification regarding information already provided in the submission within the last three months before the PDUFA goal date.

The FDA reviews NDA and BLA applications to determine, among other things, whether the proposed product is safe and potent, and/or effective, for its intended use, and has an acceptable purity profile, and whether the product is being manufactured in accordance with GMP requirements to assure and preserve the product's identity, safety, strength, quality, potency and purity. On the basis of the FDA's evaluation of the application and accompanying information, including the results of the inspection of the manufacturing facilities and any FDA audits of clinical trial sites to assure compliance with GCPs, the FDA may issue an approval letter, denial letter or complete response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. Under the FDCA, the FDA may approve an NDA if it determines that the product is safe and effective for its intended use, the benefits of the drug outweigh any risks, and the methods used in manufacturing the drug and the controls used to maintain the drug's quality are adequate to preserve the drug's identity, strength, quality and purity. Under the PHSa, the FDA may approve a BLA if it determines that the product is safe, pure and potent and the facility where the product will be manufactured meets

standards designed to ensure that it continues to be safe, pure and potent. If the application is not approved, the FDA may issue a complete response letter, which will contain the conditions that must be met in order to secure final approval of the application, and when possible will outline recommended actions the sponsor might take to obtain approval of the application. If a complete response letter is issued, the sponsor may either resubmit the NDA or BLA, addressing all of the deficiencies identified in the letter, or withdraw the application.

Sponsors that receive a complete response letter who elect to address the deficiencies may submit to the FDA information that represents a complete response to the issues identified by the FDA in the response letter. Such resubmissions are classified under PDUFA as either Class 1 or Class 2, based on the information submitted by a sponsor in response to an action letter. Under the goals and policies agreed to by the FDA under PDUFA, the FDA aims to review and act on a Class 1 resubmission with two months of receipt and, with respect to a Class 2 resubmission, within six months of receipt. The FDA will not approve an application until issues identified in the complete response letter have been addressed.

The FDA may also refer the application to an Advisory Committee for review, evaluation and recommendation as to whether the application should be approved and under what conditions. In particular, the FDA may refer applications for novel drug or biological products or drug or biological products that present difficult questions of safety or efficacy to an advisory committee. Typically, an Advisory Committee is a panel of independent experts, including clinicians and other scientific experts. The FDA is not bound by the recommendations of an Advisory Committee, but it considers such recommendations carefully when making decisions.

If the FDA approves a new product, it may limit the approved indications for use of the product, or limit the approval to specific dosages. It may also require that certain contraindications, warnings or precautions be included in the product labeling. In addition, the FDA may call for post-approval studies, including Phase 4 clinical trials, to further assess the product's safety after approval. The agency may also require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms, including risk evaluation and mitigation strategies, or REMS, to help ensure that the benefits of the product outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use, or ETASU. ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring and the use of patent registries. If the FDA concludes a REMS is needed, the sponsor of the NDA or BLA must submit a proposed REMS; the FDA will not approve the NDA or BLA without a REMS, if required. The FDA may prevent or limit further marketing of a product based on the results of post-marketing studies or surveillance programs. After approval, many types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval.

#### *Fast Track, Breakthrough Therapy and Priority Review Designations*

The FDA may designate certain products for expedited review if they are intended to address an unmet medical need in the treatment of a serious or life-threatening disease or condition. These programs include fast track designation, breakthrough therapy designation and priority review designation.

The FDA may designate a product for fast track review if it is intended, whether alone or in combination with one or more other products, for the treatment of a serious or life-threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such disease or condition. Fast track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a new drug or biologic may request that the FDA designate the drug or biologic as a fast track product at any time during the clinical development of the product. For fast track products, sponsors may have greater interactions with the FDA and the FDA may initiate review of sections of a fast track product's application before the application is complete. This rolling review may be available if the FDA determines, after preliminary evaluation of clinical data submitted by the sponsor, that a fast track product may be effective. The sponsor must also provide, and the FDA must approve, a schedule for the submission of the remaining information and the sponsor must pay applicable user fees. However, the FDA's time period goal for reviewing a fast track application does not begin until the last section of the application is submitted. Fast track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

In 2012, Congress enacted the Food and Drug Administration Safety and Innovation Act, or the FDASIA. This law established a new regulatory scheme allowing for expedited review of products designated as "breakthrough therapies." A product may be designated as a breakthrough therapy if it is intended, either alone or in combination with one or more other

products, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The FDA may take certain actions with respect to breakthrough therapies, including holding meetings with the sponsor throughout the development process; providing timely advice to the product sponsor regarding development and approval; involving more senior staff in the review process; assigning a cross-disciplinary project lead for the review team; and taking other steps to facilitate the design of clinical trials in an efficient manner.

The FDA may designate a product for priority review if it is a product that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. The FDA determines, on a case-by-case basis, whether the proposed product represents a significant improvement when compared with other available therapies. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting product reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes and evidence of safety and effectiveness in a new subpopulation. A priority designation is intended to direct overall attention and resources to the evaluation of such applications, and to shorten the FDA's goal for taking action on a marketing application to six months (compared to 10 months under standard review).

Fast track designation, priority review and breakthrough therapy designation may expedite the development or approval process, but do not change the standards for approval.

#### *Accelerated Approval Pathway*

The FDA may grant accelerated approval to a product for a serious or life-threatening condition that provides meaningful therapeutic advantage to patients over existing treatments based upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. The FDA may also grant accelerated approval for such a condition when the product has an effect on an intermediate clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality, or IMM, and that is reasonably likely to predict an effect on IMM or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. Products granted accelerated approval must meet the same statutory standards for safety and effectiveness as those granted traditional approval.

For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. An intermediate clinical endpoint is a measurement of a therapeutic effect that is considered reasonably likely to predict the clinical benefit of a product, such as an effect on IMM. The FDA has stated that although it has limited experience with accelerated approvals based on intermediate clinical endpoints, such endpoints generally may support accelerated approval where the therapeutic effect measured by the endpoint is not itself a clinical benefit and basis for traditional approval, if there is a basis for concluding that the therapeutic effect is reasonably likely to predict the ultimate clinical benefit of a product.

The accelerated approval pathway is most often used in settings in which the course of a disease is long and an extended period of time is required to measure the intended clinical benefit of a product. Thus, accelerated approval has been used extensively in the development and approval of products for treatment of a variety of cancers in which the goal of therapy is generally to improve survival or decrease morbidity and the duration of the typical disease course requires lengthy and sometimes large trials to demonstrate a clinical or survival benefit.

The accelerated approval pathway is usually contingent on a sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the product's clinical benefit. As a result, a product candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or to confirm a clinical benefit during post-marketing studies, may lead the FDA to withdraw the product from the market. All promotional materials for product candidates approved under accelerated regulations are subject to prior review by the FDA.

Accelerated approval pathways are available for regenerative medicine therapies that meet certain conditions. Regenerative medicine therapies include cell therapies (both allogenic and autologous), therapeutic tissue engineering products, human cell and tissue products, and combination products using any such therapies or products, except those

regulated under section 361 of the PHSA. Human gene therapies, including genetically modified cells, that lead to a sustained effect on cells or tissues, may also meet the definition of a regenerative medicine therapy, as may xenogeneic cell products.

Regenerative medicine therapies designed to treat, modify, reverse or cure serious conditions are eligible for FDA's expedited programs, including fast track designation, breakthrough therapy designation, priority review and accelerated approval, if they meet the criteria for such programs. They may also be eligible for Regenerative Medicine Advanced Therapy Designation, or RMAT designation.

An investigational drug is eligible for RMAT designation if it meets the definition of regenerative medicine therapy, it is intended to treat, modify, reverse or cure a serious condition, and preliminary clinical evidence indicates that the regenerative medicine therapy has the potential to address unmet medical needs for such condition. An unmet medical need is a condition whose treatment or diagnosis is not addressed adequately by available therapy.

RMAT designation confers all the benefits of the fast track and breakthrough therapy designation programs, including early interactions with the FDA. The FDA reviews each application on a case-by-case basis to determine whether the clinical evidence is sufficient to support RMAT designation, considering factors such as the rigor of data collection, the consistency and persuasiveness of the outcomes, the number of patients, and the severity, rarity or prevalence of the condition, among other factors. The FDA may decline to grant RMAT designation if it finds the clinical evidence insufficient.

RMAT designation may expedite the development or approval process, but it does not change the standards for approval.

#### *Emergency Use Authorizations*

The Secretary of Health and Human Services has the authority to authorize unapproved medical products, including vaccines, to be marketed in the context of an actual or potential emergency that has been designated by government officials. The COVID-19 pandemic has been designated such a national emergency. After an emergency has been announced, the Secretary of Health and Human Services may authorize the issuance of, and the FDA Commissioner may issue, Emergency Use Authorizations, or EUAs, for the use of specific products based on criteria established by statute, including that the product at issue may be effective in diagnosing, treating, or preventing serious or life-threatening diseases when there are no adequate, approved, and available alternatives. An EUA is subject to additional conditions and restrictions and is product-specific. An EUA terminates when the emergency determination underlying the EUA terminates. An EUA is not a long-term alternative to obtaining FDA approval, licensure, or clearance for a product. FDA may revoke an EUA where it is determined that the underlying health emergency no longer exists or warrants such authorization, so it is not possible to predict how long an EUA may remain in place.

#### *Post-Approval Regulation*

If regulatory approval for marketing of a product or for a new indication for an existing product is obtained, the sponsor will be required to comply with rigorous and extensive post-approval regulatory requirements as well as any post-approval requirements that the FDA has imposed on the particular product as part of the approval process. The sponsor will be required, among other things, to report certain adverse reactions and production problems to the FDA, provide updated safety and efficacy information and comply with requirements concerning advertising and promotional labeling. Manufacturers and certain of their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with ongoing regulatory requirements, including GMP regulations, which impose certain procedural and documentation requirements upon manufacturers. Accordingly, the BLA holder and its third-party manufacturers must continue to expend time, money and effort in the areas of production and quality control to maintain compliance with GMP regulations and other regulatory requirements. In addition, changes to the manufacturing process or facility generally require prior FDA approval before being implemented, and other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market study requirements or clinical trial requirements to assess new safety risks; or

imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, untitled letters or warning letters or holds on post-approval clinical trials;
- adverse publicity;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions, fines, debarment, disgorgement of profits or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Pharmaceutical products may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

#### *Orphan Drug Designation*

Orphan drug designation in the United States is designed to encourage sponsors to develop products intended for rare diseases or conditions. In the United States, a rare disease or condition is statutorily defined as a disease or condition that affects fewer than 200,000 individuals in the United States or that affects more than 200,000 individuals in the United States but for which there is no reasonable expectation that the cost of developing and making available the product for the disease or condition will be recovered from sales of the product in the United States.

Orphan drug designation qualifies a company for certain financial incentives, including tax advantages and, if the product receives the first FDA approval for the indication for which it has orphan designation, market exclusivity for seven years following the date of the product's marketing approval. An application for designation as an orphan product can be made any time prior to the filing of an application for approval to market the product. Once a product receives orphan drug designation from the Office of Orphan Products Development at the FDA, the product must then go through the review and approval process like any other product.

In addition, a sponsor of a product that is otherwise the same product as an already approved orphan drug may seek and obtain orphan drug designation for the subsequent product for the same rare disease or condition if it can present a plausible hypothesis that its product may be clinically superior to the first product. More than one sponsor may receive orphan drug designation for the same product for the same rare disease or condition, but each sponsor seeking orphan drug designation must file a complete request for designation.

The period of exclusivity begins on the date that the marketing application is approved by the FDA and applies only to the indication for which the product has been designated. The FDA may approve a second application for the same product for a different use or a second application for a clinically superior version of the product for the same use. The FDA cannot, however, approve the same product made by another manufacturer for the same indication during the market exclusivity period unless it has the consent of the sponsor, the manufacturer makes a showing of clinical superiority over the product with orphan exclusivity, or the sponsor is unable to provide sufficient quantities.

Orphan product designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

#### *Pediatric Studies and Exclusivity*

Under the Pediatric Research Equity Act of 2003, an NDA or a BLA or supplement thereto must contain data that are adequate to assess the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. Sponsors who are planning to submit a marketing application for a drug or biological product that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration must also submit pediatric study plans prior to the assessment data, and no later than 60 calendar days following an end-of-Phase 2 meeting



with the FDA or, if there is no such meeting, as early as practicable before the initiation of the Phase 3 or Phase 2/3 study. Pediatric study plans must contain an outline of the proposed pediatric study or studies the sponsor plans to conduct, including study objectives and design, any deferral or waiver requests and other information required by regulation. The sponsor, the FDA, and the FDA's internal review committee must then review the information submitted, consult with each other and agree upon a final plan. The FDA or the sponsor may request an amendment to the plan at any time.

The FDA may, on its own initiative or at the request of the sponsor, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements. Additional requirements and procedures relating to deferral requests and requests for extension of deferrals are contained in FDASIA. Unless otherwise required by regulation, the pediatric data requirements do not apply to products with orphan designation.

Pediatric exclusivity is another type of non-patent marketing exclusivity in the United States and, if granted, provides for the attachment of an additional six months of marketing protection to the term of any existing regulatory exclusivity, including the non-patent and orphan exclusivity. This six-month exclusivity may be granted if an NDA or a BLA sponsor submits pediatric data that fairly respond to a written request from the FDA for such data. The data do not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, the additional protection is granted. If reports of requested pediatric studies are submitted to and accepted by the FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity or patent protection cover the product are extended by six months. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot approve another application.

#### *Biosimilars and Reference Product Exclusivity*

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the ACA, signed into law in 2010, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or the BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-approved reference biological product. To date, a number of biosimilars have been licensed under the BPCIA, and numerous biosimilars have been approved in Europe.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing that sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of its product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. At this juncture, it is unclear whether products deemed "interchangeable" by the FDA will, in fact, be readily substituted by pharmacies, which are governed by state pharmacy law.

The FDA has issued several guidance documents outlining an approach to review and approval of biosimilars. Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity and potency, can be shown through analytical studies, animal studies, and a clinical study or studies. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. Complexities associated with the larger, and often more complex, structures of biological products, as well as the processes by which such products are manufactured, pose significant hurdles to implementation of the abbreviated approval pathway that are still being worked out by the FDA.

The BPCIA is complex and continues to be interpreted and implemented by the FDA. In addition, recent government proposals have sought to reduce the 12-year reference product exclusivity period. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. As a result, the ultimate implementation and impact of the BPCIA is subject to significant uncertainty.

### ***Regulation of Combination Products in the United States***

Certain products may be comprised of components that would normally be regulated under different types of regulatory authorities and frequently by different centers at the FDA. These products are known as combination products. Specifically, under regulations issued by the FDA, a combination product may be:

- A product comprised of two or more regulated components that are physically, chemically or otherwise combined or mixed and produced as a single entity;
- Two or more separate products packaged together in a single package or as a unit and comprised of drug and device products, device and biological products, or biological and drug products;
- A drug, or device or biological product packaged separately that according to its investigational plan or proposed labeling is intended for use only with an approved individually specified drug, device or biological product where both are required to achieve the intended use, indication or effect and where upon approval of the proposed product the labeling of the approved product would need to be changed, *e.g.*, to reflect a change in intended use, dosage form, strength, route of administration or significant change in dose; or
- Any investigational drug, device or biological product packaged separately that according to its proposed labeling is for use only with another individually specified investigational drug, device or biological product where both are required to achieve the intended use, indication or effect.

Under the FDCA, the FDA is charged with assigning a center with primary jurisdiction, or a lead center, for review of a combination product. That determination is based on the “primary mode of action” of the combination product. Thus, if the primary mode of action of a device-biologic combination product is attributable to the biological product, the FDA center responsible for premarket review of the biological product would have primary jurisdiction for the combination product. The FDA has also established an Office of Combination Products to address issues surrounding combination products and provide more certainty to the regulatory review process. That office serves as a focal point for combination product issues for agency reviewers and industry. It is also responsible for developing guidance and regulations to clarify the regulation of combination products, and for assignment of the FDA center that has primary jurisdiction for review of combination products where the jurisdiction is unclear or in dispute.

In order to market any product outside of the United States, a company must also comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of products. Whether or not it obtains FDA approval for a product, an applicant will need to obtain the necessary approvals by the comparable foreign regulatory authorities before it can initiate clinical trials or market and sell the product in those countries or jurisdictions.

### ***Regulation and Procedures Governing Approval of Medicinal Products in the European Union***

The process governing approval of medicinal products, including biological medicinal products and advanced therapy medicinal products, or ATMPs, which comprise gene therapy products, somatic cell therapy products and tissue-engineered products, in the European Union generally follows the same lines as in the United States. It entails satisfactory completion of pharmaceutical development, nonclinical and clinical studies to establish the safety and efficacy of the medicinal product for each proposed indication. Moreover, an applicant must also demonstrate the ability to manufacture the product to a suitable quality.

#### ***Clinical Trial Approval***

Pursuant to the currently applicable Clinical Trials Directive 2001/20/EC and the Directive 2005/28/EC on GCP, a system for the approval of clinical trials in the European Union has been implemented through national legislation of the member states.

Clinical trials must be conducted in accordance with European Union and national regulations and the International Conference on Harmonization, or ICH, guidelines on GCP. Additional GCP guidelines from the European Commission, focusing in particular on traceability, apply to clinical trials of advanced therapy medicinal products. If the sponsor of the clinical trial is not established within the European Union, it must appoint an entity within the European Union to act as its legal representative.

Under this system, a sponsor must obtain approval from the competent national authority of a European Union member state in which the clinical trial is to be conducted or in multiple member states if the clinical trial is to be conducted

in a number of member states. Furthermore, the sponsor may only start a clinical trial at a specific study site after the independent ethics committee has issued a favorable opinion. The clinical trial application must be accompanied by a copy of the trial protocol and an investigational medicinal product dossier with supporting information prescribed by Directive 2001/20/EC and Directive 2005/28/EC and corresponding national laws of the member states and further detailed in applicable guidance documents. Moreover, the sponsor must take out a clinical trial insurance policy, and in most European Union countries the sponsor is liable to provide 'no fault' compensation to any study subject injured in the clinical trial.

In April 2014, the European Union adopted a new Clinical Trials Regulation (EU) No 536/2014, which is set to replace the current Clinical Trials Directive 2001/20/EC. It is expected that the new Clinical Trials Regulation will apply at earliest at the end of 2021. It will overhaul the current system of approvals for clinical trials in the European Union. Specifically, the new regulation, which will be directly applicable in all member states, aims to simplify and streamline the approval of clinical trials in the European Union. For instance, the new Clinical Trials Regulation provides for a streamlined application procedure using a single entry point and strictly defined deadlines for the assessment of clinical trial applications. This means that one national authority takes the lead in reviewing the application and the other national authorities have only a limited involvement. Any substantial changes to the trial protocol or other information submitted with the clinical trial applications must be notified to or approved by the relevant competent authorities and ethics committees.

The sponsor of a clinical trial must register the clinical trial in advance, and information related to the product, patient population, phase of investigation, study sites and investigators, and other aspects of the clinical trial will be made public as part of the registration. The results of the clinical trial must be submitted to the competent authorities and, with the exception of non-pediatric Phase 1 trials, will be made public at the latest within 12 months after the end of the trial.

During the development of a medicinal product, the European Medicines Agency, or EMA, and national medicines regulators within the European Union provide the opportunity for dialogue and guidance on the development program. At the EMA level, this is usually done in the form of scientific advice, which is given by the Scientific Advice Working Party of the Committee for Medicinal Products for Human Use, or CHMP. A fee is incurred with each scientific advice procedure. Advice from the EMA is typically provided based on questions concerning, for example, quality (chemistry, manufacturing and controls testing), nonclinical testing and clinical studies, and pharmacovigilance plans and risk-management programs. Advice is not legally binding with regard to any future marketing authorization application of the product concerned.

#### *Marketing Authorization*

To obtain a marketing authorization for a product under the European Union regulatory system, a sponsor must submit a marketing authorization application, or MAA, either under a centralized procedure administered by the EMA or one of the procedures administered by competent authorities in European Union member states (decentralized procedure, national procedure or mutual recognition procedure).

All application procedures require an application in the common technical document, or CTD, format, which includes the submission of detailed information about the manufacturing and quality of the product, and nonclinical and clinical trial information. There is an increasing trend in the European Union toward greater transparency and, while the manufacturing or quality information is currently generally protected as confidential information, the EMA and national regulatory authorities are now liable to disclose much of the nonclinical and clinical information in marketing authorization dossiers, including the full clinical study reports, in response to freedom of information requests after the marketing authorization has been granted. In October 2014, the EMA adopted a policy under which clinical study reports would be posted on the agency's website following the grant, denial or withdrawal of a MAA, subject to procedures for limited redactions and protection against unfair commercial use. A similar requirement is contained in the new Clinical Trials Regulation that is currently expected to take effect at earliest at the end of 2021.

A marketing authorization may be granted only to a sponsor established in the European Union. Regulation (EC) No. 1901/2006 on medicinal products for pediatric use provides that prior to obtaining a marketing authorization in the European Union in the centralized procedure, a sponsor must demonstrate compliance with all measures included in an EMA-approved Pediatric Investigation Plan covering all subsets of the pediatric population, unless the EMA has granted a product-specific waiver, class waiver or deferral for one or more of the measures included in the Pediatric Investigation Plan.

The centralized procedure provides for the grant of a single marketing authorization by the European Commission that is valid for all European Union member states. Pursuant to Regulation (EC) No. 726/2004, the centralized procedure is compulsory for specific products, including for medicines (including vaccines) produced by certain biotechnological processes, products designated as orphan medicinal products, advanced therapy medicinal products and products with a new active substance indicated for the treatment of certain diseases, including products for the treatment of cancer. For products with a new active substance indicated for the treatment of other diseases and products that are highly innovative or for which a centralized process is in the interest of patients, the centralized procedure may be optional.

Under the centralized procedure, the CHMP established at the EMA is responsible for conducting the assessment of a product to define its risk/benefit profile. Under the centralized procedure, the maximum timeframe for the evaluation of an MAA is 210 days, excluding clock stops when additional information or written or oral explanation is to be provided by the applicant in response to questions from the CHMP. Accelerated evaluation may be granted by the CHMP in exceptional cases, when a medicinal product is of major interest from the point of view of public health determined by three cumulative criteria: (i) the seriousness of the disease (*e.g.*, heavy disabling or life-threatening diseases) to be treated, (ii) the absence or insufficiency of an appropriate alternative therapeutic approach, and (iii) anticipation of high therapeutic benefit.

If the CHMP accepts such a request, the time limit of 210 days will be reduced to 150 days, but it is possible that the CHMP may revert to the standard time limit for the centralized procedure if it determines that it is no longer appropriate to conduct an accelerated assessment. The Committee for Advanced Therapies, or CAT, is responsible in conjunction with the CHMP for the evaluation of ATMPs. The CAT is primarily responsible for the scientific evaluation of ATMPs and prepares a draft opinion on the quality, safety and efficacy of each ATMP for which a MAA is submitted. The CAT's opinion is then taken into account by the CHMP when giving its final recommendation regarding the authorization of a product in view of the balance of benefits and risks identified. Although the CAT's draft opinion is submitted to the CHMP for final approval, the CHMP may depart from the draft opinion if it provides detailed scientific justification. The CHMP and CAT are also responsible for providing guidelines on ATMPs and have published numerous guidelines, including specific guidelines on gene therapies and cell therapies. These guidelines, which are not legally binding, provide additional guidance on the factors that the EMA will consider in relation to the development and evaluation of ATMPs and include, *inter alia*, the preclinical studies required to characterize ATMPs, the manufacturing and control information that should be submitted in a MAA; and post-approval measures required to monitor patients and evaluate the long term efficacy and potential adverse reactions of ATMPs.

The European Commission may grant a so-called "marketing authorization under exceptional circumstances." Such authorization is intended for products for which the applicant can demonstrate that it is unable to provide comprehensive data on the efficacy and safety under normal conditions of use, because the indications for which the product in question is intended are encountered so rarely that the applicant cannot reasonably be expected to provide comprehensive evidence, or in the present state of scientific knowledge, comprehensive information cannot be provided, or it would be contrary to generally accepted principles of medical ethics to collect such information. Consequently, marketing authorization under exceptional circumstances may be granted subject to certain specific obligations, which may include the following:

- the applicant must complete an identified program of studies within a time period specified by the competent authority, the results of which form the basis of a reassessment of the benefit/risk profile;
- the medicinal product in question may be supplied on medical prescription only and may in certain cases be administered only under strict medical supervision, possibly in a hospital, and in the case of a radio-pharmaceutical, by an authorized person; and
- the package leaflet and any medical information must draw the attention of the medical practitioner to the fact that the particulars available concerning the medicinal product in question are as yet inadequate in certain specified respects.

A marketing authorization under exceptional circumstances is subject to annual review to reassess the risk-benefit balance in an annual re-assessment procedure. Continuation of the authorization is linked to the annual reassessment and a negative assessment could potentially result in the marketing authorization being suspended or revoked. The renewal of the marketing authorization of a medicinal product under exceptional circumstances follows the same rules as a "normal" marketing authorization. After five years, the marketing authorization will then be renewed under exceptional circumstances for an unlimited period, unless the EMA decides, on justified grounds, to proceed with one additional five-year renewal.

The European Commission may also grant a so-called “conditional marketing authorization” prior to obtaining the comprehensive clinical data required for an application for a full marketing authorization. Such conditional marketing authorizations may be granted for product candidates (including medicines designated as orphan medicinal products and vaccines) if the CHMP finds that all the following requirements are met:

- the benefit-risk balance of the product is positive;
- it is likely that the applicant will be able to provide comprehensive data;
- unmet medical needs will be fulfilled; and
- the benefit to public health of the medicinal product’s immediate availability on the market outweighs the risks due to need for further data.

A conditional marketing authorization may contain specific obligations to be fulfilled by the marketing authorization holder, including obligations with respect to the completion of ongoing or new studies, and with respect to the collection of pharmacovigilance data. Conditional marketing authorizations are valid for one year, and may be renewed annually, if the risk-benefit balance remains positive, and after an assessment of the need for additional or modified conditions and/or specific obligations. The timelines for the centralized procedure described above also apply with respect to the review by the CHMP of applications for a conditional marketing authorization. Once comprehensive data on the medicinal product have been obtained, the marketing authorization may be converted into a standard marketing authorization which is no longer subject to specific obligations. Initially, this is valid for five years, but can be renewed for unlimited validity.

For COVID-19 vaccines to date, the EMA has followed a so-called ‘rolling review’ process, an *ad hoc* procedure by which data is assessed as it becomes available with the aim of granting a conditional marketing authorization.

The European Union medicines rules expressly permit the member states to adopt national legislation prohibiting or restricting the sale, supply or use of any medicinal products containing, consisting of or derived from a specific type of human or animal cell, such as embryonic stem cells.

#### *Periods of Authorization and Renewals*

A marketing authorization is valid for five years, in principle, and it may be renewed after five years on the basis of a reevaluation of the risk benefit balance by the EMA or by the competent authority of the authorizing Member State. To that end, the marketing authorization holder must provide the EMA or the competent authority with a consolidated version of the file in respect of quality, safety and efficacy, including all variations introduced since the marketing authorization was granted, at least six months before the marketing authorization ceases to be valid. Once renewed, the marketing authorization is valid for an unlimited period, unless the European Commission or the competent authority decides, on justified grounds relating to pharmacovigilance, to proceed with one additional five-year renewal period. Any authorization that is not followed by the placement of the product on the European Union market (in the case of the centralized procedure) or on the market of the authorizing Member State within three years after authorization ceases to be valid.

#### *Emergency Use Authorizations*

The European Union medicines rules, as implemented into the national laws of the EU member states, permit national authorities to authorize temporarily the distribution of an unapproved medicinal product in certain emergency situations, including suspected or confirmed spread of pathogenic agents. Such an Emergency Use Authorization (EUA) would apply for the duration of the emergency only and would be limited to the member state in which it has been issued. When considering whether to grant an EUA, the relevant member state decides, which data it requires for the grant of the EUA. For COVID-19 vaccines to date, the EU member states have not relied on EUAs. Rather products have followed the centralized procedure combined with a rolling review of data with a view to granting conditional marketing authorizations. Member states have relied on EUAs to permit the distribution and use of certain unapproved medicines for in unapproved indications to assist in the treatment of COVID-19 patients.

#### *Regulatory Requirements after Marketing Authorization*

Following approval, the holder of the marketing authorization is required to comply with a range of requirements applicable to the manufacturing, marketing, promotion and sale of the medicinal product. These include compliance with the European Union’s stringent pharmacovigilance or safety reporting rules, pursuant to which post-authorization studies and additional monitoring obligations can be imposed. The holder of a marketing authorization must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance who is responsible for

oversight of that system. Key obligations include expedited reporting of suspected serious adverse reactions and submission of periodic safety update reports, or PSURs. All new MAAs must include a risk management plan, or RMP, describing the risk management system that the company will put in place and documenting measures to prevent or minimize the risks associated with the product. The regulatory authorities may also impose specific obligations as a condition of the marketing authorization. Such risk-minimization measures or post-authorization obligations may include additional safety monitoring, more frequent submission of PSURs, or the conduct of additional clinical trials or post-authorization safety studies. RMPs and PSURs are routinely available to third parties requesting access, subject to limited redactions.

In addition, the manufacturing of authorized products, for which a separate manufacturer's license is mandatory, must also be conducted in strict compliance with the EMA's GMP requirements and comparable requirements of other regulatory bodies in the European Union, which mandate the methods, facilities and controls used in the manufacturing, processing and packing of products to assure their safety and identity. Specifically, medicinal products may only be manufactured in the European Union, or imported into the European Union from another country, by the holder of a manufacturing/import authorization from the competent national authority. The manufacturer or importer must have a qualified person who is responsible for certifying that each batch of product has been manufactured in accordance with European Union standards of good manufacturing practice, or GMP, before releasing the product for commercial distribution in the European Union or for use in a clinical trial. Manufacturing facilities are subject to periodic inspections by the competent authorities for compliance with GMP.

Finally, the marketing and promotion of authorized products, including industry-sponsored continuing medical education and advertising directed toward the prescribers of products and/or the general public, are strictly regulated in the European Union. In principle, all advertising and promotional activities for the product must be consistent with the approved summary of product characteristics, and therefore all off-label promotion is prohibited. Direct-to-consumer advertising of prescription medicines (including vaccines) is also prohibited in the European Union. Although general requirements for advertising and promotion of medicinal products are established under Directive 2001/83/EC, as amended, the details are governed by regulations in each member state and can differ from one country to another.

#### *Human Cells and Tissues*

Human cells and tissues that are intended for human applications but that do not fall within the scope of rules governing medicinal products or medical devices are not subject to premarket review and approval, nor do they require extensive preclinical and clinical testing. However, there are European Union rules governing the donation, procurement, testing and storage of human cells and tissues intended for human application, whether or not they are ATMPs. These rules also cover the processing, preservation and distribution of human cell and tissues that are not ATMPs. Establishments that conduct such activities must be licensed and are subject to inspection by regulatory authorities. Such establishments must implement appropriate quality systems and maintain appropriate records to ensure that cells and tissues can be traced from the donor to the recipient and vice versa. There are also requirements to report serious adverse events and reactions linked to the quality and safety of cells and tissues. More detailed rules may exist at the national level.

#### *Named Patient Supplies*

The European Union medicines rules allow individual member states to permit the supply of a medicinal product without a marketing authorization to fulfill special needs, where the product is supplied in response to a bona fide unsolicited order, formulated in accordance with the specifications of a healthcare professional and for use by an individual patient under his direct personal responsibility. This may in certain countries also apply to products manufactured in a country outside the European Union and imported to treat specific patients or small groups of patients.

#### *Orphan Drug Designation and Exclusivity*

Regulation (EC) No. 141/2000 and Regulation (EC) No. 847/2000 provide that a product can be designated as an orphan drug by the European Commission if its sponsor can establish: that the product is intended for the diagnosis, prevention or treatment of (i) a life-threatening or chronically debilitating condition affecting not more than five in 10,000 persons in the European Union when the application is made, or (ii) a life-threatening, seriously debilitating or serious and chronic condition in the European Union and that without incentives it is unlikely that the marketing of the product in the European Union would generate sufficient return to justify the necessary investment. For either of these conditions, the sponsor must demonstrate that there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorized in the European Union or, if such method exists, the product has to be of significant benefit compared to products available for the condition.

An orphan drug designation provides a number of benefits, including fee reductions, regulatory assistance and the possibility to apply for a centralized European Union marketing authorization. Marketing authorization for an orphan drug leads to a 10-year period of market exclusivity. During this market exclusivity period, neither the EMA nor the European Commission or the member states can accept an application or grant a marketing authorization for a “similar medicinal product.” A “similar medicinal product” is defined as a medicinal product containing a similar active substance or substances as contained in a currently authorized orphan medicinal product, and which is intended for the same therapeutic indication. The market exclusivity period for the authorized therapeutic indication may, however, be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan drug designation because, for example, the product is sufficiently profitable not to justify market exclusivity.

#### *European Data Collection and Data Protection Laws*

We are required to comply with strict data protection and privacy legislation in the jurisdictions in which we operate, including the General Data Protection Regulation (EU) 2016/679, or GDPR. The GDPR governs our collection and use of personal data in the European Union relating to individuals (e.g., patients). The GDPR imposes several requirements on organizations that process such data, including: to observe core data processing principles; to comply with various accountability measures; to provide more detailed information to individuals about data processing activities; to establish a legal basis to process personal data (including enhanced consent requirements); to maintain the integrity, security and confidentiality of personal data; and to report personal data breaches. The GDPR also restricts the transfer of personal data outside of the European Economic Area (e.g., to the United States and other countries that are not deemed to provide adequate protection under their domestic laws). The GDPR may impose additional responsibility and liability in relation to personal data that we process, and require us to put in place additional mechanisms ensuring compliance with the new data protection rules. This may be onerous and adversely affect our business, financial condition, results of operations and prospects. Failure to comply with the requirements of the GDPR and related national data protection laws of European Union member states may result in a variety of enforcement measures, including significant fines and other administrative measures. The GDPR has introduced substantial fines for breaches of the data protection rules, increased powers for regulators, enhanced rights for individuals, and new rules on judicial remedies and collective redress. We may be subject to claims by third parties, such as patients or regulatory bodies, that we or our employees or independent contractors inadvertently or otherwise breached GDPR and related data protection rules. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and if we do not prevail, we could be required to pay substantial fines and/or damages and could suffer significant reputational harm. Even if we are successful, litigation could result in substantial cost and be a distraction to management and other employees.

#### *Coverage, Pricing and Reimbursement*

Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we may obtain regulatory approval. Even if our product candidates are approved for marketing, sales of such product candidates will depend, in part, on the extent to which third-party payors, including government health programs in the United States (such as Medicare and Medicaid), commercial health insurers and managed care organizations, provide coverage and establish adequate reimbursement levels for such product candidates. In the United States, the member states of the European Union and markets in other countries, patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Reimbursement rules and levels are not harmonized in the European Union and therefore differ from member state to member state. Patients are unlikely to use any product candidates we may develop unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of such product candidates. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services and imposing controls to manage costs.

In order to secure coverage and reimbursement for any product that might be approved for sale, a company may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product, and the cost of these studies would be in addition to the costs required to obtain FDA or other comparable marketing approvals. Even after pharmacoeconomic studies are conducted, product candidates may not be considered medically necessary or cost effective. A decision by a third-party payor not to cover any product candidates we may develop could reduce physician utilization of such product candidates once approved and have a material adverse effect on our sales, results of operations and financial condition. Additionally, a payor’s decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. For example, the payor may require co-payments that patients find unacceptably high. Further, one payor’s determination to provide coverage for a product does not assure that

such coverage will continue or that other payors will also provide coverage and reimbursement for the product, and the level of coverage and reimbursement can differ significantly from payor to payor. Third-party reimbursement and coverage may not be adequate to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development. The insurance coverage and reimbursement status of newly approved products for orphan diseases is particularly uncertain, and failure to obtain or maintain adequate coverage and reimbursement for any such product candidates could limit a company's ability to generate revenue.

The containment of healthcare costs also has become a priority of federal, state and foreign governments as well as other third-party payors such as statutory health insurance funds, and the prices of pharmaceuticals have been a focus in this effort. Governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit a company's revenue from the sale of any approved products. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which a company or its collaborators receive marketing approval, less favorable coverage policies and reimbursement rates may be implemented or coverage may be ended in the future.

Outside the United States, we will face challenges in ensuring and obtaining adequate coverage and payment for any product candidates we may develop. Pricing of prescription pharmaceuticals is subject to governmental control in many countries, including in particular the member states of the European Union. Pricing negotiations with governmental authorities or other third-party payors such as statutory health insurance funds can extend well beyond the receipt of regulatory marketing approval for a product and may require us to conduct a clinical trial that compares the cost effectiveness of any product candidates we may develop to other available therapies. The conduct of such a clinical trial could be expensive and result in delays in our commercialization efforts.

In the European Union, pricing and reimbursement schemes vary widely from country to country. Some countries provide that products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost effectiveness of a particular product candidate to currently available therapies (so called health technology assessments) in order to obtain reimbursement or pricing approval. Moreover, European Union member states may restrict the range of products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. Member states may approve a specific price for a product or may instead adopt a system of direct or indirect controls on the profitability of the company placing the product on the market. Other member states allow companies to fix their own prices for products, but monitor and control prescription volumes and issue guidance to physicians to limit prescriptions. Recently, many countries in the European Union have increased the amount of discounts required on pharmaceuticals and these efforts could continue as countries attempt to manage healthcare expenditures, especially in light of the severe fiscal and debt crises experienced by many countries in the European Union. The downward pressure on health care costs in general, particularly prescription products, has become intense. As a result, increasingly high barriers are being erected to the entry of new products in the marketplace. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various European Union member states and parallel trade (arbitrage between low-priced and high-priced member states) can further reduce prices. Special pricing and reimbursement rules may apply to orphan drugs. Inclusion of orphan drugs in reimbursement systems tend to focus on the medical usefulness, need, quality and economic benefits to patients and the healthcare system as for any product. Acceptance of any medicinal product for reimbursement may come with cost, use and often volume restrictions, which again can vary by country. In addition, results based rules of reimbursement may apply. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products, if approved in those countries.

For COVID-19 vaccine candidates in the European Union, no pricing and reimbursement or health technology assessments discussions have taken place with the respective health insurances and competent bodies at a national member state level. Currently, COVID-19 vaccine candidates are supplied in the European Union based on vaccine supply agreements with the European Commission that is acting on behalf and in the name of the member states of the European Union.

#### ***Brexit and the Regulatory Framework in the United Kingdom***

On June 23, 2016, in a national referendum, a majority of the electorate voted in favour of the United Kingdom leaving the European Union (commonly referred to as "Brexit"). On March 29, 2017, the United Kingdom Government



formally notified the European Union of its intention to withdraw from the Union pursuant to Article 50 of the Treaty on the European Union. The United Kingdom formally left the European Union on January 31, 2020. Pursuant to the terms of the Withdrawal Agreement between the European Union and the United Kingdom, a transitional period ran between February 1, 2020 and December 31, 2020, during which all applicable EU law, including the regulation of medicinal products, applied to and in the United Kingdom. This transitional period has now come to an end. On December 24, 2020, the United Kingdom and the European Union announced that they have reached agreement on the terms of their future relationship as set out in the Trade and Cooperation Agreement (“TCA”). The European Union and the United Kingdom have agreed to provisionally apply the terms of the TCA, while the formal execution is still ongoing. While the TCA governs tariff and quota free trade between the United Kingdom and the European Union markets, it does not provide for regulatory alignment. The regulatory framework for medicinal products in the United Kingdom is predominantly derived from European Union law. Currently, domestic United Kingdom law provides that all existing European Union law is transposed into national law, subject to certain revisions that have become necessary as a result of Brexit. Thus, at least initially, the United Kingdom and the European Union laws are aligned. However, Brexit could have a material impact on the regulatory regime in the United Kingdom, as the country is free to deviate from the European Union regime. One example of such deviation is the approval of COVID-19 vaccines. While in the European Union vaccines have been granted conditional marketing authorizations, in the United Kingdom, vaccine candidates were granted emergency use authorizations.

#### ***Rest of the World Regulation***

The requirements governing the conduct of clinical trials, product (including vaccine) licensing, pricing, and reimbursement vary from country to country in markets outside the EU and the United States. In many markets, clinical trials must be conducted in accordance with Good Clinical Practice and applicable regulatory requirements. Ethical standards typically follow the Declaration of Helsinki principles. In response to the COVID-19 pandemic, some markets have granted or are considering the grant of emergency use authorizations for vaccine candidates instead of the otherwise available regulatory approval pathways. Supply of the COVID-19 vaccine to a number of countries outside of the US and the EU is similarly governed by vaccine supply agreements with local governments.

Failure to adhere to regulatory requirements may lead to, among others, fines, suspension or withdrawal of regulatory authorizations or approvals, product recalls, seizure of products, restrictions or suspensions of operations, or criminal prosecution.

#### **Greater China**

##### *a.) Mainland China*

Similar to the United States and the European Union, Mainland China has rules governing the approval for development and commercialization of drugs, including specialized rules for vaccines. China’s drug law and regulations require that the National Medical Products Administration’s, or NMPA’s, Center for Drug Evaluation, or CDE, approve a clinical trial application prior to initiating a study to support the safety and effectiveness of a drug. This clinical trial application and the testing procedure that may precede it can be expedited if there is a pressing declared health emergency, as was the case with COVID-19.

Once approved, vaccine clinical trials must be conducted at sites that are qualified disease prevention and control, or CDC, institutions and grade III hospitals, and the implementation of the trial must be in accordance with China’s vaccine good clinical practice regulations and related guidelines. Furthermore, prior to the commencement of the clinical trial in China the site’s ethics committees must approve the trial, and the Office of Human Genetic Resources Administration must approve the use of samples and related data. The human genetic resources, or HGR, approval requires a joint approval or record-filing application with the Chinese and foreign parties, setting forth the parties that will handle data and samples, the type and amount of samples that will be utilized during the study, the tests/analysis run, and the plans for storage or destruction, and the intellectual property sharing arrangement among the parties, among other items. Once approved, the HGR approval/filing may require updates and amendments and additional procedures to transfer data to certain foreign parties. Once a clinical trial in China is complete and/or foreign data is assembled, a company may submit an application for a marketing authorization, or MA, of the vaccine. This procedure will include submission of clinical data, manufacturing information and test results, among other items, and may include an onsite pre-market verification by the NMPA. This application may be expedited under various expedited programs, including “special approval” procedures for drugs needed to control a public health emergency. Therapeutic biologics and small molecule drugs follow similar steps to approval for development and marketing.

At both the clinical trial and MA stages, drug applicants located outside of China must list a regulatory agent on the application. The agent must be an entity in China, and it assists the sponsor and marketing authorization holder, or MAH, with fulfilling its drug regulatory obligations in China. The agent of the MAH is jointly liable with the MAH for these drug regulatory obligations.

Once approved, vaccines may be procured by the CDC through platforms organized by the provincial governments. Vaccines in China must be sold and directly distributed by domestic manufacturers or general distributors appointed to represent overseas makers to municipal level CDCs, which handle allocation and distribution to points of vaccination in China. Distributors of all drugs must possess a MA for the drug they are distributing or a drug distribution license. As is the case with all drugs, once on the market, MAHs will also have post-market obligations, including safety reporting and compensation for injuries caused adverse events following inoculation, or AEFIs. MAHs of vaccines that are not part of the National Inoculation Program, or NIP, must bear the cost of injuries determined by experts to be AEFI injuries. The government bears the cost of NIP vaccines and related AEFIs. Vaccine MAHs are also subject to other post-market obligations for drug marketing authorization holders, including recalls, annual reporting, and inspections. Vaccine MAs must typically be renewed every five years.

b.) *Hong Kong and Macao*

Mainland China's drug regulatory system does not apply in Hong Kong or Macao. These administrative regions are governed by separate laws on the development and approval of drugs, including vaccines. They also have separate laws on the importation and distribution of those vaccines.

**Turkey**

Other countries such as Turkey and those in the Middle East have regulatory review processes and data requirements for medicinal products, including vaccines, similar to those described for the European Union. The regulatory licensing process in these countries may include local marketing authorization requirements, manufacturing/testing facility inspections, testing of drug product upon importation and other domestic requirements. Some countries, such as Turkey, have introduced specific emergency authorization regimes for COVID-19 vaccines.

**Healthcare Law and Regulation**

Healthcare providers and third-party payors play a primary role in the recommendation and prescription of pharmaceutical products that are granted marketing approval. Our current and future arrangements with providers, researchers, consultants, third-party payors and customers are subject to broadly applicable federal and state fraud and abuse, anti-kickback, false claims, transparency and patient privacy laws and regulations and other healthcare laws and regulations that may constrain our business and/or financial arrangements. Restrictions under applicable federal and state healthcare laws and regulations include, without limitation, the following:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in-cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or a specific intent to violate it in order to have committed a violation. Moreover, the government may assert that a claim that includes items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;
- the federal civil and criminal false claims laws, including the civil False Claims Act, and civil monetary penalties laws, which prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false, fictitious, or fraudulent or knowingly making, using, or causing to be made or used a false record or statement to avoid, decrease, or conceal an obligation to pay money to the federal government;
- HIPAA, which created additional federal criminal laws that prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or a specific intent to violate it in order to have committed a violation;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and their respective implementing regulations, including the Final Omnibus Rule published in January 2013, which impose obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without the appropriate authorization by entities subject to the law, such as healthcare providers, health plans and healthcare clearinghouses and their respective business associates;
- the federal transparency requirements known as the federal Physician Payments Sunshine Act, under the ACA, which requires certain manufacturers of drugs, devices, biologics and medical supplies to report annually to the Centers for Medicare & Medicaid Services, or CMS, within the U.S. Department of Health and Human Services, information related to payments and other transfers of value made by that entity to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- federal government price reporting laws, which require us to calculate and report complex pricing metrics to government programs and which may be used in the calculation of reimbursement and/or discounts on marketed products;
- the Foreign Corrupt Practices Act, a U.S. law which regulates certain financial relationships with foreign government officials (which could include, for example, certain medical professionals);
- the national anti-bribery laws and laws governing interactions with healthcare professionals of European Union member states;
- the U.K. Bribery Act 2010; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to healthcare items or services that are reimbursed by non-governmental third-party payors, including private insurers.

Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring pharmaceutical manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures and pricing information. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry.

Violations of these laws can subject us to criminal, civil and administrative sanctions including monetary penalties, damages, fines, disgorgement, individual imprisonment and exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, reputational harm, and we may be required to curtail or restructure our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to similar actions, penalties, and sanctions. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource-consuming and can divert a company's attention from the business. Moreover, we expect that there will continue to be federal and state laws and regulations, proposed and implemented, that could impact our future operations and business.

#### ***Current and Future Healthcare Reform Legislation***

In the United States and foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our investigational medicines, restrict or regulate post-approval activities, and affect our ability to profitably sell any investigational medicines

for which we obtain marketing approval. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we, or any collaborators, may receive for any approved products.

The ACA, for example, contains provisions that subject biological products to potential competition by lower-cost biosimilars and may reduce the profitability of drug products through increased rebates for drugs reimbursed by Medicaid programs, extension of Medicaid rebates to Medicaid-managed care plans, mandatory discounts for certain Medicare Part D beneficiaries, and annual fees based on pharmaceutical companies' share of sales to federal health care programs. With the current presidential administration and Congress, there may be additional administrative or legislative changes, including modification, repeal or replacement of all, or certain provisions of, the ACA, which may impact reimbursement for drugs and biologics. On January 20, 2017, an Executive Order was signed directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. On October 13, 2017, an executive order was signed terminating the cost-sharing subsidies that reimburse insurers under the ACA. Several state Attorneys General filed suit to stop the administration from terminating the subsidies, but their request for a restraining order was denied by a federal judge in California on October 25, 2017. In addition, CMS has recently proposed regulations that would give states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces. Further, each chamber of Congress has put forth multiple bills this year designed to repeal or repeal and replace portions of the ACA. While Congress has not passed repeal legislation, the TCJA includes a provision repealing the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." Congress may consider other legislation to repeal and replace elements of the ACA. Litigation and legislation over the ACA are likely to continue, with unpredictable and uncertain results.

Additionally, other federal health reform measures have been proposed and adopted in the United States since the ACA was enacted:

- The Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. These changes included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013 and will remain in effect through 2025 unless additional Congressional action is taken.
- The American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.
- The Middle Class Tax Relief and Job Creation Act of 2012 required that CMS reduce the Medicare clinical laboratory fee schedule by 2% in 2013, which served as a base for 2014 and subsequent years. In addition, effective January 1, 2014, CMS also began bundling the Medicare payments for certain laboratory tests ordered while a patient received services in a hospital outpatient setting.

Further, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which have resulted in several recent Congressional inquiries and proposed bills designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. In addition, the federal government, state legislatures and foreign governments have shown significant interest in implementing cost containment programs, including price-controls, restrictions on reimbursement, and requirements for substitution of generic products for branded prescription drugs to limit the growth of government-paid health care costs. For example, the federal government has passed legislation requiring pharmaceutical manufacturers to provide rebates and discounts to certain entities and governmental payors to participate in federal healthcare programs. Individual states in the United States have also become increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation, from other countries and bulk purchasing.

#### **Packaging and Distribution in the United States**

If our products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. Products must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act. Manufacturing, sales, promotion and other activities also are potentially subject to federal and state consumer protection and unfair competition laws.

The distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products.

The failure to comply with any of these laws or regulatory requirements subjects firms to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in criminal prosecution, fines or other penalties, injunctions, exclusion from federal healthcare programs, requests for recall, seizure of products, total or partial suspension of production, denial or withdrawal of product approvals, or refusal to allow a firm to enter into supply contracts, including government contracts. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Prohibitions or restrictions on sales or withdrawal of future products marketed by us could materially affect our business in an adverse way.

Changes in regulations, statutes, or the interpretation of existing regulations could impact our business in the future by requiring, for example, (i) changes to our manufacturing arrangements, (ii) additions or modifications to product labeling, (iii) the recall or discontinuation of our products or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

#### **Other U.S. Environmental, Health and Safety Laws and Regulations**

We may be subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. From time to time and in the future, our operations may involve the use of hazardous and flammable materials, including chemicals and biological materials, and may also produce hazardous waste products. Even if we contract with third parties for the disposal of these materials and waste products, we cannot completely eliminate the risk of contamination or injury resulting from these materials. In the event of contamination or injury resulting from the use or disposal of our hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

We maintain workers' compensation employers' liability insurance to cover us for costs and expenses we may incur due to injuries to our employees, but this insurance may not provide adequate coverage against potential liabilities.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. Current or future environmental laws and regulations may impair our research, development or production efforts. In addition, failure to comply with these laws and regulations may result in substantial fines, penalties or other sanctions.

### **XIV. Intellectual Property**

#### **A. Introduction**

We pursue a layered intellectual property strategy to protect our various technology platforms and their application to the treatment of cancer and other serious diseases. One focus of our intellectual property strategy is to provide protection for our platforms and products as they are developed. We also pursue intellectual property protection for assets that may be used in future development programs and/or that may be of interest to our collaborators, or otherwise may prove valuable in the field.

Various aspects of our technology platforms and our product candidates are claimed by patent filings. We also pursue other modalities of protection, including trademark and trade secret protection, as appropriate. Many of our intellectual property assets were developed and are owned solely by us, some have been developed via collaboration and are jointly owned, and some have been acquired by acquisition and/or licensed from third parties. We expect that we will continue to make additional patent application filings, and will continue to pursue opportunities to acquire and license additional intellectual property assets, technologies, platforms or product candidates, as developments arise or are identified.

Regardless, we cannot be certain that any of the patent filings or other intellectual property rights that we have pursued or obtained will provide protection for any products as commercialized. Our product candidates are currently in clinical testing, with no certainty that they will be successful, or that significant modification or adjustment may not be required for successful commercialization; even our COVID-19 vaccine product has been granted only emergency use, temporary use or conditional marketing approval; its composition, manufacture, and use may yet be adjusted or modified and our filings may not protect it.

Our future commercial success depends, in part, on our ability to obtain and maintain patent and other proprietary protection for commercially important technology, inventions and know-how related to our business; defend and enforce our patents and other intellectual property; preserve the confidentiality of our trade secrets; and operate without infringing, misappropriating or violating the valid and enforceable patents and other intellectual property rights of third parties. Our ability to stop third parties from making, using, selling, offering to sell or importing our products may depend on the extent to which we have rights under valid and enforceable patents, trade secrets or other intellectual property rights that cover these activities. With respect to both our owned and licensed intellectual property, we cannot be sure that patents will issue with respect to any of the owned or licensed pending patent applications or with respect to any patent applications that we, our co-owners or our licensors may file in the future, nor can we be sure that any of our owned or licensed patents or any patents that may be issued in the future to us or our licensors will be commercially useful in protecting any products that we ultimately attempt to commercialize or any method of making or using such products. Moreover, we may be unable to obtain patent protection for certain of our product candidates generally as well as with respect to certain indications. See “Risk Factors—Risks Related to our Intellectual Property” in this Annual Report on Form 20-F.

As of January 15, 2020, our overall owned and in-licensed patent portfolio included more than 200 patent families, each of which includes at least one filing in the United States or Europe, and several of which are pending or granted in multiple jurisdictions. The patent families include at least 100 patent families that are solely or jointly owned by BioNTech, including certain families acquired through our acquisitions of antibody assets and infrastructure from MabVax Therapeutics Holdings, Inc. as well as intellectual property assets acquired through our acquisitions of Lipocalyx GmbH and Neon, and others that we have licensed from a third party.

An issued patent provides its owner (or possibly its licensee) with a right to exclude others from making, using or selling that which is claimed in the patent, for a specified period of time (the “term” of the patent), in the jurisdiction in which the patent is issued. In the United States, and in many other countries, patents have a presumptive term of 20 years from their effective filing date (which is the earliest non-provisional filing date to which the patent claims priority). However, many jurisdictions, including the United States, require the payment of periodic maintenance fees in order for patents to remain in force for the full 20-year term. The United States also has provisions that require a patent term to be shortened if its claims are too similar to another patent owned by the same party that has a shorter term. The United States and certain other jurisdictions also have provisions that permit extension of patent term for patents that claim a drug or drug product, or its approved use, if the patent was issued before clinical trials were completed and certain other requirements were satisfied. In the United States, such extension is called a Patent Term Extension, or PTE, and it is limited to a period of not more than five years, or the total patent term including the PTE cannot exceed 14 years after the date of regulatory approval; only one patent can be extended per product approval. The United States also offers a different form of patent term extension, known as Patent Term Adjustment, or PTA, whereby a particular patent’s term is automatically extended beyond the 20-year date if the United States Patent and Trademark Office, or the USPTO, caused delay during its examination; however, potentially available PTA is reduced by any amount of any delay caused by the patent applicant.

Below, we provide a summary of the contours of our current patent portfolio as it relates to different aspects of relevant technology, including noting ownership and 20-year terms for filings included in the portfolio that are directed to such aspects. Particularly given our pre-commercial state of development, we cannot be certain that any of the patent filings in our portfolio will provide meaningful protection for any product we ultimately attempt to commercialize.

## **B. Patent Portfolio**

The patent portfolios for our most advanced programs are summarized below. Patent prosecution is a lengthy process, during which the scope of the claims initially submitted for examination by the USPTO and its foreign equivalents can be significantly narrowed by the time they issue, if they issue at all. We expect this could be the case with respect to some of our pending patent applications referred to below.

### **1. mRNA**

The patent portfolio for our mRNA therapeutic platforms and product candidates includes patent filings directed to features of therapeutic mRNA structures, some of which are included in current development candidates. Our patent portfolio also includes patent filings directed to mRNA formulations, including the lipoplex formulations currently utilized with our FixVac and iNeST platforms, and the lipid nanoparticles currently utilized with our RiboMab and RiboCytokine platforms, as well as patent filings directed to mRNA manufacturing, and to uses of mRNA therapeutics. We provide more detail below regarding the patent filings directed to these features.

#### **mRNA Structure**

Our patent portfolio includes patent filings directed to various features of mRNA structure, which may, for example, contribute to increased immunogenicity (*e.g.*, antigen presentation), translation efficiency, and/or stability of mRNA constructs that include them. Such features include, for example, antigen-MHC fusions, 5' cap structures, 3' UTR structures, polyA tails, reduced-uracil content mRNAs, and modified nucleoside RNAs. Filings directed to each of these features, or collectively, the mRNA Structure Filings, have been made in the United States and various foreign jurisdictions. Some such mRNA Structure Filings are owned solely by BioNTech SE or BioNTech RNA which are referred to collectively in this section as BioNTech, some jointly by BioNTech and one or more third parties, and some by BioNTech licensors, such as Louisiana State University, or LSU, and the terms of the applicable agreement with LSU, are further summarized below in “—C. In-Licensing.” We have non-exclusive rights to use certain US and European patent filings owned by University of Pennsylvania and relating to RNA containing modified nucleosides through our sublicense agreements with mRNA RiboTherapeutics, Inc. (MRT) and CellScript, LLC, collectively the MRT-CellScript Sublicenses and summarized below in “--C. In-Licensing”. Issued existing mRNA Structure Filings have, and pending existing mRNA Structure Filings, if issued, would have, 20-year terms that extend into the mid-2020s to the mid-2030s.

#### **mRNA Formulations**

Our patent portfolio includes patent filings directed to various formulations for mRNA delivery, some of which are utilized with current development candidates. For example, our portfolio includes patent filings directed to lipoplex formulations, with 20-year terms that extend into 2038, if issued, or collectively, the mRNA Lipoplex Filings, although none of these filings is currently an issued patent. Such mRNA Lipoplex Filings are solely owned by BioNTech RNA.

In addition, our portfolio includes U.S. and foreign patent filings directed to lipid nanoparticles and polyplex technologies, which are jointly owned by BioNTech RNA and TRON, or collectively, the mRNA Lipid Nanoparticle/Polyplex Filings. Issued mRNA Lipid Nanoparticle/Polyplex Filings have, and pending mRNA Lipid Nanoparticle/Polyplex Filings, if issued, would have, 20 year terms that extend into the mid- to late-2030s. Some such mRNA Lipid Nanoparticle/Polyplex Filings were granted in certain foreign jurisdictions, but do not currently include any U.S. issued patents. The terms of the co-ownership of such patent filings with TRON are summarized below in “—C. In-Licensing.”

#### **mRNA Manufacturing**

As discussed below, we utilize trade secret protection for many aspects of our mRNA manufacturing technologies, including as currently utilized for production of certain of our development candidates. In addition, our patent portfolio includes certain patent filings relevant to mRNA manufacturing, or collectively, the mRNA Manufacturing Filings, which we believe may provide commercial value to protect product candidates and/or support collaborations or other licensing arrangements. For example, our mRNA Manufacturing Filings include U.S. and foreign patent filings relating to certain aspects of mRNA purification and production. These mRNA Manufacturing Filings are either solely owned by BioNTech SE or BioNTech RNA, or jointly owned by BioNTech RNA and TRON and, if issued, would have 20-year terms that would extend into mid 2030 to early 2040s, although none is currently an issued patent.

#### **mRNA Commercial Products and Product Candidates**

Our COVID-19 vaccine, Our COVID-19 vaccine (BNT162b2) is our most advanced mRNA product, and has received conditional marketing approval in various jurisdictions. Additional COVID-19 vaccine candidates, and certain mRNA oncology product candidates are in clinical development and involve various platforms. Our pipeline also includes mRNA product candidates for treatment of certain infectious diseases beyond COVID-19, and mRNA product candidates for protein replacement therapy in certain rare diseases.

#### **BNT162b2 and Other COVID-19 Vaccine mRNA Product Candidates**

Our COVID-19 vaccine (BNT162b2) is a nucleoside-modified mRNA formulated in lipid nanoparticles and encodes an optimized SARS-COV-2 full-length spike protein antigen.

Our platform patent filings relevant to Our COVID-19 vaccine (BNT162b2), collectively, the “BNT162b2 Platform Filings”, include certain mRNA Structure Filings relating to features for increasing translation efficiency and/or stability of mRNA constructs (*e.g.*, certain 3' UTR structures containing a specific sequence element, and interrupted polyA tails), including filings which are jointly owned by BioNTech RNA and TRON; also relevant are certain mRNA Manufacturing Filings. Issued BNT162b2 Platform Filings have, and pending BNT162b2 Platform Filings, if issued, would have 20-year terms extending into the late-2020s to the early-2040s. We also have undertaken various patent filings specifically related to BNT162b2 structure, composition, formulation, packaging, use and/or manufacture, or the BNT162b2 Platform Filings, including filings that have arisen through collaboration with third parties such as Pfizer. Such filings relevant to our COVID-19 vaccine, if issued, would have 20-year terms that would extend into early 2040s; there are presently no issued patents within the BNT162b2 Platform Filings.

As noted above, our MRT-CellScript Sublicenses grant us rights to use certain U.S. and European patents and applications relating to RNAs containing modified nucleosides, including as used in BNT162b2. We also have a non-exclusive license from the National Institutes of Health granting us right to use certain US and European patent filings relating to SARS-COV-2 spike (S) protein variants that lock the S protein in an antigenically preferred prefusion conformation; such a variant is utilized in BNT162b2.

Additionally, we have obtained third-party licenses to technologies relating to certain lipids and/or lipid nanoparticles and formulations used in BNT162b2, including a non-exclusive license from Acuitas Therapeutics, grants use rights relevant to proprietary lipid nanoparticles and formulations used in BNT162b2.

Other COVID-19 Vaccine mRNA product candidates are being developed and tested in clinical trials, which share with BNT162b2 certain structural elements, and/or features of composition, formulation, packaging, use and manufacture. Thus, some or all of the BNT162b2 Platform Filings and/or BNT162b2 Filings, as well as the in-licensed rights discussed above with respect to BNT162b2, may be relevant to certain of these candidates.

#### *Oncology mRNA Product Candidates*

All our current clinical programs outside of COVID-19 are in oncology. Our most advanced clinical oncology programs involve our iNeST immunotherapy product candidates being developed with our collaborator, Genentech. We also have FixVac product candidates in Phase 1 clinical trials and have initiated Phase 1 clinical trials of our mRNA-based intratumoral immunotherapy developed through our collaboration with Sanofi.

#### FixVac

Our FixVac product candidates share many of the structural elements involved in our iNeST product candidates. Thus, some or all of the mRNA Structure Filings relevant to our iNeST product candidates and discussed below are also relevant to our FixVac product candidates. These patent filings, or the FixVac Platform Filings, include mRNA Structure Filings relating to antigen-MHC fusions, certain 5' cap structures, 3' UTR structures containing a specific sequence element, and interrupted polyA tails, which are solely or jointly owned by BioNTech or BioNTech's licensors. Issued FixVAC Platform Filings have, and pending FixVac Platform Filings, if issued, would have, 20-year terms extending into the mid-2020s to the mid-2030s. While we have pursued or obtained patent protection covering components of FixVac product candidates, manufacturing-related methods and/or formulations, we do not currently have any claims in our owned or in-licensed issued patents that cover the overall construct used in our FixVac product candidates.

Our patent portfolio further includes U.S. and foreign patent filings relating to combined uses of our FixVac and iNeST product candidates. Such issued patent filings have, and such pending patent filings, if issued, would have, 20-year terms that extend into 2033, and are jointly owned by BioNTech RNA and TRON.

Our current Phase 1 clinical trials for FixVac product candidates are studying such product candidates in treatment of advanced melanoma, head and neck cancer, breast cancer (particularly triple negative breast cancer), prostate cancer, and ovarian cancer. While we do not currently have any claims in our owned or in-licensed issued patents that are directed to use of our FixVac product candidates in the indications of these clinical trials, certain FixVac Platform Filings include specific reference to treatment of each of these indications. Additionally, our patent portfolio relevant to FixVac product candidates further includes U.S. and foreign patent filings relating to use of particular tumor antigens for treatment of triple negative breast cancer included in Phase 1 clinical trials, or the Triple Negative Breast Cancer FixVAC Filings. Issued



Triple Negative Breast Cancer FixVac Filings have, and pending Triple Negative Breast Cancer FixVac Filings, if issued, would have, 20-year terms extending into the early- to mid-2030s, and are jointly owned by BioNTech SE and TRON.

#### iNeST

Our patent filings relevant to our iNeST product candidates include mRNA Structure Filings relating to features for increasing antigen presentation (*e.g.*, antigen-MHC fusions) and features for increasing translation efficiency and/or stability of mRNA constructs (*e.g.*, certain 5' cap structures, 3' UTR structures containing a specific sequence element, and polyA tails of a particular length or interrupted polyA tails); mRNA Lipoplex Filings relating to negatively charged lipoplexes (*e.g.*, for spleen targeting); and mRNA Manufacturing Filings, or collectively, the iNeST mRNA Platform Filings. While we have pursued or obtained patent protection covering components of iNeST product candidates, manufacturing-related methods and/or formulations, we do not currently have any claims in our owned or in-licensed issued patents that cover the overall construct used in our iNeST product candidates.

Our patent portfolio further includes U.S. and foreign filings directed to the process of identifying neoantigens in patient samples and/or predicting those that will be immunoreactive in an iNeST immunotherapy product, or collectively, the Neoantigen Filings. Certain issued Neoantigen Filings have, and certain pending Neoantigen Filings, if issued, would have 20-year terms that extend into the 2030s, although none is a U.S. issued patent. Many of the Neoantigen Filings are solely owned by BioNTech RNA, or jointly owned by BioNTech RNA and TRON; our acquisition of Neon added various Neoantigen Filings, including both BioNTech US-owned and in-licensed filings. BioNTech RNA and TRON jointly own issued EP patent number 2714071, whose claims recite steps relating to neoantigen selection, that has recently been opposed by multiple third parties; claims in the related U.S. case have recently been allowed. If we are unsuccessful in these oppositions, the patent claims for our iNeST product candidates may be narrowed, or a patent may not issue at all. See "Risk Factors—Risks Related to our Intellectual Property" in this Annual Report on Form 20-F.

We are currently studying our iNeST product candidates for the treatment of metastatic melanoma in Phase 2 clinical trials and those for the treatment of various solid tumors in Phase 1 clinical trials. Certain iNeST mRNA Platform Filings and Neoantigen Filings cover treatment of each of these indications. However, we do not currently have any claims in our owned or in-licensed issued patents that are directed to use of iNeST product candidates in the indications of these clinical trials.

#### Intratumoral Immunotherapies

Certain of the mRNA Structure Filings (including some that are relevant to iNeST and/or FixVac product candidates, as discussed above) are also directed to one or more features of our intratumoral immunotherapies, including our most advanced intratumoral immunotherapy, which we are developing through our collaboration with Sanofi, and which has recently entered Phase 1 clinical trials. For example, mRNA Structure Filings relating to 3' UTR structures containing a specific sequence element, interrupted polyA tail structures, and reduced-uracil content mRNAs, which, as noted above are solely or jointly owned by BioNTech and, if issued, would have 20-year terms extending into the mid-2030s, provide protection to our current intratumoral immunotherapy development candidate. However, these filings do not currently include any issued patents.

Certain patent filings that are relevant to intratumoral immunotherapies include certain patent filings under the MRT-CellScript Sublicenses, which include patent filings directed to nucleotide-modified mRNAs.

Additionally, certain patent filings have arisen from our collaboration relating to compositions including mRNAs encoding particular cytokines for treatment of solid tumors, or the mRNA Cytokine Filings. Such mRNA Cytokine Filings, if issued, would have 20-year terms that would extend into 2038. However, these filings do not currently include any issued patents.

#### RiboMabs and RiboCytokines

We own or license a number of patent filings directed to our RiboMab and RiboCytokine programs. Many are owned solely by us, some are jointly owned, and some have been acquired or licensed.

Patent filings relevant to our RiboMab and RiboCytokine programs include certain mRNA Structure Filings relevant to our iNeST and/or FixVac product candidates, specifically relating to 3' UTR structures containing a specific sequence element, interrupted polyA tail structures, and reduced-uracil content mRNAs; mRNA Lipid Nanoparticle/Polyplex Filings; and patent filings under the MRT-CellScript Sublicenses relating to nucleoside-modified mRNAs.

We have also recently acquired patent assets from MabVax Therapeutics Holding, Inc., or the MabVax Filings, that relate to various antibodies, including certain antibodies targeting sialyl Lewis A and ganglioside GD2, as well as nucleic acid encoding them. Issued MabVax Filings have, and the pending MabVax Filings, if issued, would have, 20-year terms that extend into the mid-2030s.

#### Infectious Diseases beyond COVID-19

As is discussed elsewhere, we have collaborated with third parties, including Pfizer and Penn to develop infectious disease mRNA vaccines.

Certain patent filings that might be useful to our infectious disease mRNA vaccines include certain of the mRNA Structure Filings and the mRNA Lipid Nanoparticle/Polyplex Filings as well as certain patent filings under the MRT-CellScript Sublicenses, which include patent filings directed to nucleotide-modified mRNAs. Self-Amplifying RNA Filings as discussed above may also be relevant.

We have also licensed technologies relating to certain lipids and/or lipid nanoparticles and formulations that may be useful for certain infectious disease mRNA vaccines.

#### Rare Diseases

We are developing mRNA-based protein replacement therapy for several rare disease indications through our collaboration with Genevant.

Certain of the mRNA Structure Filings (including some that are relevant to iNeST and/or FixVac product candidates, as discussed above) and patent filings under the MRT-CellScript Sublicenses include patent filings directed to nucleoside-modified mRNAs also provide protection for one or more features of mRNA-based protein replacement product candidates. For example, mRNA Structure Filings include patent filings directed to 3' UTR structures containing a specific sequence element, interrupted poly A tail structures and reduced-uracil content mRNAs, which, as noted above are solely or jointly owned by BioNTech, and, if issued, would have 20-year terms that would extend into the mid-2030s. However, these filings do not currently include any issued patents.

Our patent portfolio relating to our rare disease programs also include certain patent filings that we have licensed from Genevant, or the Genevant Filings. Specifically, the Genevant Filings are owned by Arbutus Biopharma Corporation and relate primarily to lipid or non-liposomal formulations that might be useful in these programs, and have been filed primarily in the United States and Europe, with 20-year terms that extend into mid-2020s to mid-2030s for the issued Genevant Filings and the pending Genevant Filings, if issued.

## **2. Cell Therapy**

### *Engineered Cell Therapy*

Our engineered cell therapy product class features use of chimeric antigen receptor, or CAR-, T cell or individualized T cell receptors for oncology therapy. Our patent filings relevant to these platforms and product candidates, or the CAR-T/TCR Filings, are generally co-owned by BioNTech Cell & Gene Therapies GmbH, or BioNTech C&GT, and TRON. For example, the CAR-T/TCR Filings include patent filings directed to various CAR-T formats and methods of enhancing CAR-T cells by nucleic acid vaccination, as well as patent filings directed to processes of identifying and/or making individualized T cell receptors. The CAR-T/TCR Patent Filings, if issued, would have 20-year terms that would extend into the mid- to late-2030s. However, these filings do not currently include any issued patents.

Certain CAR-T programs involve CAR-T cell product candidates that target different members of the claudin family. Our patent portfolio includes certain patent filings specifically relevant to our claudin-specific CAR-T cell product candidates and are jointly owned by BioNTech C&GT, TRON and Ganymed, or the Claudin-Specific CAR-T Cell Filings. The issued Claudin-Specific CAR-T Cell Filings have, and the pending Claudin-Specific CAR-T Cell Filings, if issued, would have, 20-year terms extending into the mid-2030s. However, these filings do not currently include any U.S. issued patents. The terms of our co-ownership of such patent filings with TRON and Ganymed are summarized below in “—C. In-Licensing.”

### *Activated T Cells*

Our acquisition of Neon included technologies for using peripheral blood mononuclear cells, or PBMCs, (e.g., collected from apheresis material of patients) as a starting material to induce and/or expand *ex vivo* functional T cells specific for therapeutically-relevant neoantigens.

Our BNT221 program, formerly Neon's NEO-PTC-01 program, is a personalized adoptive T cell therapy, which uses multiple T cell populations expanded from an individual patient's PBMCs that together target a set of neoantigens expressed by that patient's tumor.

Patent filings relevant to BNT221, referred to herein as the T Cell Induction/Expansion Filings, are generally solely owned by BioNTech US, or co-owned by BioNTech US and the Netherlands Cancer Institute (NKI). For example, the T Cell Induction/Expansion Filings include patent filings directed to therapeutic T cell compositions and methods of *ex vivo* induction and/or expansion of antigen-specific T cells, for example, using T cells of specific phenotypes for induction/expansion. The T Cell Induction/Expansion Filings, if issued, would have 20-year terms that would extend into the late-2030s to early-2040s. These filings do not currently include any issued patents.

Certain of the Neoantigens Filings may also be relevant to BNT221.

### **3. Antibodies**

Our antibodies product class features bispecific checkpoint immunomodulators for oncology therapy, which are developed through collaboration with Genmab. Our development candidates include bispecific antibodies that are designed to activate 4-1BB upon simultaneous binding to PD-L1 or CD-40. Our patent portfolio includes certain patent filings relevant to such bispecific antibodies, or the Bispecific Checkpoint Modulator Filings, co-owned by us and Genmab. Such Bispecific Checkpoint Modulator Filings, if issued, would have 20-year terms that would extend into the late-2030s and do not currently include any issued patents.

### **4. Small Molecule Immunomodulators**

Our small molecule therapeutics product class features oncology treatment using small molecule product candidates that activate the immune system via TLR7 agonism. Our patent portfolio includes patent filings relevant to these TLR7 agonists, or the TLR7 Agonist Filings. Certain TLR7 Agonist Filings are directed to substituted imidazoquinolines, and, if issued, would have 20-year terms that would extend into the late 2030s. However, these filings do not currently include any issued patents.

### **C. In-Licensing**

Some of our intellectual property assets have been acquired by acquisition and/or in-licensing.

We have pursued a strategy of identifying and in-licensing third-party patents that we believe are complementary to or otherwise interact synergistically with our own intellectual property portfolio. We have entered into material intellectual property licensing or option arrangements with TRON, Louisiana State University and MRT-CellScript.

The key terms of these arrangements are summarized below.

#### ***TRON Agreements***

In 2015, we and our subsidiaries BioNTech RNA, BioNTech Diagnostics GmbH, BioNTech Protein Therapeutics GmbH, BioNTech Cell & Gene Therapies GmbH, Eufets GmbH and JPT Peptide Technologies GmbH entered into a Master Agreement for Research Services with TRON. Concurrently with this Master Agreement for Research Services, or the TRON Research Agreement, we entered into a License Agreement with Ganymed, TRON, Johannes Gutenberg-Universität Mainz and Universitätsmedizin der Johannes Gutenberg-Universität Mainz, or the TRON License Agreement. The TRON Research Agreement and TRON License Agreement together replaced and superseded our 2008 Cooperation, Purchase and Licensing Agreement with the University Mainz, or the 2008 Cooperation Agreement. In 2019, we and our subsidiaries BioNTech RNA Pharmaceuticals GmbH, BioNTech Diagnostics GmbH, BioNTech Protein Therapeutics GmbH, BioNTech Cell & Gene Therapies GmbH, BioNTech Innovative Manufacturing Services GmbH and JPT Peptide Technologies GmbH, entered into a Framework Collaboration Agreement with TRON, or the TRON Collaboration Agreement.

#### **TRON Research Agreement**

Under the TRON Research Agreement, TRON from time to time performs certain services for us under work orders, which may comprise innovative applied research projects, pre-defined research and development or clinical research services. We and TRON meet at regular intervals, but no less than annually, to prepare an overall non-binding project plan, which sets the scope, period and costs for the relevant projects contemplated for that period. Individual work orders set the specific binding terms of each project or service. TRON is obligated to render services in accordance with the scientific standards, all applicable laboratory and legal provisions and with the care customary in the industry.

We are entitled to the exclusive rights to all inventions, methods, specifications, materials, documents, data, know-how and other results (together, the Results) developed or discovered by TRON or by us and TRON jointly under the TRON Research Agreement, except to the extent they constitute improvements of the technologies applied by TRON in the relevant projects. Under the TRON Research Agreement, TRON granted us a non-exclusive, royalty-free license to use TRON Improvements if such TRON Improvements are necessary for the continued development and exploitation of the Results or the manufacture or marketing of products which contain any of the Results and are covered by a patent claiming any of the Results.

Under the TRON Research Agreement, TRON's services rendered in the field of applied research are invoiced at cost. For other services, fixed prices are to be set forth in the individual work orders. TRON invoices us monthly and our payments are due no later than 10 days thereafter. Additionally, we are obligated to pay to TRON low single-digit tiered royalties on net sales of any product developed under the TRON Research Agreement that is covered by a patent claiming any of the Results.

The TRON Research Agreement limits each party's liability to the other to intentional and grossly negligent actions and, in the case of gross negligence, liability for indirect and consequential damages and lost profits is excluded. We are obligated to indemnify TRON for all product liability claims in connection with the products and for third-party claims asserting that the Results violate third-party intellectual property rights.

The TRON Research Agreement has an indefinite term, but may be terminated by either party on six months' notice. If one of our subsidiaries terminates its role in the TRON Research Agreement, the agreement will survive and continue without that subsidiary.

In November 2017, we and TRON entered into an agreement to include certain research and development activities regarding neopeptide RNA immunotherapies as work included in the TRON Research Agreement.

#### **TRON License Agreement**

The TRON License Agreement governs the ownership of and licenses under certain patents, inventions, know-how, technologies and other knowledge (together, the Development Results) filed and created before January 1, 2015 in the course of our collaboration with TRON, Johannes Gutenberg-Universität Mainz and Universitätsmedizin der Johannes Gutenberg-Universität Mainz (collectively, the University Parties) and Ganymed pursuant to the 2008 Cooperation Agreement.

The TRON License Agreement sets forth the parties' rights with respect to the Development Results, mainly depending on which parties have contributed to such Development Results. Ownership of the Development Results and any patents and other intellectual property in certain shares to TRON, on the one hand, and BioNTech and/or Ganymed, on the other hand included therein is allocated. Each party may assign its share in the co-owned Development Results to its affiliates provided that such party provide notice of the transfer and the identity of the new co-owner to the other co-owners. However, in case of an assignment of such share to a third party (except in case of a material asset sale), the assigning party must obligate the assignee to comply with the terms of the TRON License Agreement and the assigning party will remain bound by the obligations of the TRON License Agreement unless the other co-owners have consented to discharge the assigning party from such obligations.

The parties to the TRON License Agreement grant licenses to each other under their shares in the Development Results substantially as follows. Ganymed is exclusively entitled to use the Development Results for certain antibodies and antibody fragments that bind to certain defined targets, or the Ganymed Field of Use. We are exclusively entitled to use the Development Results in any other field of use (including immunological therapeutics, small molecule compounds, siRNA-based therapeutics, micro-proteins, antibody based *in vitro* (except for those in the Ganymed Field of Use), diagnostics and therapeutics based on long-chain RNA as well as other cell therapy applications, immune cells transgenized with

recombinant directed against certain defined targets or chimeric antigene receptors and RNA-based pharmaceuticals). The University Parties may use the Development Results for internal research purposes only. We have an obligation to use reasonable efforts to develop and commercialize products in our field of use worldwide.

Under the TRON License Agreement, we and Ganymed must agree on which party will have the primary role in filing, prosecuting, maintaining and defending jointly owned patents. We and Ganymed each have the exclusive right to enforce the Development Results in our respective fields of use, subject to certain step-in rights of the other parties.

We are obligated to pay to the University Parties low single-digit tiered royalties on net sales on any product that is covered by certain of the patents including in the Development Results. If licenses are granted to third parties, we are obligated to pay to the University Parties a mid-single-digit share of all upfront payments, milestone payments and other remuneration we receive from such third parties in consideration for the license. Regarding upfront payments only, the University Parties' share will be offset against subsequent license fees on net sales. In addition, we are obligated to pay certain development and regulatory milestones up to a low seven-figure amount to Johannes Gutenberg-Universität Mainz.

The TRON License Agreement contains a limitation on liability as between the parties, wherein the parties will only be liable to each other for intentional and grossly negligent actions, and, in the case of gross negligence, liability for indirect and consequential damages and lost profits is excluded. We are obligated to indemnify the University Parties and Ganymed for third-party claims of product liability or violation of applicable law based on our distribution of our products or if we breach the TRON License Agreement or if we or one of our agents acts culpably.

The TRON License Agreement will remain in effect as long as there are any obligations on us or Ganymed to pay license fees. After expiry of the TRON License Agreement, each party will have a perpetual, non-exclusive, royalty-free license to use the Developments Results. The TRON License Agreement may be terminated by any party on six months' notice. The licenses granted between the parties will survive such termination. The TRON License Agreement also grants all parties termination rights for uncured material breaches. If only one party terminates its role in the Agreement, the Agreement will survive and continue between the other parties.

#### ***TRON Collaboration Agreement***

Under the TRON Collaboration Agreement, TRON from time to time undertakes certain projects in collaboration with us under separate project specific agreements, comprising innovative non-clinical research and development projects. We and TRON meet regularly to review and update project plans, and no less than annually to agree the budget for the on-going projects for the coming calendar year. Individual project agreements set the specific binding terms of each project. TRON is obligated to perform its obligations in accordance with the scientific standards, all applicable technical laboratory and legal provisions and with the care customary in the non-clinical biotechnology research industry.

Except for the results of a particular research project which has been funded exclusively by TRON, or the RNT Project, all of the inventions, methods, specifications, materials, documents, data, know-how and other results (together, the Results) developed or discovered by TRON or by us and TRON jointly under the TRON Collaboration Agreement are jointly owned. The Results of the RNT Project are owned exclusively by TRON. Under the TRON Collaboration Agreement, TRON grants us an exclusive, worldwide, sublicensable license under its interest in the Results to research and have researched, develop and have developed, make and have made, use, and otherwise commercialize or have commercialized, and otherwise commercially exploit, products in a field that is specified in the corresponding project agreement. The field of use is either (a) the prophylaxis, diagnosis and treatment of all indications in humans and animals; (b) the prophylaxis, diagnosis and treatment of oncological diseases, infectious diseases and rare genetic diseases; or (c) in the case of the Results from the RNT Project only, the prophylaxis, diagnosis and treatment of rectal neuroendocrine tumors in humans. We are required to use our reasonable efforts to develop and commercialize products that exploit the Results.

Under the TRON Collaboration Agreement, TRON's activities are invoiced at cost. TRON invoices us monthly and our payments are due no later than 10 days thereafter. Additionally, we are obligated to pay to TRON low single-digit tiered royalties on net sales of any product developed under the TRON Collaboration Agreement that is covered by a patent claiming any of the Results or, in certain circumstances, by a patentable invention forming part of the Results which we elect to maintain as a trade secret. If licenses under Results are granted to third parties, we are obligated to pay to TRON a mid-single-digit share of all upfront payments, milestone payments and other remuneration we receive from such third parties in consideration for the license. In addition, we are obligated to pay a one-time only milestone of a low seven-figure

amount to TRON the first time annual sales of a product developed under the TRON Collaboration Agreement reach a low nine-figure number.

The TRON Collaboration Agreement limits each party's liability to the other to cases of willful misconduct and gross negligence and, in the case of gross negligence, liability for indirect and consequential damages and lost profits is excluded. We are obligated to indemnify TRON for all product liability claims in connection with the products and for third-party claims asserting that the Results violate third-party intellectual property rights.

The TRON Collaboration Agreement came into force with retroactive effect from January 2015 and has an indefinite term, but may be terminated by either party on nine months' notice. If one of our subsidiaries terminates its role in the TRON Collaboration Agreement, the agreement will survive and continue without that subsidiary.

#### **LSU License Agreement**

In May 2015, we entered into a Patent License Agreement with the Board of Supervisors of Louisiana State University and Agricultural and Mechanical College, or LSU, and the University of Warsaw, or UW. The agreement (which we refer to as the LSU Agreement) replaces and supersedes the earlier license agreement between the parties.

Under the LSU Agreement, UW and LSU granted to us an exclusive royalty-bearing license under certain patent rights relating to mRNA cap analogs and the synthesis and use of anti-reverse phosphorothioate analogs of the mRNA cap in the United States, certain jurisdictions in the European Union and other countries. As consideration for the license granted, we are obligated to pay running royalties in the low single digits on all net sales of products utilizing the licensed patents and to pay annual maintenance fees to LSU.

We are obligated to use commercially reasonable efforts to develop one or more marketable products utilizing the licensed patents, upon which we would owe additional milestone payments to LSU.

The LSU Agreement remains in effect until expiration of the licensed patents. We have the right to terminate the LSU Agreement for convenience with 60 days' prior notice, and LSU and UW may terminate for our uncured material breach.

#### **CellScript and mRNA Ribotherapeutics License Agreement**

BioNTech RNA entered into the two MRT-CellScript Sublicenses discussed above. Together, the MRT-CellScript Sublicenses grant BioNTech RNA worldwide, non-exclusive sublicenses under the Penn Modified mRNA Patent Rights (as defined in the MRT-CellScript Sublicenses) to research, develop, make, import, use and commercialize products for *in vivo* uses in humans and non-human animals, including therapeutic and prophylactic applications, and for certain uses in the diagnostic and prognostic field of use and certain laboratory research or screening uses. Under these sublicenses, BioNTech RNA has the right to grant sublicenses to affiliates and third parties.

BioNTech RNA must use reasonable efforts to develop and commercialize products under the sublicenses. Furthermore, BioNTech RNA is obliged to pay MRT and CellScript development milestone payments of up to approximately \$26 million as well as royalties in the low to mid-single digits on net sales of licensed products, depending on the field of use.

The agreements continue until the expiration or abandonment of the last licensed patent to expire or be abandoned. BioNTech RNA may terminate the agreement for convenience with respect to all or certain patent rights with 60 days' prior written notice. MRT or CellScript may terminate the respective sublicense agreement for payment default, uncured material breach or the bankruptcy of BioNTech RNA.

#### **D. Trademark Portfolio**

Certain features of our business and our product candidates are protected by trademarks. Our trademark portfolio includes, but is not limited to, registrations for each of COMIRNATY®, FixVac®, IVAC®, RiboCytokine®, RiboMab®, RECON®, NEO-STIM®, Precision NEO-STIM® and MAPTAC®, as well as certain other trademarks, including design versions of some of these trademarks.

#### **E. Trade Secret Protection**

Certain of our technologies, including in particular certain proprietary manufacturing processes or technologies and/or neoantigen prediction technologies, are protected as trade secrets.

In addition to patent protection, we rely upon unpatented trade secrets and confidential know-how and continuing technological innovation to develop and maintain our competitive position. We protect certain of our technologies, including, in particular, certain proprietary manufacturing processes and technologies and/or neoantigen prediction technologies, as trade secrets. However, trade secrets and confidential know-how are difficult to protect. We seek to protect our proprietary information, in part, by using confidentiality agreements with any future collaborators, scientific advisors, employees and consultants, and invention assignment agreements with our employees. We also have agreements requiring assignment of inventions with selected consultants, scientific advisors and collaborators. These agreements may not provide meaningful protection. These agreements may also be breached, and we may not have an adequate remedy for any such breach. In addition, our trade secrets and/or confidential know-how may become known or be independently developed by a third party, or misused by any collaborator to whom we disclose such information. Despite any measures taken to protect our intellectual property, unauthorized parties may attempt to copy aspects of our products or to obtain or use information that we regard as proprietary. Although we take steps to protect our proprietary information, third parties may independently develop the same or similar proprietary information or may otherwise gain access to our proprietary information. As a result, we may be unable to meaningfully protect our trade secrets and proprietary information.

#### **XV. Competition**

We compete in an industry characterized by rapidly advancing technologies, intense competition and a complex intellectual property landscape. We face substantial competition from many different sources, including large and specialty pharmaceutical and biotechnology companies, academic research institutions and governmental agencies and public and private research institutions.

Many of our competitors and potential competitors, either alone or with their collaborators, have greater scientific, research and product development capabilities as well as greater financial, marketing, sales and human resources and experience than we do. In addition, smaller or early-stage companies, including immunotherapy-focused therapeutics companies, may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Some of our collaborators, such as Genmab, Pfizer and Sanofi, may also be competitors within the same market or other markets. Accordingly, our competitors may be more successful than us in developing and potentially commercializing technologies and achieving widespread market acceptance. In addition, our competitors may design technologies that are more efficacious, safer or more effectively marketed than ours or have fewer side effects, or may obtain regulatory approvals more quickly than we are able, which could eliminate or reduce our commercial potential. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

We anticipate that the key competitive factors affecting our technologies will be efficacy, safety, cost and convenience, ease of distribution, storage and administration, as well as our ability to build a fully-integrated biotechnology company. The availability of reimbursement from government and other third-party payors will also significantly affect the pricing and competitiveness of our products. The timing of market introduction of our products and competitive products will also affect competition among products. We expect the relative speed with which we can develop our products, complete the clinical trials and approval processes, and supply commercial quantities of the products to the market to be important competitive factors. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market.

Specifically, BNT162b2 competes with, and any other COVID-19 vaccines we and Pfizer develop would compete with, other COVID-19 vaccines that have been approved or authorized for temporary or emergency use and a large number of vaccine manufacturers, academic institutions and other organizations currently have programs to develop COVID-19 vaccine candidates.

#### **XVI. Legal Proceedings**

From time to time, we may be involved in legal proceedings in the ordinary course of business. We are currently not a party to any material legal or administrative proceedings. In addition, we are not aware of any material legal or administrative proceedings contemplated to be brought against us. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

**C. Organizational Structure**

See Item 18.

**D. Property, Plant and Equipment**

Our headquarters are located in Mainz, Germany, where we occupy:

- Approximately 9,416 square meters (equivalent to approximately 101,353 square feet) of laboratory, GMP manufacturing, storage and office space under a lease for the entire building located at An der Goldgrube 12, 55131 Mainz under a lease that has an initial term that expires on October 31, 2027, but which we have the option to extend until October, 2042.
- Approximately 1,069 square meters (equivalent to approximately 11,507 square feet) of office and GMP manufacturing space under a lease for part of the building located at Kupferbergterrasse 15, 17019, 44116 Mainz under a lease that expires in March 31, 2022.
- Approximately 4,882 square meters (equivalent to approximately 52,549 square feet) of flexible use space intended for laboratory and office use located at Adam-Opel-Straße 10, 55129 Mainz, which is owned by us.
- Approximately 210,639 square meters (equivalent to approximately 22,673 square feet) of office and storage space under a lease for part of the building located at Robert-Koch- Straße 50, 55129 Mainz under a lease that expires in November 15, 2025.
- Approximately 82,881 square meters (equivalent to approximately 892,124 square feet) of office space and a further area of land associated with this office space of approximately 12,600 square meters (equivalent to approximately 135,625 square feet), which is owned by BioNTech.
- Approximately 360 square meters (equivalent to approximately 3,875 square feet) of office space under a lease for part of the building located at Heiligkreuzweg 90, 55130 Mainz under a lease that expires in December 31, 2022.
- We also own a plot of land of approximately 8,753 square meters (equivalent to 94,216 square feet) at Hechtsheimer Straße, 55131 Mainz, where construction for a GMP manufacturing facility has commenced early this year.

In addition, our BioNTech IMFS facility in Idar-Oberstein, Germany, occupies approximately 2,800 square meters (equivalent to approximately 30,140 square feet). This includes 650 square meters (approximately 7,000 square feet) of clean room area, and 700 square meters (approximately 7,500 square feet) of development and quality control laboratories. We occupy approximately 575 square meters (equivalent to approximately 6,200 square feet) of this space, which is used primarily for storage, under a lease that has an initial expiry date of October 1, 2021, but which we have the right to extend by an additional five years. We occupy approximately 100 square meters (equivalent to approximately 1,075 square feet) of this space, which is used primarily for storage, under a lease that can be terminated by either party on six months' written notice (but not earlier than May 1, 2020). We occupy approximately 80 square meters (equivalent to approximately 860 square feet) of this space, which is used as office space, under a lease that can be terminated by either party on three months' written notice. The rest of this facility, including the GMP-certified manufacturing suites, is owned by BioNTech. We also recently purchased a building of approximately 802 square meters (equivalent to 8,632 square feet) near our IMFS facility in Idar-Oberstein, which will be used as office space.

We have completed construction of two new buildings at our BioNTech IMFS facility in Idar-Oberstein, Germany, occupy an additional 780 square meters (equivalent to approximately 8,395 square feet) of clean room space and 550 square meters (equivalent to approximately 5,900 square feet) of laboratory space, expanding our capacity for GMP cell therapy manufacturing and 650 square meters (equivalent to approximately 7,000 square feet) of office space.

At our manufacturing facility in Marburg, Germany, we occupy approximately 10,240 square meters (equivalent to approximately 110,220 square feet), including 4,589 square meters (equivalent to approximately 49,400 square feet) of GMP space, 2,422 square meters (equivalent to approximately 26,070 square feet) of technical and storage facilities, 540 square meters (equivalent to approximately 5,810 square feet) of laboratory space and 2,690 square meters (equivalent to approximately 28,960 square feet) of offices. That lease will expire December 31, 2034.



At our JPT facility in Berlin, Germany, we occupy approximately 1,794 square meters (equivalent to approximately 19,299 square feet) of office, laboratory and other space. Approximately 250 square meters of that space (equivalent to approximately 2,690 square feet) is occupied under a lease, which has an expiry date of June 20, 2020 and will continue for further six-month periods, unless terminated by either party on three months' prior written notice. Approximately 1,523 square meters (equivalent to approximately 16,199 square feet) are occupied under a lease for an indeterminate period but which may be terminated by either party on 12 months' prior written notice. The remaining approximately 20 square meters (equivalent to approximately 215 square feet) of storage space is occupied under a lease on a monthly basis and can be terminated by either party giving two weeks' written notice.

In Martinsried, Germany, outside Munich, Germany, we occupy approximately 1,681 square meters (equivalent to approximately 18,100 square feet) under a lease that had an initial term which expired on December 31, 2020, but which we exercised the option to extend until December 31, 2024.

In Neuried, Germany, outside Munich, Germany, we occupy approximately 725 square meters (equivalent to approximately 7,800 square feet) of laboratory and office space under a lease that expires on December 31, 2021, but which we have the option to extend until December 31, 2026. If the lease is not terminated before December 31, 2021 (where the option is not exercised) or December 31, 2026 (where the option is exercised) the lease will renew automatically for an additional one-year period until terminated by either party on 12 months' prior written notice.

In Halle (Saale), Germany, we have since the beginning of 2020 occupied approximately 415 square meters (equivalent to approximately 4,467 square feet) of office and other space under a lease that expires on February 28, 2022. We further occupy 90 square meters (equivalent to approximately 968 square feet) of laboratory space under a lease that also expires on February 28, 2022. Each lease will renew automatically for an additional one-year period until terminated by either party on six months' prior written notice to expire at the end of the lease period (or any extension thereof).

In Cambridge, Massachusetts we occupy approximately 2,490 square meters (equivalent to approximately 26,802 square feet) of laboratory and office space under a lease that has an initial term that expires on September 30, 2024, but which we have the option to extend until December 31, 2024.

We intend to expand our capacity as follows:

- In the second quarter of 2021, we will commence construction of a four-story building at our BioNTech Campus at An der Goldgrube 12 in Mainz, Germany, which we will own. We have planned laboratory space for research and development, offices, storage facilities, a conference center and cafeteria. As a result, we will occupy an additional 24,000 square meters (equivalent to approximately 258,300 square feet) of laboratory space and office space.
- We anticipate purchasing property and the construction of a new office building adjacent to the planned iNeST GMP manufacturing facility. Upon completion of the construction project, we will occupy up to approximately 6100 additional square meters (equivalent to approximately 65,650 square feet) of useable floor space for offices, storage, meeting areas and cafeteria.
- We anticipate completing the construction of a new building complex for our JPT business in Berlin, Germany, possibly as early as 2023. Upon completion of the construction project, we will occupy up to approximately 5,000 additional square meters (equivalent to approximately 53,820 square feet) of useable floor space split between laboratories, offices and storage.

We are committed to the continued development of world-class laboratory and manufacturing operations to support our research and development and clinical manufacturing needs, to prepare for commercial scale manufacturing of our product candidates, and to realize external commercial opportunities. Our planned laboratory and manufacturing investments include:

- two new buildings at our BioNTech IMFS facility, including three floors each of clean rooms and additional development and quality control laboratories;
- our planned commercial scale facility in Mainz, which will occupy more than 100,000 square feet and will house cleanrooms, laboratories and offices;
- an expansion of our JPT facility, which is designed to more than double our capacity; and
- an expansion of our laboratory space for research and development on our Mainz campus.

**Item 4A. Unresolved Staff Comments**

There are no written comments from the staff of the U.S. Securities and Exchange Commission which remain unresolved before the end of the fiscal year to which the Annual Report relates.

**Item 5. Operating and Financial Review and Prospects**

The following "Operating and Financial Review and Prospects" should be read together with the information in our financial statements and related notes included elsewhere in this Annual Report. The following discussion is based on our financial information prepared in accordance with the International Financial Reporting Standards, or IFRS, as issued by the International Accounting Standards Board, or IASB, which may differ in material respects from generally accepted accounting principles in other jurisdictions, including U.S. GAAP. The following discussion includes forward-looking statements that involve risks, uncertainties and assumptions. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of many factors, including but not limited to those described in "Risk Factors" and elsewhere in this Annual Report. Please also see "Cautionary Statement Regarding Forward-Looking Statements."

**A. Operating Results****Financial Operations Overview**

The following table shows our consolidated statements of operations for each period presented:

<i>(in thousands)</i>	Years ended December 31,		
	2020	2019	2018
Revenues			
Research & development revenues	€178,849	€84,428	€101,837
Commercial revenues	303,476	24,161	25,738
<b>Total revenues</b>	<b>482,325</b>	<b>108,589</b>	<b>127,575</b>
Cost of sales	(59,333)	(17,361)	(13,690)
Research and development expenses	(645,029)	(226,466)	(143,040)
Sales and marketing expenses	(14,512)	(2,718)	(3,041)
General and administrative expenses	(94,049)	(45,547)	(26,334)
Other operating expenses	(2,358)	(739)	(720)
Other operating income	250,539	2,724	5,396
<b>Operating loss</b>	<b>€(82,417)</b>	<b>€(181,518)</b>	<b>€(53,854)</b>
Finance income*	1,564	4,122	8,046
Finance expenses*	(62,946)	(326)	(48)
Interest expenses related to lease liabilities	(2,003)	(1,718)	(1,721)
Share of loss of equity method investees	-	-	(84)
<b>Loss before tax</b>	<b>€(145,802)</b>	<b>€(179,440)</b>	<b>€(47,662)</b>
Income taxes	161,000	268	(600)
<b>Profit / (Loss) for the period</b>	<b>€15,198</b>	<b>€(179,172)</b>	<b>€(48,262)</b>

\* Foreign exchange differences on a cumulative basis are either shown as finance income or expenses.

**Important Financial and Operating Terms and Concepts****Revenues**

Historically, our revenue has primarily been derived from our collaborations and license agreements in the research and development phase. Research and development revenues were derived from upfront payments, development milestone payments and reimbursement of development expenses.

Since December 2020, our COVID-19 vaccine has been authorized or approved for emergency or temporary use or granted conditional marketing authorization in over 65 countries worldwide, which resulted in recognition of revenues from the sale of pharmaceutical products for the first time. Consequently, we have progressed from earning revenues primarily for research and development to earning our first revenues from commercial sales.

Our commercial revenues are primarily collaboration revenues from earnings based on our partners' gross profit, which is shared under the respective collaboration agreements and sales milestone payments in addition to revenue from other sales transactions, which consists of sales of diagnostic products, peptides, retroviral vectors for clinical supply, and development and manufacturing services sold to third-party customers. We recognize revenues from selling COVID-19 vaccine manufactured by us to collaboration partners for further processing and to external customers in markets within our territory. Revenues for our share of the collaboration partners' profit is recognized as sales occur which is when the performance obligation has been satisfied. As described further in "Critical Accounting Policies and Use of Estimates" and Note 3 to our consolidated financial statements included elsewhere in this Annual Report, we use certain information from our collaboration partners, some of which is based on preliminary data shared between the partners and might vary once final data is available.

Our ability to generate revenue from sales of pharmaceutical products and sustain profitability depends upon our and our collaborators' ability to further successfully commercialize our product candidates and products. Our ability to generate COVID-19 vaccine revenues depends, in part, upon our production capacity. The timing of product manufacturing and delivery will determine the period in which revenue may be recognized.

To the extent that existing or potential future collaborations generate revenue, our revenue may vary due to many uncertainties in the development of further product candidates and other factors.

For further information on our revenue recognition policies, see "—Critical Accounting Policies and Use of Estimates—Revenue Recognition."

#### *Cost of sales*

Our cost of sales includes royalty expenses, purchased services, personnel-related expenses and laboratory supplies, which are generally expensed in the period in which the associated revenue occurs. Cost of sales also includes amounts paid to collaboration partners for their share of profits earned in collaboration arrangements where we are the principal in the transaction.

Our cost of sales may increase subject to us progressing our commercial activities with respect to our COVID-19 vaccine.

#### *Research and Development Expenses*

The nature of our business and primary focus of our activities, including development of our platforms and manufacturing technologies, generate a significant amount of research and development expenses, which in this respect, still account for the largest component of our total operating expenses. Research and development expenses include our share of expenses under the terms of collaboration agreements and 100% of the expenses for wholly-owned product candidates. Research and development expenses shared under our collaboration agreements, which are initially incurred by the collaboration partners and subsequently charged to us, are recorded as purchased services classified within research and development. Cost reimbursements from partners for research and development expenses initially incurred by us and due to us under the agreements, are recorded as a reduction to purchased services classified within research and development expenses.

We have entered into agreements under which third parties grant licenses to us. Consideration paid under those agreements include upfront payments, development milestone payments and development expense reimbursements as well as sales-based milestone and royalty payments. Milestone payments are recorded when the specific milestone has been achieved. If those licenses grant access to technologies, both parties jointly perform research or development activities and both are exposed to significant risks and rewards of the activities. Costs incurred with the agreements are not treated differently from costs related to own product candidates. If the agreements grant us rights to use certain patents and technologies that meet the definition of an identifiable assets, they are treated as acquired intangible assets. This assessment is made based on the facts and circumstances of each contractual agreement.

The value of goods and services received from contract research organizations, or CROs, and contract manufacturing organizations, or CMOs, in the reporting period are estimated based on the level of services performed and progress made in the respective period. Amounts are recorded as accrued expenses if we have not received an invoice from the service provider. Advance payments for goods or services that will be used or rendered for future research and development activities are recognized as other current assets or other current financial assets respectively. The amounts are currently expensed as the related goods are delivered or the services performed. Management's estimates are based on the best information available at the time. However, additional information may become available in the future and management may adjust the estimate in such future periods. In this event, we may be required to record adjustments to research and development expenses in future periods when the actual level of activity becomes more certain. We consider resulting increases or decreases in cost as changes in estimates and reflects such changes in research and development expenses in the period identified.

Research costs are expensed as incurred. Development expenditures on an individual project are recognized as an intangible asset if, and only if, the capitalization criteria are met. Due to the inherent risk of failure in pharmaceutical development and the uncertainty of approval, management has determined that these criteria are not met in the biotech sector. The related expenditure is reflected in the consolidated statements of operations in the period in which the expenditure is incurred. Sales-based milestone or royalty payments incurred under license agreements relating to self-developed intangibles after the approval date of the respective pharmaceutical product are considered as contingent considerations. These contingent considerations are recognized as expenses as incurred. Costs relating to production of pre-launch products are expensed as research and development expenses in the period incurred. If pre-launch products are sold, the respective product gross margin may be higher compared to the expected recurring margin as the underlying costs will not be included in cost of sales.

Research and development expenses represent costs incurred for the following:

- costs to develop our platforms;
- discovery efforts leading to product candidates;
- clinical development expenses for our programs;
- costs related to pre-launch products;
- costs to develop our manufacturing technology and infrastructure; and
- digital infrastructure costs.

The costs above comprise the following categories:

- personnel-related expenses, including salaries, benefits, share-based compensation expense and social security expense;
- shared development expenses incurred under collaboration agreements with our partners;
- expenses incurred under agreements with third parties, such as consultants, investigative sites, CROs that conduct our preclinical studies and clinical trials, and in-licensing arrangements;
- costs of acquiring, developing and manufacturing materials for preclinical studies and clinical trials, including both internal manufacturing and CMO;
- expenses incurred for the procurement of materials, laboratory supplies and non-capital equipment used in the research and development process; and
- facilities, depreciation and amortization, and other direct and allocated expenses incurred as a result of research and development activities.

We cannot reasonably estimate the nature, timing and amount of research and development expenses required to complete the development of the product candidates we are currently developing or may develop in the future. A change in expectations or outcomes of any of the known or unknown risks and uncertainties may materially impact our expected research and development expenditures.

Continued research and development is central to the ongoing activities of our business. Product candidates in later stages of clinical development generally have higher development expenses than those in earlier stages of clinical

development, primarily due to the increased size and duration of later-stage clinical trials. We expect these costs to continue to increase in the future as our product candidates progress through the development phases and as we identify and develop additional programs. However, we do not believe that it is possible at this time to accurately project total program-specific expenses through commercialization. There are numerous factors associated with the successful commercialization of any of our product candidates or products, including future trial design and various regulatory requirements, many of which cannot be determined with accuracy at this time based on our stage of development. Additionally, future commercial and regulatory factors beyond our control will impact our clinical development programs and plans.

#### *Sales and Marketing Expenses*

Our sales and marketing expenses mainly consist of purchased services and personnel-related costs.

Our sales and marketing expenses may increase subject to us progressing our commercial activities with respect to our COVID-19 vaccine.

#### *General and Administrative Expenses*

General and administrative expenses consist primarily of personnel-related costs including salaries, benefits, share-based compensation expense and social security expense for finance, legal, human resources, business development and other administrative and operational functions, professional fees, accounting and legal services, information technology and facility-related costs. These costs relate to the operation of the business, unrelated to the research and development function or any individual program.

We anticipate general and administrative expenses will increase as research, development and commercial activities expand. This increase will likely relate to additional personnel and increased purchased service costs related in part to finance, legal and intellectual property-related matters along with increased expenses related to administrating our commercial activities with respect to our COVID-19 vaccine.

#### *Other Operating Income / Expenses*

Our other operating income and expenses consists primarily of income from government grants.

#### *Finance Income / Expenses*

Our finance income and expenses consist of interest income and interest expenses on cash, fair value changes on certain financial liabilities as well as foreign exchange gains and losses.

#### *Income Taxes*

Income taxes mainly include deferred tax benefits derived from recording deferred tax assets on differences between financial reporting and tax bases of assets and liabilities tax loss carry forwards.

The realization of deferred tax assets is dependent upon the generation of future taxable income, the amount and timing of which are subject to uncertainties. We may become subject to income tax audits and adjustments by local tax authorities. The assessments as to the recoverability of deferred tax assets and the nature of uncertain tax positions is subject to significant judgment by management and subject to change, which may be substantial.

For further information on our income tax policies, see “—Critical Accounting Policies and Use of Estimates—Income Tax.”

Comparison of the year ended December 31, 2020 and year ended December 31, 2019

Revenues

The following is a summary of revenues recognized for the periods indicated:

(in thousands)	Years ended December 31,		Change	
	2020	2019	€	%
<b>Revenues</b>				
<b>Research &amp; development revenues from collaborations</b>	<b>€178,849</b>	<b>€84,428</b>	<b>€94,421</b>	<b>112</b>
Pfizer Inc.	121,597	14,348	107,249	747
Genentech Inc.	49,195	64,026	(14,831)	(23)
Shanghai Fosun Pharmaceutical (Group) Co., Ltd	5,074	-	5,074	-
Other	2,983	6,054	(3,071)	(51)
<b>Commercial revenues</b>	<b>303,476</b>	<b>24,161</b>	<b>279,315</b>	<b>1,156</b>
COVID-19 vaccine revenues	270,490	-	270,490	-
Sales to collaboration partner*	61,460	-	61,460	-
Direct product sales to BioNTech customers	20,553	-	20,553	-
Share of collaboration partner's gross profit	188,477	-	188,477	-
Other sales	32,986	24,161	8,825	37
<b>Total revenues</b>	<b>€482,325</b>	<b>€108,589</b>	<b>€373,736</b>	<b>344</b>

\*Represents sales to our collaboration partner of products manufactured by us.

From the year ended December 31, 2019 to year ended December 31, 2020 total revenues from contracts with customers increased by €373.7 million or 344% from €108.6 million to €482.3 million, which is mainly due to revenues recognized for the first time under our two new collaboration agreements which we entered into during the year ended December 31, 2020 in order to develop a COVID-19 vaccine and ultimately led to the recognition of COVID-19 vaccine commercial revenues.

*Research & Development Revenues from Collaborations*

As part of our BNT162 program we collaborate with Pfizer and Fosun Pharma.

Revenue from Pfizer was mainly derived from the collaboration and license agreement to develop a COVID-19 vaccine and, in addition, includes an amount of €3.5 million revenue derived from our existing Influenza collaboration. During the year ended December 31, 2020 a non-refundable upfront cash payment of €66.3 million was received. A regulatory milestone payment of €51.8 million became due, but has not yet been received. Both were fully recognized as revenue during the year ended December 31, 2020.

Fosun Pharma is the collaboration partner with whom we work together on the development of a COVID-19 vaccine in China. Through the collaboration agreement, we are conducting clinical trials in China, using BioNTech's proprietary mRNA technology and leveraging Fosun Pharma's extensive clinical development, regulatory, and commercial capabilities in the country. Fosun Pharma has paid a non-refundable upfront cash payment of €0.9 million and development milestones of €4.2 million that were recognized as revenue during year ended December 31, 2020.

For certain collaboration programs, the commencement of trials has been delayed, partially due to slowed patient enrollment or other delays as a result of the COVID-19 pandemic. Accordingly, during the year ended December 31, 2020, revenues from our collaboration programs with Genentech, Sanofi and from the Influenza collaboration with Pfizer have generally decreased compared to the prior year periods.

*Commercial Revenues*

Our COVID-19 vaccine has evolved from the BNT162 program and has been authorized or approved for emergency or temporary use or has been granted conditional marketing authorization in over 65 countries worldwide, which resulted in recognition of revenues from the sale of pharmaceutical products for the first time. We are the marketing authorization holder in the European Union, and holder of emergency use authorizations or equivalent in the United States, United

Kingdom, Canada and other countries in advance of a planned application for full marketing authorizations in these countries. We have marketing and distribution rights in Germany and Turkey. Pfizer has marketing and distribution rights worldwide with the exception of China, Germany and Turkey. Fosun Pharma has marketing and distribution rights in China.

The COVID-19 vaccine manufacturing process leverages Pfizer's and our manufacturing facilities, consequently responsibilities are shared between Pfizer and us. Whenever responsibilities in the manufacturing and supply process of the COVID-19 vaccine shift and the COVID-19 vaccine is transferred, it is sold from one partner to the other. During the year ended December 31, 2020, we recognized €61.5 million of revenues from selling drug product batches manufactured by us to Pfizer's manufacturing site for fill and finish.

Upon receiving a conditional marketing authorization, emergency or temporary use authorization, we and Pfizer started selling the product. The allocation of marketing and distribution rights defines territories in which the collaboration partners act as a principal respectively. For supplying our territory, Germany, we acquired the COVID-19 vaccine from Pfizer and recognized €20.6 million of revenues from direct COVID-19 vaccine sales during the year ended December 31, 2020. The share of gross profit that our collaboration partner has earned based on these sales, is recognized as cost of sales.

Based on Pfizer's COVID-19 vaccine sales in the collaboration partner's territory, we are eligible to receive a share of the respective gross profit which represents a net figure and is recognized as collaboration revenues during the commercial phase. During the year ended December 31, 2020, we recognized a gross profit share of €188.5 million. In order to determine our share of collaboration partner's gross profits, we used certain information from our collaboration partner, including revenue from the sale of products, some of which is based on preliminary data shared between the partners and might vary once final data is available.

Revenues resulting from other sales transaction increased by €8.8 million, or 36%, to €24.2 million in the year ended December 31, 2019 to €33.0 million in the year ended December 31, 2020.

#### Cost of Sales

The following table summarizes our cost of sales for the periods indicated:

(in thousands)	Years ended December 31,		Change	
	2020	2019	€	%
<b>Cost of sales</b>				
Cost of sales related to COVID-19 vaccine revenues	€35,616	-	€35,616	-
Cost related to other sales	23,717	17,361	6,356	37
<b>Total cost of sales</b>	<b>€59,333</b>	<b>€17,361</b>	<b>€41,972</b>	<b>242</b>

From the year ended December 31, 2019 to the year ended December 31, 2020, cost of sales increased by €41.9 million or 241% from €17.4 million to €59.3 million. Cost of sales were recognized for the first time with respect to our COVID-19 vaccine sales and included Pfizer's share of gross profit earned by us in transactions, where we are the principal. Costs of sales do not include costs relating to production of pre-launch products since those are expensed as research and development expenses in the period incurred.

Research and Development Expenses

The following table summarizes our research and development expenses for the periods indicated:

(in thousands)	Years ended December 31,		Change	
	2020	2019	€	%
<b>Research and development expenses</b>				
Purchased services	€359,880	€65,552	€294,328	449
Wages, benefits and social security expense	126,298	83,213	43,085	52
Laboratory supplies	107,792	37,218	70,574	190
Depreciation and amortization	30,192	27,533	2,659	10
IT costs	5,118	3,800	1,318	35
Lease and lease related cost	3,725	2,527	1,198	47
Transport costs	2,135	1,081	1,054	98
Other	9,889	5,542	4,347	78
<b>Total research and development expenses</b>	<b>€645,029</b>	<b>€226,466</b>	<b>€418,563</b>	<b>185</b>

Research and development expenses increased by €418.5 million or 185% from €226.5 million during the year ended December 31, 2019 to €645.0 million during the year ended December 31, 2020. The increase was mainly due to an increase in research and development expenses from our BNT162 program. Research and development expenses include our share of expenses under the terms of the Pfizer collaboration agreement. Development costs, which are shared, are divided equally between Pfizer and us. The amount of shared development expenses, which were initially incurred by Pfizer and subsequently charged to us were recorded as purchased services classified within research and development and the reimbursement from Pfizer for research and development expenses initially incurred by us were recorded as a reduction to research and development expenses. The increase was further driven by an increase in expenses for purchased laboratory supplies as well as an increase in headcount leading to higher wages, benefits and social security expenses. In addition, from May 6, 2020, the date of acquisition, our new U.S.-based subsidiary, BioNTech US Inc., contributed €21.0 million to the research and development expenses of the Group.

Sales and Marketing Expenses

The following table summarizes our sales and marketing expenses for the periods indicated:

(in thousands)	Years ended December 31,		Change	
	2020	2019	€	%
<b>Sales and marketing expenses</b>				
Purchased services	€10,929	€247	€10,682	4,325
Wages, benefits and social security expense	1,636	1,938	(302)	(16)
Other	1,947	533	1,414	265
<b>Total sales and marketing expenses</b>	<b>€14,512</b>	<b>€2,718</b>	<b>€11,794</b>	<b>434</b>

Sales and marketing expenses increased by €11.8 million or 437% from €2.7 million during the year ended December 31, 2019 to €14.5 million during the year ended December 31, 2020 which is mainly due to an increase in purchased service which we incurred in connection with progressing our commercial activities with respect to our COVID-19 vaccine.



General and Administrative Expenses

The following table summarizes our general and administrative expenses for the periods indicated:

(in thousands)	Years ended December 31,		Change	
	2020	2019	€	%
<b>General and administrative expenses</b>				
Wages, benefits and social security expense	€33,007	€19,122	€13,885	73
Purchased services	26,022	6,419	19,603	305
IT and office equipment	7,404	4,573	2,831	62
Depreciation and amortization	5,104	4,855	249	5
Insurance premiums	4,840	1,061	3,779	356
Job advertisement expenses	2,897	548	2,349	429
Lease and lease related cost	2,390	1,715	675	39
Research services	2,033	232	1,801	776
Laboratory supplies	1,191	785	406	52
Contract staffing	1,108	686	422	62
Other	8,053	5,551	2,502	45
<b>Total general and administrative expenses</b>	<b>€94,049</b>	<b>€45,547</b>	<b>€48,502</b>	<b>106</b>

General and administrative expenses increased by €48.5 million or 107% from €45.5 million during the year ended December 31, 2019 to €94.0 million during the year ended December 31, 2020. The increase was mainly influenced by higher expenses for purchased management consulting and legal services, an increase in headcount leading to higher wages, benefits and social security expenses and higher insurance premiums. In addition, from May 6, 2020, the date of acquisition, our new U.S.-based subsidiary, BioNTech US Inc., contributed €7.4 million to the general and administrative expenses of the Group, respectively.

Other Operating Income / Expenses

The following table summarizes our other result, including other operating income and expenses, for the periods indicated:

(in thousands)	Years ended December 31,		Change	
	2020	2019	€	%
<b>Other result</b>				
Government grants	€239,017	€1,547	€237,470	15,350
Bargain purchase	7,002	-	7,002	-
Other operating income	4,520	1,177	3,343	284
<b>Other operating income</b>	<b>250,539</b>	<b>2,724</b>	<b>247,815</b>	<b>9,097</b>
Other operating expenses	(2,358)	(739)	(1,619)	219
<b>Other operating expenses</b>	<b>(2,358)</b>	<b>(739)</b>	<b>(1,619)</b>	<b>219</b>
<b>Total other result</b>	<b>€248,181</b>	<b>€1,985</b>	<b>€246,196</b>	<b>12,403</b>

Our other result increased by €246.2 million from €2.0 million during the year ended December 31, 2019 to €248.2 million during the year ended December 31, 2020. The increase mainly results from government grants for which we became eligible as part of an initiative by the German Federal Ministry of Education (*Bundesministerium für Bildung und Forschung*, or the BMBF) to support our COVID-19 vaccine program, BNT162 (as described below in "—Liquidity and Capital Resources"). The proportion of the grant that related to expenses incurred by us is recognized as other operating income with an amount of €238.9 million; the proportion which was received and will compensate us for future expenses, has been deferred and is presented as government grant in the consolidated statements of financial position with an amount of €88.0 million.

The following table summarizes our finance result for the periods indicated:

(in thousands)	Years ended December 31,		Change €	%
	2020	2019		
<b>Finance result</b>				
Interest income	€1,564	€1,781	€(217)	(12)
Foreign exchange gains, net	-	2,341	(2,341)	(100)
<b>Finance income</b>	<b>1,564</b>	<b>4,122</b>	<b>(2,558)</b>	<b>(62)</b>
Amortization of financial instruments	(3,048)	(326)	(2,722)	835
Fair value adjustments of financial instruments measured at fair value	(17,289)	-	(17,289)	-
Foreign exchange loss, net	(42,609)	-	(42,609)	-
<b>Finance expenses</b>	<b>(62,946)</b>	<b>(326)</b>	<b>(62,620)</b>	<b>19,209</b>
<b>Interest expenses related to lease liabilities</b>	<b>(2,003)</b>	<b>(1,718)</b>	<b>(285)</b>	<b>17</b>
<b>Total finance result</b>	<b>€(63,385)</b>	<b>€2,078</b>	<b>€(65,463)</b>	<b>(3,150)</b>

Our financial result decreased by €65.5 million from €2.1 million finance income, net during the year ended December 31, 2019 to €63.4 million finance expenses, net during the year ended December 31, 2020. The latter included €17.3 million in expenses arising from fair value measurement adjustments of the derivative embedded within the convertible note. Furthermore, there were €42.6 million in foreign exchange losses that occurred during the year ended December 31, 2020 compared to €2.3 million foreign exchange gains that had been recorded during the year ended December 31, 2019. Foreign exchange differences on a cumulative basis, are either shown as finance income or expenses. The increase in foreign exchange losses is mainly due to higher balances in U.S. dollar bank accounts and the weakening of the U.S. dollar when compared to the Euro.

#### Income Taxes

As of December 31, 2020, we had accumulated tax losses with respect to corporate tax and trade tax. Our accumulated tax losses amounted to €596.4 million with respect to corporate income tax and €513.6 million with respect to trade tax comprising tax losses of our German tax group, German entities not within the tax group and our U.S. tax group.

The accumulated tax losses related to the German tax group include €457.9 million corporate income tax losses and €450.9 million trade tax losses. Under German law, tax losses do not expire. Deferred tax assets on tax losses had not been capitalized in previous years, as there was not sufficient probability in terms of IAS 12 that there would have been future taxable profits available against which the unused tax losses could have been utilized. Following the authorization and approval of our COVID-19 vaccine for emergency or temporary use or having been granted conditional marketing authorization in over 65 countries worldwide, we re-evaluated previously unrecognized tax losses. Based on our product-based business plan, including commercial supply commitments agreed with various governments and health ministries under which we either directly supply the COVID-19 vaccine or, if they relate to territories which have been allocated to Pfizer, we will receive the profit share to which we are eligible, it is now considered highly probable that taxable profits for the German tax group will be available against which the tax losses can be utilized. On this basis, we have recognized deferred tax assets and liabilities with a net amount of €161.0 million for the cumulative tax losses and temporary differences determined for the German tax group as of December 31, 2020.

The accumulated tax losses related to German entities not within the tax group include €1.7 million corporate income tax losses and €1.8 million trade tax losses. With respect to those tax losses, no deferred tax assets have been capitalized, as there is not sufficient probability in terms of IAS 12 that there will be future taxable profits available against which the unused tax losses can be utilized.

The accumulated tax losses related to U.S. tax group include €136.8 million federal tax losses and €60.9 million state tax losses. The tax losses related to the U.S. tax group include €20.9 million federal losses that are expected to expire in 2033 and €115.9 million federal losses which have no expiration date and can be carried forward indefinitely. In addition, the U.S. tax group has state tax losses of €60.9 million, which may be available to offset future income tax liabilities that expire at various dates beginning in 2033. Our forecast for the U.S. tax group does not provide sufficient probability for the

use of existing tax loss carryforwards in the near future. Therefore, the requirements set out by IAS 12 are not fulfilled for the U.S. tax group. As of December 31, 2020, deferred tax assets are only recognized to the extent of deferred tax liabilities.

In addition to accumulated tax losses, we had accumulated federal tax credits of €0.8 million and state tax credits of €0.3 million in the United States as of December 31, 2020. The tax credits in the United States will expire at various dates beginning in 2035 if they are not used.

The realization of deferred tax assets is dependent upon the generation of future taxable income, the amount and timing of which are subject to uncertainties. We may become subject to income tax audits and adjustments by local tax authorities. The assessments as to the recoverability of deferred tax assets and the nature of uncertain tax positions is subject to significant judgment by management and subject to change, which may be substantial.

#### Comparison of the year ended December 31, 2019 and year ended December 31, 2018

##### Revenue

The following is a summary of revenues recognized for the periods indicated:

<i>(in thousands)</i>	Years ended December 31,		Change	
	2019	2018	€	%
<b>Revenues</b>				
<b>Research &amp; development revenues from collaborations</b>	<b>€84,428</b>	<b>€101,837</b>	<b>€(17,409)</b>	<b>(17)</b>
<i>Pfizer Inc.</i>	14,348	7,173	7,175	100
<i>Genentech Inc.</i>	64,026	49,536	14,490	29
<i>Other</i>	6,054	45,128	(39,074)	(87)
<b>Commercial revenues</b>	<b>24,161</b>	<b>25,738</b>	<b>(1,577)</b>	<b>(6)</b>
<b>Total revenues</b>	<b>€108,589</b>	<b>€127,575</b>	<b>€(18,986)</b>	<b>(15)</b>

From the year ended December 31, 2018 to the year ended December 31, 2019 total revenues decreased by €19.0 million or 15% from €127.6 million to €108.6 million. The revenue recognized in the year ended December 31, 2018 included an amount of €33.2 million collaboration revenues from our Sanofi collaboration for a reimbursement of 50% of CellScript sublicense costs pursuant to a separate sub-sublicense agreement dated December 22, 2018. This transaction only occurred in the year ended December 31, 2018.

##### Cost of Sales

The following table summarizes our cost of sales for the periods indicated:

<i>(in thousands)</i>	Years ended December 31,		Change	
	2019	2018	€	%
<b>Cost of sales</b>				
Cost of product sales	€17,361	€13,690	€3,671	27
<b>Total cost of sales</b>	<b>€17,361</b>	<b>€13,690</b>	<b>€3,671</b>	<b>27</b>

### Research and Development Expenses

The following table summarizes our research and development expenses for the periods indicated:

<i>(in thousands)</i>	Years ended December 31,		Change	
	2019	2018	€	%
<b>Research and development expenses</b>				
Purchased services	€65,552	€42,079	€23,473	56
Wages, benefits and social security expense	83,213	45,668	37,545	82
Laboratory supplies	37,218	22,921	14,297	62
Depreciation and amortization	27,533	18,312	9,221	50
IT costs	3,800	1,572	2,228	142
Lease and lease related cost	2,527	2,404	123	5
Transport costs	1,081	668	413	62
Other	5,542	9,416	(3,874)	(41)
<b>Total research and development expenses</b>	<b>€226,466</b>	<b>€143,040</b>	<b>€83,426</b>	<b>58</b>

Research and development expenses increased by €83.5 million or 58% from €143.0 million during the year ended December 31, 2018 to €226.5 million during the year ended December 31, 2019 mainly due to an increase in wages, benefits and social security expenses due to an increase in headcount and the full-year reflection of the ESOP program expenses during the year ended December 31, 2019 as well as higher development expenses spent on purchased services and laboratory supplies.

### Sales and Marketing Expenses

Sales and marketing expenses amounted to €2.7 million during the year ended December 31, 2019, €0.2 million of which constituted expenses for purchased services. Sales and marketing expenses amounted to €3.0 million during the year ended December 31, 2018, €0.8 million of which constituted expenses for purchased services.

### General and Administrative Expenses

The following table summarizes our general and administrative expenses for the periods indicated:

<i>(in thousands)</i>	Years ended December 31,		Change	
	2019	2018	€	%
<b>General and administrative expenses</b>				
Wages, benefits and social security expense	€19,122	€8,582	€10,540	123
Purchased services	6,419	5,177	1,242	24
IT and office equipment	4,573	3,774	799	21
Depreciation and amortization	4,855	2,284	2,571	113
Insurance premiums	1,061	145	916	632
Job advertisement expenses	548	861	(313)	(36)
Lease and lease related cost	1,715	1,012	703	69
Research services	232	26	206	792
Laboratory supplies	785	456	329	72
Contract staffing	686	781	(95)	(12)
Other	5,551	3,236	2,315	72
<b>Total general and administrative expenses</b>	<b>€45,547</b>	<b>€26,334</b>	<b>€19,213</b>	<b>73</b>

General and administrative expenses increased by €19.2 million or 73% from €26.3 million during the year ended December 31, 2018 to €45.5 million during the year ended December 31, 2019. This increase was mainly influenced by an increase in headcount and the full-year reflection of the ESOP program expenses during the year ended December 31, 2019 as well as a charge of €2.6 million in connection with certain withholding tax payments for intellectual property licenses

related to prior years that was recorded during the year ended December 31, 2019 but not during the year ended December 31, 2018.

#### *Other Operating Income / Expenses*

During the year ended December 31, 2019, our other operating income amounted to €2.7 million, €1.5 million of which constituted government grants. In the year ended December 31, 2018, our other operating income amounted to €5.4 million, €4.2 million of which constituted government grants.

#### *Finance Income / Expenses*

During the year ended December 31, 2019, our finance income amounted to €4.1 million, €2.3 million of which was attributable to unrealized foreign exchange gains. During the year ended December 31, 2018, our finance income amounted to €8.0 million, €6.1 million of which was attributable to unrealized foreign exchange gains.

During the year ended December 31, 2019, our finance expense amounted to €0.3 million. During the year ended December 31, 2018, our finance expense amounted to €48 thousand. In both years, no foreign exchange losses were reported under finance expense.

During the years ended December 31, 2019 and December 31, 2018, interest expenses related to lease liabilities amounted to €1.7 million, for each year.

#### *Tax Losses*

As of December 31, 2019, we had accumulated tax losses of €356.0 million with respect to corporate tax and €352.3 million with respect to trade tax as of December 31, 2019.

Deferred tax assets on tax losses had not been capitalized in previous years, as there was not sufficient probability in terms of IAS 12 that there would have been future taxable profits available against which the unused tax losses could have been utilized. The accumulated tax losses as at December 31, 2019 relate to Germany and the United States (as at December 31, 2018: Germany). There is no expiration date for any of the accumulated tax losses under German tax law. The tax losses generated in the United States prior to December 31, 2017 begin to expire in 2033. Any tax losses generated after that date have no expiration date and can be carried forward indefinitely. The tax credits incurred in the United States are expected to expire at various dates beginning in 2035.

#### **Information about our operating segments**

Historically we reported four segments: Clinical, Technology Platform, Manufacturing and Product Sales & External Services. In the course of the year ended December 31, 2020, we leveraged the breadth of our immunotherapy technologies and used our expertise to mobilize these rapidly to address the COVID-19 pandemic. In December 2020, our COVID-19 vaccine was authorized or approved for emergency or temporary use or granted conditional marketing authorization in over 65 countries worldwide. Beginning in the fourth quarter, given the financial and operational significance of the activities to develop and then market, produce and transport the COVID-19 vaccine, our Management Board, as the chief operating decision maker (CODM), reviewed financial information presented on a consolidated basis. Decisions with respect to business operations and resource allocations are made by the CODM based on BioNTech as a whole. Accordingly, we operate and make decisions as a single operating segment, which is also our reporting segment.

#### **Related Party Transactions**

Related party transactions that occurred during the years ended December 31, 2020 and December 31, 2019 are explained in Item 7 of this Annual Report as well as in Note 21 of our consolidated financial statements included elsewhere in this Annual Report.

#### **Merger Agreement with BioNTech US Inc. (formerly Neon Therapeutics, Inc.)**

On May 6, 2020, we acquired Neon Therapeutics, Inc. (formerly Nasdaq: NTGN), or Neon, a biotechnology company developing novel neoantigen-based T-cell therapies, through a stock transaction and including de minimis cash consideration, or the Merger. The Merger was announced on January 16, 2020. Neon, now BioNTech US Inc., or BioNTech US, is operated as a wholly-owned subsidiary of BioNTech SE. The new subsidiary is based in Cambridge, Massachusetts and serves as our U.S. headquarters.

The transaction combines two organizations with a common culture of pioneering translational science and a shared vision for the future of cancer immunotherapy. Through the acquisition, we leverage Neon's deep expertise in the development of neoantigen therapies, with both vaccine and T-cell capabilities. Our most advanced program acquired in the Merger is BNT221 (NEO-PTC-01), a personalized neoantigen-targeted T-cell therapy candidate consisting of multiple T-cell populations targeting the most therapeutically relevant neoantigens from each patient's tumor. We also acquired a precision T-cell therapy program targeting shared neoantigens in genetically defined patient populations. The lead program from this approach, BNT222 (NEO-STC-01), is a T-cell therapy candidate targeting shared RAS neoantigens. In addition, Neon had assembled libraries of high-quality TCRs against various shared neoantigens across common HLAs. This pipeline is underpinned by Neon's platform technologies including RECON®, its machine-learning bioinformatics platform, and NEO-STIM™, its proprietary process to directly prime, activate and expand neoantigen-targeting T-cells ex vivo.

Further details are explained in Note 5 of our consolidated financial statements included elsewhere in this Annual Report.

#### **Impact of COVID-19**

As we advance our clinical programs, we are in close contact with our principal investigators and clinical sites, which are located in jurisdictions affected by the COVID-19 pandemic, and are assessing the impact of the COVID-19 pandemic on our clinical trials, expected timelines and costs on an ongoing basis. We have modified our business practices in response to the spread of COVID-19, including restricting employee travel, developing social distancing plans for employees and cancelling physical participation in meetings, events and conferences. In addition, for certain programs, including BNT111, BNT113, BNT122, BNT141 and BNT142 (RiboMabs), BNT151 and BNT152/153 (RiboCytokines), BNT221, BNT161 (Influenza) and BNT171 (Rare Disease), the commencement of trials has been delayed, partially due to slowed patient enrollment or other delays as a result of the COVID-19 pandemic. After several months of delay to focus efforts on our COVID-19 vaccine, we started Phase 1 clinical trials for BNT211 (CARVac), BNT151 (RiboCytokines) and BNT 411 (TLR-agonist). This partial disruption, even temporary, may severely impact our operations and overall business by delaying the progress of our clinical trials and preclinical studies. Our operations, including research and manufacturing, could also be disrupted due to the potential impact of staff absences as a result of self-isolation procedures or extended illness. Such factors were evaluated and considered carefully when preparing this annual report for the year ended December 31, 2020. We will continue to evaluate potential effects of the COVID-19 pandemic.

#### **COVID-19 Collaborations**

In response to the COVID-19 pandemic, we initiated our COVID-19 vaccine development program, BNT162, in late January 2020, leveraging our proprietary mRNA platform, and assembled a global consortium of partners including Pfizer (worldwide collaboration outside of China) and Fosun Pharma (China). In April 2020, we initiated a first-in-human clinical trial of BNT162b2 following preclinical studies. In July 2020, we initiated, along with our partner Pfizer, a phase 3 clinical trial of BNT162b2 and published the clinical results in November 2020. Subsequently, BNT162 vaccine has been authorized or approved for emergency use or temporary use or granted conditional marketing authorization in over 65 countries around the world, including the United States, the U.K., and Canada and has received CMA following rolling submissions with the EMA.

Details about our COVID-19 collaborations are described further in Items 4 and 5 as well as the notes to our consolidated financial statements included elsewhere in this Annual Report.

#### **Critical Accounting Policies and Use of Estimates**

Our consolidated financial statements for the years ended December 31, 2020 and December 31, 2019 have been prepared in accordance with IFRS, as issued by the IASB. Our accounting policies employed are described in Note 3 to our consolidated financial statements included elsewhere in this Annual Report. We have reviewed these critical accounting policies and estimates with the Audit Committee of our Supervisory Board.

In applying these policies, we make estimates and assumptions that affect the reported amounts of assets and liabilities, contingent assets and liabilities as well as revenues and expenses arising during the fiscal year. When evaluating which judgments to make, or which estimates and assumptions to apply, we consider the sensitivity of each as a range of various outcomes is possible. We ultimately base our assumptions and estimates on the most appropriate parameters available when the consolidated financial statements were prepared. Existing circumstances and assumptions about future

developments, however, may change due to market changes or circumstances arising that are beyond our control. Hence, the actual outcome may differ from those estimates.

Some of these policies require a high level of judgment because the areas are especially subjective or complex. The most critical accounting policies and significant areas of judgment and estimation are in the areas discussed in further detail below.

The accounting policies applied and the estimates and assumptions used when preparing the consolidated financial statements have not changed compared to prior year. However, upon receiving regulatory authorization and approval for emergency or temporary use or being granted conditional marketing authorization for our COVID-19 vaccine and with recognizing revenues from the sale of pharmaceutical products for the first time, certain new judgments and estimates needed to be made, most notably with respect to revenue recognition and income taxes.

With respect to revenue recognition and research and development expenses, our judgments and estimates made in evaluating cut-off may impact the financial results between periods. Fair values in business combinations, share-based payment arrangements and financial instruments are determined using valuation models which could differ in outcome depending on input parameters used. We have estimated fair values based on reasonable assumptions as described below.

#### **Revenue Recognition**

We recognize revenue through collaboration and license agreements, rendering of services and sales of products based on the facts and circumstances of each contractual agreement.

##### *Identification and Determination of Performance Obligations*

Our collaboration and license agreements, described in more detail in “Business—XIV. Third-Party Collaborations”, typically contain multiple elements, and have been determined as qualifying as contracts with customers. At inception of each agreement, we apply judgment when determining which promises represent distinct performance obligations. When licenses are granted, we determined that the grant of the license is the predominant promise within the combined performance obligations and the promise to grant a license is accounted for as a performance obligation satisfied over time as our customer simultaneously receives and consumes the benefits from our performance.

##### *Measurement of the Transaction Price*

Milestone payments are contingent upon the occurrence of a future event and represent variable consideration. As there are usually only two possible outcomes (*i.e.*, milestone is reached or not), we have assessed that the method of the most likely amount is the best method to predict the amount of consideration to which we will be entitled. At contract inception, the most likely amount for milestone payments is estimated to be zero. At each reporting date, we use judgment to determine when to include variable consideration in the transaction price, such that it is highly probable that a significant revenue reversal in the amount of cumulative revenue recognized will not occur when the associated uncertainty with respect to the variable consideration is subsequently resolved. We have concluded that future milestone payments are fully constrained at the end of the current fiscal year.

##### *Allocation of the Transaction Price to Performance Obligations and Revenue Recognition as Performance Obligations are satisfied*

We allocate the transaction price to performance obligations based on their relative standalone selling prices, which are generally based on our best estimates and interpretations of facts and circumstances of each contractual agreement and may require significant judgment to determine appropriate allocation.

Upfront payments and reimbursement for expenses are initially deferred on our consolidated statements of financial position. We assessed that no significant financing component exists within our collaboration agreements since the overall business purpose of advanced payments is to support the payment structure other than to provide a significant benefit of financing. For performance obligations in which the costs vary based on progress, an input-based measure considering cost incurred depicts most reliably the progress of the related research activities. In other cases, revenue recognition on a straight-line basis may most reliably depict our performance toward complete satisfaction. If the contractual activities progress, the achievement of development milestones will be used to measure the progress toward complete satisfaction. We evaluate the measure of progress each reporting period and, if necessary, adjust the measure of performance and related revenue recognition. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenues and net loss in the period of adjustment.

Upon successfully commercializing a pharmaceutical product, the collaboration and license agreements also provide for additional profit-sharing or tiered royalties earned when customers recognize net sales of licensed products as well as sales milestone payments. Revenue is recognized based on the sales-based or usage-based royalty exemption when, or as, the underlying sales occur, which is when the performance obligation has been satisfied.

#### Principal-Agent Considerations

Collaboration agreements that involve two or more partners who contribute to the provision of a specific good or service to a customer are assessed in terms of principal-agent considerations. Under our current collaboration agreements, the allocation of marketing and distribution rights defines territories in which the collaboration partner acts as a principal respectively. We recognize revenue net based on the collaboration partners' gross profit in territories where the partner is responsible for supply and on a gross basis when directly supplying our customers in our territories when control has been transferred. Amounts paid to collaboration partners for their share of our profits earned where we are the principal in the transaction are recorded as cost of sales.

#### Pfizer Agreement Characteristics

With respect to our collaboration with Pfizer, commercial revenue is recognized based on our collaboration partners' gross profit from COVID-19 vaccine sales, which is shared under the respective collaboration agreement. In determining commercial revenue pursuant to this collaboration agreement, we are reliant on our collaboration partner for detail regarding its gross profit for the period at hand. We have been informed by our collaboration partner that certain of the information it intends to provide us with regard to the gross profit will be, by necessity, preliminary and subject to change. This is mainly due to the fact that our partner's financial reporting cycle differs from ours. Pfizer's subsidiaries outside the United States have a fiscal year-end of November 30; that is, the details on sales in these territories are required by us in advance of closing the respective reporting periods. As a result, our determination of our share of such gross profit for the purposes of recognizing revenues will be subject to risks that amounts reported might vary from actual amounts reported once our collaboration partner's final financial results are available.

For the period covered in the financial statements presented in this Annual Report, Pfizer has calculated gross profit for COVID-19 vaccine sales in the U.S. territory as well as shared preliminary gross profit for COVID-19 vaccine sales in territories outside the United States, both of which will be reconciled and finalized. The respective gross profit shares are calculated based on sales and include consideration of transfer prices. The latter includes manufacturing and shipping costs, which represent standard prices and include mark-ups on manufacturing costs as specified by the terms of the agreement. Manufacturing and shipping cost variances were considered as far as those have been identified. Nevertheless, those input parameters maybe adjusted once actual costs are determined. The sales for the U.S. territory, as reported by Pfizer, as well as sales preliminary reported for territories outside the United States have been used to estimate license obligations in terms of royalties and sales milestones. Sales milestones and royalties are recognized as they are earned by the partners. Sales milestones are shared equally, while royalty payments are shared on the basis of revenue in the territories for which the partners are responsible. The estimated royalty fees applied to net sales reflect the license obligations to the extent currently identified from third party contractual arrangements. Changes in estimates are accounted for prospectively, when determined.

These estimated figures are likely to change prospectively in future periods as we receive final data from Pfizer. Those changes in our share of the collaboration partner's gross profit will be recognized prospectively as changes to our commercial revenues. To the extent that Pfizer does not provide such preliminary information in the future, our provisional sales figures for territories outside of the United States will be subject to a greater level of estimation and judgment.

(in thousands)	Year ended December 31, 2020			Total
	German territory	U.S. territory	Territories outside the U.S.	
Direct product sales to BioNTech customers	€ 20,553			€ 20,553
Share of collaboration partner's gross profit		€ 46,997	€ 141,480	€ 188,477
Input parameters used within gross profit share calculation				
Sales		reported	preliminary	
Transfer price (manufacturing, shipping costs and respective variances)		standard prices	reported standard prices	



Pfizer's determination of manufacturing and shipping costs also affects the transfer prices that have been charged to COVID-19 vaccine supplies that it manufactures and supplies to us and may be subject to adjustment whenever manufacturing and shipping cost variances are identified. Likewise, our own cost of sales and the respective gross profit share owed to our partner may be adjusted prospectively, when changes are determined.

For further information regarding our revenue recognition policy, please refer to Note 2.3.4 to our consolidated financial statements included elsewhere in this Annual Report.

#### **Business Combinations**

The allocation of the purchase price for business acquisitions to the identifiable assets acquired and liabilities assumed based on their respective fair values, requires use of accounting estimates and judgment. Acquired intangible assets are valued using valuation models such as the Multi Period Excess Earnings Method under which fair values are derived from future net cash flows, which are discounted to the acquisition date using an appropriate discount factor. We have estimated fair values of assets acquired, liabilities assumed and contingent considerations based on reasonable assumptions.

We continue to collect information and reevaluate these provisional estimates and assumptions in accordance with IFRS 3. We record any adjustments to these provisional estimates and assumptions against goodwill provided they arise within the measurement period. Upon the conclusion of the measurement period or final determination of the fair value of assets acquired or liabilities assumed, whichever comes first, any subsequent adjustments are recorded to the consolidated statements of operations. For further information regarding our business combination policy, please refer to Note 2.3.1 to our consolidated financial statements included elsewhere in this Annual Report.

#### **Share-Based Awards**

We used valuation models like a binomial or Monte-Carlo simulation model, for the measurement of the cash- and equity-settled transactions' fair value at the grant date considering certain assumption relating to, *e.g.*, the volatility of stock price, the determination of an appropriate risk-free interest rate, expected dividends and the probability of reaching a minimum hurdle to exercise the relevant options. For awards which were granted prior to the initial public offering, at a time where no quoted market prices existed, the valuation model assumptions included the option's underlying share price. For awards which were granted post the initial public offering, the grant date's share prices on the Nasdaq Global Select Market were included in the valuation.

For further information regarding our share-based payments accounting policy and disclosures, see Note 2.3.17 and Note 17 to our consolidated financial statements included elsewhere in this Annual Report.

#### **Embedded Derivatives**

We used the Cox-Rubinstein binomial tree model when determining the fair value of the conversion right, the embedded derivative which was bifurcated from the convertible note, as host contract. The primary inputs used in the model include stock price volatility, credit spreads, risk-free interest rate and foreign exchange forward rates. Stock price volatility is based on our implied volatility, credit risk is model implied and adjusted for movement in credit spreads for B-rated corporates at each valuation date, the risk-free interest rate is based on currency specific time congruent IBOR and swap rates whereas the foreign exchange forward rates are based on observable market data.

For further information regarding our financial instrument policy and disclosures relating to financial instruments, see Note 2.3.11 and Note 12 to our consolidated financial statements included elsewhere in this Annual Report.

#### **Income Taxes**

When determining whether sufficient future taxable profit will be available against which the deductible temporary differences, tax loss carry forwards and tax credits can be utilized, significant management judgment is required. This includes management's assessment on the character and amounts of taxable future profits, the periods in which those profits are expected to occur, and the availability of tax planning opportunities. As a matter of policy, convincing evidence

supporting the recognition of deferred tax assets is required if an entity has suffered a loss in either the current or the preceding periods.

As of December 31, 2020, based on our product-based business plan, including commercial supply commitments agreed with various governments and health ministries under which we either directly supply the COVID-19 vaccine or, if they relate to territories which have been allocated to Pfizer, we will receive the profit share to which we are eligible, it is now considered highly probable that taxable profits for the German tax group will be available against which the tax losses can be utilized. On this basis, we have determined that we can recognize a deferred tax asset with respect to the German tax group's tax losses carried forward.

On the other hand, management has determined that deferred tax assets on tax losses carried forward that relate to subsidiaries which have a loss making history cannot be recognized. This includes the assessment that those subsidiaries neither have any taxable temporary difference nor any tax planning opportunities available that could support the recognition of deferred tax assets.

For further disclosures relating to deferred taxes, see Note 8 to our consolidated financial statements included elsewhere in this Annual Report.

**B. Research and Development, Patents and Licenses, etc.**

Full details of our research and development activities and expenditures are given in Item 4 and under the description of the "Operating Results" in this Item 5 within this Annual Report.

**C. Trend Information**

See the description of "Operating Results" in this Item 5 within this Annual Report.

**D. Liquidity and Capital Resources**

We have historically funded our operations primarily from private placements of our ordinary shares, from issuing ordinary shares in connection with public financing transactions, which includes our initial public offering in 2019 and the global offering in 2020, from generating proceeds under our collaboration agreements and receiving proceeds from secured bank loans. Recently we issued a convertible note as part of a private investment. As of December 31, 2020, we had cash and cash equivalents of €1.2 billion. Cash and cash equivalents are invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation, and consist primarily of cash in banks and on hand and short-term deposits with an original maturity of three months or less, which are stated at fair value.

We maintain two secured loans with Deutsche Bank AG, or Deutsche Bank, to finance the buildouts of our JPT Peptide Technologies GmbH facility and BioNTech Innovative Manufacturing Services GmbH facility. Our €10.0 million secured credit facility, entered into with Deutsche Bank by our subsidiary BioNTech Innovative Manufacturing Services GmbH, bears interest at a rate of 2.15% and matures on December 30, 2027. The loan is repayable in equal quarterly installments of €0.3 million commencing on June 30, 2020. As of December 31, 2020, the full amount under this facility is drawn down and the first three scheduled repayments have occurred. Our €9.45 million secured credit facility, entered into with Deutsche Bank by our subsidiary JPT Peptide Technologies GmbH, bears interest at a rate of 2.08% and matures on September 30, 2028. The loan is repayable by quarterly installments of €0.3 million commencing on September 30, 2020. As of December 31, 2020, the full amount under this facility is drawn down and the first two scheduled repayments have occurred. Each of these facilities is secured by liens over our property.

In December 31, 2019, we signed a financing arrangement with the European Investment Bank, or the EIB, to partially support the implementation of certain technical aspects of our investment in the development of patient-tailored therapeutic vaccines for cancer in Germany, or the Investment. Under this arrangement, the EIB has agreed to provide us with a credit in an amount of up to €50 million to partially finance the Investment, provided that the amount of credit does not exceed 50% of the cost of the Investment. The credit consists of (i) a term loan in the amount of €25 million that may be drawn in a single tranche upon the achievement of certain milestone events, not all of which have been achieved (Credit A), and (ii) a term loan in the amount of €25 million that may be drawn in a maximum of four tranches each of which must be for a minimum of €5 million or the balance of the remaining facility (Credit B). Tranches under Credit B may only be drawn after Credit A has been drawn down and upon the achievement of certain milestone events. Each tranche under Credit A and Credit B must be repaid within six years from the date on which the tranche is disbursed to us. The financing

arrangement is to be secured by way of liens over certain of our property. As of December 31, 2020, there has been no draw down.

In June 2020, we entered into an agreement with the EIB for a €100 million credit facility to partially support the development of BNT162 and fund expansion of our manufacturing capacity to provide worldwide supply of BNT162 in response to the COVID-19 pandemic. The credit consists of (i) a term loan in the amount of €50 million that may be drawn in a single tranche upon the achievement of certain milestone events (Credit A), and (ii) a term loan in the amount of €50 million that may be drawn in a single tranche (Credit B). Credit B may only be drawn down after Credit A has been drawn down and upon the achievement of certain milestone events. The financing arrangement is to be secured by way of liens over certain of our property. On December 21, 2020, €50 million from Credit A was drawn down. Interest is payable on the outstanding balance of Credit A at the cash interest fixed rate of 1% per annum quarterly in arrears, plus deferred interest at fixed rate of 2.5% per annum. The nominal amount must be repaid on December 21, 2026.

On July 27, 2020, 5,500,000 ADS each representing one of our ordinary shares were offered on the Nasdaq Global Select Market at a public offering price of \$93.00 per ADS ("Underwritten Offering"). On August 27, 2020, following the Underwritten Offering, 16,124 ADS each representing one of our ordinary shares were issued additionally at a public offering price of \$93.00 per ADS ("Rights Offering"). The Underwritten Offering and the Rights Offering are part of a single, global offering, which we refer to as the Global Offering. The gross proceeds of the Global Offering were €436.3 million (\$513.0 million).

A fund associated with Temasek Capital Management Pte. Ltd., or Temasek, and another accredited investor, contributed a private investment, which closed as of August 28, 2020 following the satisfaction of customary closing conditions. The private placement includes an investment in ordinary shares and a €100.0 million four-year mandatory convertible note with a coupon of 4.5% per annum and a conversion premium of 20% above the reference price. The investment of €123.9 million for 2,595,996 of our ordinary shares was registered with the commercial register (*Handelsregister*) on September 8, 2020.

In September 2020, we became eligible to receive up to €375.0 million in funding from an initiative by the German Federal Ministry of Education (*Bundesministerium für Bildung und Forschung*, or the BMBF) to support our COVID-19 vaccine program, BNT162. The BMBF funding was granted to accelerate our vaccine development and to upscale manufacturing capabilities in Germany. The funding will also compensate further costs that incur since the COVID-19 vaccine continues to be tested in clinical trials, for example to test it against new variants or to approve it for additional groups (pregnant women, individuals less 16 years), and because study participants will continue to be followed for two years to continue evaluating safety and efficacy.

In November 2020, we entered into a sales agreement (the "Sales Agreement") with Jefferies LLC and SVB Leerink LLC, as sales agents, to establish an at-the-market offering program, pursuant to which the Company may sell, from time to time, ADSs representing ordinary shares for aggregate gross proceeds of up to \$500 million. During the year ended December 31, 2020, we sold 735,490 ADSs, each representing one of our ordinary shares and previously held in treasury, under the Sales Agreement for aggregate gross proceeds of €76.5 million (\$92.9 million). The remaining capacity under the Sales Agreement is \$407.1 million.

#### Cash Flow

The following table summarizes the primary sources and uses of cash for each period presented:

(in thousands)	Years ended December 31,		
	2020	2019	2018
<b>Net cash flows from (used in):</b>			
Operating activities	€(13,474)	€(198,537)	€(58,877)
Investing activities	(144,848)	(77,115)	(66,452)
Financing activities	894,725	383,290	365,177
<b>Total cash inflow</b>	<b>€736,403</b>	<b>€107,638</b>	<b>€239,848</b>

#### *Operating Activities*

We derive cash flows from operations primarily from collaborations, the sale of products and services rendered. Our cash flows from operating activities are significantly influenced by our use of cash for operating expenses and working capital to support the business. We have historically experienced negative cash flows from operating activities as we have invested in the development of our technologies and manufacturing capabilities, as well as for clinical and preclinical development of our product candidates.

Net cash used in operating activities for the year ended December 31, 2020 was €13.5 million, comprising a loss before tax of €145.8 million, non-cash adjustments of €227.2 million, and a net negative change in assets and liabilities of €93.1 million. Non-cash items primarily included movements in government grant, depreciation and amortization as well as share-based compensation expenses and non-cash effective finance expenses. The net negative change in assets and liabilities was primarily due to an increase in trade receivables and a decrease in payables and liabilities as well as inventories.

Net cash used in operating activities for the year ended December 31, 2019 was €198.5 million, comprising a loss before tax of €179.4 million, non-cash adjustments of €65.0 million, and a net negative change in assets and liabilities of €83.4 million. Non-cash items primarily included depreciation and amortization as well as share-based compensation expenses. The net negative change in assets and liabilities was primarily due to a decrease in contract liabilities and trade payables.

Net cash used in operating activities for the year ended December 31, 2018 was €58.9 million, comprising a loss before tax of €47.7 million, non-cash adjustments of €29.9 million, and a net negative change in assets and liabilities of €41.1 million. Non-cash items primarily included depreciation and amortization as well as share-based compensation expenses. The net negative change in assets and liabilities was primarily due to a decrease in payables and liabilities.

The decrease in net cash used in operating activities from the year ended December 31, 2019 to the year ended December 31, 2020 was primarily due to the fact that higher spending has been overcompensated by upfront and grant funding received as well as increased deferred payments.

The increase in net cash used in operating activities from the year ended December 31, 2018 to the year ended December 31, 2019 was primarily due to an increase in amounts spent for wages, benefits and social security expenses as headcount increases and higher research and development expenditures.

#### *Investing Activities*

Net cash used in investing activities for the year ended December 31, 2020 was €144.8 million, of which €66.0 million was attributable to the purchase of property, plant and equipment, partially offset by proceeds from the sale of property, plant and equipment amounting to €1.2 million and €60.6 million were mainly attributable to the acquisition of our new manufacturing facility in Marburg, Germany.

Net cash used in investing activities for the year ended December 31, 2019 was €77.1 million, of which €32.5 million was attributable to the purchase of intangible assets, including the final installment payment for the license agreement for the CellScript patent, and €38.6 million was attributable to the purchase of property, plant and equipment.

Net cash used in investing activities for the year ended December 31, 2018 was €66.5 million, of which €37.3 million was attributable to the purchase of intangible assets, including the payment for the license agreement for the CellScript patent, and €29.9 million was attributable to the purchase of property, plant and equipment.

#### *Financing Activities*

Our primary financing activities consist of issuances of share capital, proceeds from bank loans and payments of lease liabilities.

During the year ended December 31, 2020, we generated cash from financing activities of €894.7 million, primarily from proceeds from the issuance of shares in the amount of €753.0 million and proceeds from loans and borrowings in the amount of €156.0 million, partially offset by the payment of lease liabilities in the amount of €12.7 million.

During the year ended December 31, 2019, we generated cash from financing activities of €383.3 million, primarily from proceeds from the issuance of shares in the amount of €375.4 million and proceeds from loans and borrowings in the amount of €11.0 million, partially offset by the payment of lease liabilities in the amount of €3.1 million.

During the year ended December 31, 2018, we generated cash from financing activities of €365.2 million, primarily from proceeds from the issuance of shares in the amount of €361.7 million and proceeds from loans and borrowings in the amount of €5.6 million, partially offset by the payment of lease liabilities in the amount of €2.1 million.

#### **Operation and Funding Requirements**

Since our inception, we have incurred significant losses and negative cash flows from operations due to our significant research and development expenses and our investment in our manufacturing capabilities. We have accumulated losses of €409.6 million as of December 31, 2020 and €424.8 million as of December 31, 2019.

We expect to continue to incur significant and increasing operating expenses for the foreseeable future. We anticipate that our expenses will increase substantially if and as we and our collaborators:

- continue or expand our research or development of our programs in preclinical development;
- continue or expand the scope of our clinical trials for our product candidates;
- initiate additional preclinical, clinical, or other trials for our product candidates, including under our collaboration agreements;
- continue to invest in our immunotherapy platforms to conduct research to identify novel technologies;
- change or increase our manufacturing capacity or capability;
- change or add additional suppliers;
- add additional infrastructure to our quality control, quality assurance, legal, compliance and other groups to support our operations as a public company and our product development and commercialization efforts, including expansion of sites in Germany and new sites in the United States, and potentially others globally;
- attract and retain skilled personnel;
- seek marketing approvals and reimbursement for our product candidates;
- develop our sales, marketing, and distribution infrastructure for our COVID-19 vaccine and any other products for which we may obtain marketing approval or emergency use authorization;
- seek to identify and validate additional product candidates;
- acquire or in-license other product candidates and technologies;
- make milestone or other payments under any in-license agreements;
- maintain, protect, defend, enforce and expand our intellectual property portfolio; and
- experience any delays or encounter issues with any of the above.

We are a party to license and research and development agreements with universities and other third parties, as well as patent assignment agreements, under which we have obtained rights to patents, patent applications and know-how. We enter into contracts in the normal course of business with CROs for clinical trials, clinical and commercial supply manufacturing, with vendors for preclinical research studies and for other services and products for operating purposes. We work together with CMOs, who manufacture our product candidates and products and enter into lease agreements to lease laboratory, GMP manufacturing, storage and office spaces. Purchase obligations under our agreements to the extent that they are quantifiable and not cancelable have been considered when defining our guidance for future cash commitments. Most of the committed cash outflow within the next twelve months in 2021 is related to CMO purchase obligations amounting to €144.5 million and lease payments amounting to €8.5 million. Further, we have purchase obligations with an amount of €97.8 million for the year 2022 and lease payment obligations of €99.1 million for the years 2022 and beyond. The Group has various lease contracts that have not yet commenced as of December 31, 2020. The future lease payments for these non-cancellable lease contracts are €2.8 million for the year 2021 and €10.2 million for the years 2022 and beyond.

We are subject to all of the risks related to the development and commercialization of pharmaceutical products, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. We intend to invest the revenues we generate from sales of our COVID-19 vaccine to accelerate the maturation of our oncology and infectious disease pipeline and the expansion into additional therapeutic areas.

Our future funding requirements, both near and long term, will depend on many factors, including, but not limited to:

- the initiation, progress, timing, costs, and results of preclinical or nonclinical studies and clinical trials for our product candidates;
- the amount and timing of revenues and associated costs from sales of our COVID-19 vaccine;
- the results of research and our other platform activities;
- the clinical development plans we establish for our product candidates;
- the terms of any agreements with our current or future collaborators, and the achievement of any milestone payments under such agreements to be paid to us or our collaborators;
- the number and characteristics of product candidates that we develop or may in-license;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA, the EMA and other comparable regulatory authorities;
- the cost of filing, prosecuting, obtaining, maintaining, protecting, defending and enforcing our patent claims and other intellectual property rights, including actions for patent and other intellectual property infringement, misappropriation and other violations brought by third parties against us regarding our product candidates or actions by us challenging the patent or intellectual property rights of others;
- the effect of competing technological and market developments, including other products that may compete with one or more of our product candidates;
- the cost and timing of completion and further expansion of clinical and commercial scale manufacturing activities sufficient to support all of our current and future programs; and
- the cost of establishing sales, marketing, and distribution capabilities for any product candidates for which we may receive marketing approval and reimbursement in regions where we choose to commercialize our products on our own.

**E. Off-Balance Sheet Arrangements**

We do not have any off-balance sheet arrangements.

**F. Tabular Disclosure of Contractual Obligations**

During 2020, the Securities and Exchange Commission (SEC) voted to adopt amendments to certain financial disclosure requirements in Regulation S-K (also referred to as “November 19, 2020 amendments to Regulation S-K”). Compliance is mandatory on August 9, 2021 and rules can be applied early on or after February 10, 2020. We have elected to early adopt the November 19, 2020 amendments to Regulation S-K in this Annual Report and have omitted the presentation of contractual obligations in a tabular form.

**G. Safe Harbor**

See the beginning of this Item and “Cautionary Statement Regarding Forward-Looking Statements” included elsewhere in this Annual Report.

**Item 6. Directors, Senior Management and Employees****A. Directors and Senior Management****Management Board (Vorstand)**

The following table sets forth the names and functions of the current members of our Management Board, their ages as of December 31, 2020 and their terms:

<b>Name</b>	<b>Age</b>	<b>Term Expires</b>	<b>Position</b>
Prof. Ugur Sahin, M.D.	55	2022	Chief Executive Officer
Sean Marett	55	2022	Chief Business Officer and Chief Commercial Officer
Dr. Sierk Poetting	47	2022	Chief Financial Officer and Chief Operating Officer
Dr. Özlem Türeci, M.D.	53	2022	Chief Medical Officer
Ryan Richardson	41	2022	Chief Strategy Officer

The business address of the members of our Management Board is the same as our business address: An der Goldgrube 12, D-55131 Mainz, Germany.

The following is a brief summary of the business experience of the members of our Management Board:

**Prof. Ugur Sahin, M.D.** co-founded BioNTech in 2008 and has served as our Chief Executive Officer since that time. Prof. Sahin also served as the head of the Scientific Advisory Board of Ganymed Pharmaceuticals AG from 2008 until the company was acquired by Astellas Pharma Inc., or Astellas, in 2016. In 2010, Prof. Sahin co-founded TRON, and served as a Managing Director from 2010 until 2019 and he currently supports the research and development at TRON as a close scientific advisor and supervisor for PhD students. Prof. Sahin has also been a professor (W3) at the Mainz University Medical Center since 2014. Prof. Sahin co-founded the Ci3, the German Cluster Initiative of Individualized ImmunIntervention (Ci3), a non-profit organization. Prof. Sahin earned an M.D. in 1990 from the University of Cologne. Prof. Sahin is married to Dr. Özlem Türeci.

**Sean Marett** joined BioNTech in 2012. Prior to joining BioNTech, he worked in global strategic and regional marketing and sales roles at GlaxoSmithKline in the United States and Pfizer in Europe before taking business development executive roles at Evotec and Lorantis, the latter of which he helped to successfully sell to Celldex Therapeutics, Inc. He has successfully executed complex licensing transactions with large pharmaceutical companies, negotiated M&A transactions and raised finance from investors. Mr. Marett built and ran a contract clinical manufacturing organization with operations across Europe and the United States for over half a decade for the contract manufacturer, NextPharma. Mr. Marett has been Chairman of PHMR Ltd, a company specializing in market access and pharmaceutical reimbursement, since 2017. He became a member of the supervisory board of AiCuris AG in February 2021. He previously held non-executive directorship of KWS BioTest Ltd (successfully sold to Charles River) from 2011 until 2018 and was a member of the investment committee of Mann BioInvest Ltd, a fund dedicated to biotechnology and pharmaceutical company investments from 2013 until 2016. He holds a BSc (Hons) in Biochemistry from Kings College London and an MBA from Manchester Business School.

**Dr. Sierk Poetting** is our Chief Financial Officer and Chief Operating Officer. Dr. Poetting joined BioNTech in September 2014 from Novartis, where he served from May 2012 to August 2014 as Vice President and Chief Financial Officer for the Sandoz Division in North America. Dr. Poetting started his career as a consultant with McKinsey & Company. A German citizen, Dr. Poetting holds a Master of Science in Optical Sciences from the University of Arizona and a Ph.D. in Physics from the Ludwig-Maximilians University in Munich.

**Dr. Özlem Türeci** is our Chief Medical Officer. Dr. Türeci joined BioNTech in 2008 as a clinical and scientific advisory board member, before becoming our Chief Medical Officer in 2018. Dr. Türeci co-founded Ganymed Pharmaceuticals AG, now a subsidiary of Astellas, in 2001 as Chief Scientific Officer and became its Chief Executive Officer in 2008. Dr. Türeci is chairman and co-initiator of Ci3. Dr. Türeci is also President of the Association for Cancer Immunotherapy (CIMT). Dr. Türeci earned her M.D. from Saarland University Faculty of Medicine, Homburg. Dr. Türeci is married to Prof. Ugur Sahin, M.D.

**Ryan Richardson** is our Chief Strategy Officer. Mr. Richardson joined BioNTech in September 2018 from J.P. Morgan Securities LLC, where he served from June 2010 to September 2018 in various roles, including as Executive Director, Healthcare Investment Banking. Prior to his time at J.P. Morgan Securities LLC, Mr. Richardson served in various roles in the healthcare economics and consulting field, including as co-founder of Quantitative Insights. Mr. Richardson earned an MBA from the University of Chicago Booth School of Business, a MSc from the London School of Economics and Political Science and a B.S. in Biology from the University of Kansas.

#### Supervisory Board (Aufsichtsrat)

The following table sets forth the names and functions of the current members of our Supervisory Board, their ages as of December 31, 2020, their terms (which expire on the date of the relevant year's general shareholders' meeting) and their principal occupations outside of our Company:

Name	Age	Term Expires	Principal Occupation
Helmut Jeggle	50	2023	General Partner ATHOS KG
Michael Motschmann	63	2023	Member of the Board of Management and Head of Equity Investments of MIG Verwaltungs AG
Prof. Christoph Huber, M.D.	76	2023	Chairman Emeritus at the Johannes-Gutenberg University Mainz
Dr. Ulrich Wandschneider	59	2023	Independent consultant to companies in the pharma, biotech, medtech sciences and health care industry

The business address of the members of our Supervisory Board is the same as our business address: An der Goldgrube 12, D-55131 Mainz, Germany.

The following is a brief summary of the prior business experience of the members of our Supervisory Board:

**Helmut Jeggle** has served as the Chairman of our Supervisory Board since 2008. Mr. Jeggle has served as General Partner at ATHOS KG, the family office of the Strüngmann brothers, since 2015. From 2007 until 2015, Mr. Jeggle served as the Head of Direct Investments of ATHOS Service GmbH. From 2002 until 2007, Mr. Jeggle held various positions with Hexal AG, including Head of Business Planning & Analyses. Mr. Jeggle is currently the Chief Executive Officer of each of Salvia GmbH (since 2014), Neula Holding GmbH (since 2010) and AT-Gruppe (since 2008) and a manager of Santo Group (since 2011). Mr. Jeggle is a member of the supervisory board of 4SC AG and AiCuris AG. Mr. Jeggle has a degree in business administration from the University of Applied Sciences Neu-Ulm and earned his Master of Business Administration from the Stuttgart Institute of Management and Technology.

**Michael Motschmann** has served as a member of our Supervisory Board since 2008. Mr. Motschmann co-founded MIG Verwaltungs AG, or MIG, in 2004, where he serves on the Management Board and as Head of Equity Investments. In his role with MIG, Mr. Motschmann currently serves on the supervisory boards of several private portfolio companies.

**Prof. Christoph Huber, M.D.** is a co-founder of BioNTech and has served as a member of our Supervisory Board since 2008. Prof. Huber has more than 50 years of professional experience in hematology, oncology and translational immunology. Prof. Huber served as Chairman of the Department of Hematology and Oncology at the Johannes-Gutenberg University Mainz from 1990 to 2009 and, since 2009, has served as Chairman Emeritus of the Department of Hematology and Oncology. Prof. Huber was a co-founder of Ganymed Pharmaceuticals AG, now a subsidiary of Astellas. He is an executive board member of CIMT and a board member of Ci3. From 2018 to April 2019, Prof. Huber served as a member of the supervisory board of TRON. Prof. Huber earned his M.D. at the University of Innsbruck.

**Dr. Ulrich Wandschneider, Ph.D.** has served as a member of our Supervisory Board since 2018. Dr. Wandschneider has more than 20 years of experience in the healthcare sector as a manager in the operative business and as a member of boards and committees. He was a Partner at Arthur Andersen until 2002 and at Deloitte from 2002 to 2004 in the healthcare and life science sector for many years. From 2004 to 2016 Dr. Wandschneider served as Chief Executive Officer first of Mediclin AG later of Asklepios Kliniken GmbH & Co. KGaA. Dr. Wandschneider currently serves on various supervisory and advisory boards.



## B. Compensation

### Remuneration of Supervisory Board Members

Our Articles of Association provide for a fixed annual remuneration for each member of the Supervisory Board of €50,000 per year. However, the chairman is entitled to receive €150,000 per year and the vice chairman €75,000 per year. In addition, the chairman of the audit committee is entitled to be paid an additional €20,000 per year. All members of the Supervisory Board are reimbursed for their expenses.

<i>(in thousands)</i>	<b>Helmut Jeggle</b>	<b>Michael Motschmann</b>	<b>Prof. Dr. Christoph Huber, M.D.</b>	<b>Dr. Ulrich Wandschneider</b>
<b>2020</b>	€150	€50	€50	€95
<b>2019</b>	€150	€50	€50	€95

A member of the Supervisory Board who serves for only a portion of a given fiscal year or who holds the position of chairman or vice chairman of the Supervisory Board or of chairman of the Audit Committee for only a portion of a given fiscal year shall only be remunerated pro-rata. The same is true if the clause of the Articles of Association regarding the remuneration of the members of the Supervisory Board becomes ineffective (e.g., because it is repealed) during the course of a year.

In case any remuneration or reimbursement of expenses is subject to value added tax, such amount shall be paid additionally by the Company.

There are no arrangements or understandings between us and any member of our Supervisory Board providing for benefits upon termination of their service as director.

### Remuneration of the Members of Our Management Board

We have entered into agreements with all current members of our Management Board.

We believe that the agreements between us and the members of our Management Board provide for payments and benefits (including upon termination of employment) that are in line with customary market practice.

The following sets forth the end dates of the current service agreements of our Management Board:

- Prof. Ugur Sahin: December 31, 2022
- Sean Marett: September 30, 2022
- Dr. Sierk Poetting: September 30, 2022
- Dr. Özlem Türeci: May 31, 2022
- Ryan Richardson: December 31, 2022

From January 1, 2019 until August 31, 2019, the annual base salaries for our Management Board members, Prof. Ugur Sahin, Sean Marett, Dr. Sierk Poetting and Dr. Özlem Türeci, were €210,000, €360,000, €300,000 and €300,000, respectively. Effective September 1, 2019 the annual base salaries for Prof. Ugur Sahin, Sean Marett, Dr. Sierk Poetting and Dr. Özlem Türeci are €360,000, €400,000, €360,000 and €360,000, respectively. Effective January 1, 2020 the annual base salary for Ryan Richardson is €320,000. In December 2019, the Management Board members, Prof. Ugur Sahin, Sean Marett, Dr. Sierk Poetting and Dr. Özlem Türeci, were each awarded a cash bonus of €50,000, which was paid in 2020.

Our current service agreements with our Management Board provide for short-term incentive compensation of up to a maximum of 50% of the annual base salary. The amount of such short-term incentive compensation will depend on the achievement of certain company goals in a particular fiscal year, which goals will be set uniformly for all members of the Management Board. Half of the incentive compensation will be paid promptly upon achievement of the applicable company goals, with the remaining amount payable one year later, subject to adjustment relative to our share price performance during that year. The provisions in relation to the short-term incentive compensation took effect from January 1, 2020, being the beginning of the first year after the year in which BioNTech Shares or ADSs of the Company were listed on a stock exchange or other multilateral trading system.

The service agreements of our Management Board provide for long-term incentive compensation in terms of a yearly grant of options to purchase BioNTech Shares. The options granted each year will be subject to the terms, conditions, definitions and provisions of our ESOP and the applicable option agreement thereunder. The number of options to be granted each year to Prof. Ugur Sahin, Sean Marett, Dr. Sierk Poetting, Dr. Özlem Türeci and Ryan Richardson is to be calculated based on a value of €750,000, €300,000, €300,000, €300,000 and €260,000, respectively, in each case divided by the amount by which a certain target share price exceeds the exercise price (which in the case of each grant is equal to the stock price as of the time of that grant). The value used to calculate the number of options for Ryan Richardson increases to €280,000 for the year 2022. These provisions in relation to the long-term incentive compensation took effect from January 1, 2020.

There are no arrangements or understandings between us and any member of our Management Board providing for benefits upon termination of their service as director.

In the years ended December 31, 2020 and December 31, 2019, the members of our Management Board received aggregate remuneration of €23.7 million and €19.6 million, respectively.

<i>(in thousands)</i>	<b>Prof. Ugur Sahin, M.D.</b>	<b>Sean Marett</b>	<b>Dr. Sierk Poetting</b>	<b>Dr. Özlem Türeci</b>	<b>Ryan Richardson (1)</b>
<b>Fixed compensation and short-term incentive incurred</b>					
2020	€450	€500	€450	€450	€400
2019	€311	€423	€370	€370	-
<b>Fringe Benefits (2)</b>					
2020	6	11	11	-	4
2019	5	12	11	-	-
<b>Short-term incentive accrued (3)</b>					
2020	148	163	148	148	133
2019	-	-	-	-	-
<b>Share-based payments (4)</b>					
2020	15,913	1,613	1,613	433	1,128
2019	6,748	1,180	1,180	9,043	-
<b>Total</b>					
<b>2020</b>	<b>€16,517</b>	<b>€2,287</b>	<b>€2,222</b>	<b>€1,031</b>	<b>€1,665</b>
<b>2019</b>	<b>€7,064</b>	<b>€1,615</b>	<b>€1,561</b>	<b>€9,413</b>	<b>-</b>

(1) Ryan Richardson was appointed to the Management Board as Chief Strategy Officer (CSO) and Managing Director on January 12, 2020. Expenses from a bonus arrangement agreed with Ryan Richardson in advance of his appointment to the Management Board are included in the share-based payments amount. During the year ended December 31, 2020, the arrangement was modified from an all-equity share-based payment arrangement into a partly cash and partly equity settled share-based payment arrangement including 4,534 ordinary shares which have not yet been issued.

(2) Includes social security, health and additional insurance, company bike and travel expenses.

(3) The fair value of the second installment of the short-term incentive compensation which has been classified as cash-settled share-based payment arrangement was determined pursuant to the regulations of IFRS 2 "Share-based Payments." This table shows the pro-rata share of personnel expenses for the respective financial year that are recognized over the award's vesting period beginning as of the service commencement date (January 1, 2020) until each separate determination date and are remeasured until settlement date.

(4) The fair value was determined pursuant to the regulations of IFRS 2 "Share-based Payments." This table shows the pro-rata share of personnel expenses resulting from stock-based compensation for the respective financial year.

The table below provides an overview of the share options granted to our Management Board in the years ended December 31, 2020, December 31, 2019 and December 31, 2018.

	Grant Date (1)	Number of Ordinary Shares Underlying Share Options (2)	Option Exercise Price (€)	Option Expiration Date
Prof. Ugur Sahin, M.D.	11/15/2018	1,830,348	10.14	09/17/2026
	10/10/2019 (3)	4,374,963	13.60	10/11/2029
	02/13/2020 (4)	97,420	28.32	02/13/2030
	2021 (5)	39,826 (5)	67.26 (5)	2031 (5)
	2022 (5)	39,817 (5)	67.27 (5)	2032 (5)
Sean Marett	11/15/2018	610,110	10.14	09/17/2026
	02/13/2020 (4)	38,968	28.32	02/13/2030
	2021 (5)	15,930 (5)	67.26 (5)	2031 (5)
	2022 (5)	15,927 (5)	67.27 (5)	2032 (5)
Dr. Sierk Poetting	11/15/2018	610,110	10.14	09/17/2026
	02/13/2020 (4)	38,968	28.32	02/13/2030
	2021 (5)	15,930 (5)	67.26 (5)	2031 (5)
	2022 (5)	15,927 (5)	67.27 (5)	2032 (5)
Dr. Özlem Türeçli	11/15/2018 (6)	1,952,334	10.14	09/17/2026
	02/13/2020 (4)	38,968	28.32	02/13/2030
	2021 (5)	15,930 (5)	67.26 (5)	2031 (5)
	2022 (5)	15,927 (5)	67.27 (5)	2032 (5)
Ryan Richardson (7)	11/15/2018 (8)	149,508	10.14	09/17/2026
	02/13/2020 (4)	33,772	28.32	02/13/2030
	2021 (5)	13,806 (5)	67.26 (5)	2031 (5)
	2022 (5)	14,865 (5)	67.27 (5)	2032 (5)

(1) Except as otherwise indicated, all options fully vest on September 16, 2022.

(2) 18-for-1 stock split of our ordinary shares which became effective on September 18, 2019, upon registration with the commercial register (*Handelsregister*) is reflected in share amounts granted in advance.

(3) Options vest in four equal installments on October 10 of 2020, 2021, 2022 and 2023.

(4) Options vest in four equal installments on February 13 of 2021, 2022, 2023 and 2024.

(5) As of December 31, 2020, the assessment about options expected to be granted in 2021 and 2022 was based on estimated allocation dates in the middle of the years 2021 and 2022, respectively. For the awards with estimated allocation dates the exercise prices and the numbers of options expected to be allocated have been derived from the Monte-Carlo simulation model. Those parameters will be adjusted until the actual allocation has occurred and the number of options granted and the exercise price has ultimately been determined. The options will vest annually in equal installments over four years commencing on the first anniversary of the allocation date and will be exercisable four years after the allocation date.

(6) Options fully vested on March 16, 2019, however these options will not become exercisable until September 16, 2022.

(7) Ryan Richardson was appointed to the Management Board as Chief Strategy Officer (CSO) and Managing Director on January 12, 2020. The share options granted on November 15, 2018 under the Employee Stock Ownership Plan were granted before his appointment to the Management Board.

(8) Options fully vested on October 10, 2019, however these options will not become exercisable until September 16, 2022.

## Employee Stock Ownership Plan

Based on a pertinent authorization of the general meeting on August 18, 2017, we established a share option program under which we granted selected employees options to receive our shares. The program is designed as an Employee Stock Ownership Plan, or ESOP. We have offered the participants a certain number of rights by explicit acceptance of the participants. The exercise of the option rights in accordance with the agreement gives the participants the right to obtain shares against payment of the exercise price. The option rights (other than Dr. Özlem Türeçci's and Ryan Richardson's options referred to above) generally fully vest after four years and can only be exercised if: (i) the waiting period of four years has elapsed; and (ii) at the time of exercise, the average closing price of the shares of the Company or the average closing price of the right or certificate to be converted into an amount per share on the previous ten trading days preceding the exercise of the option right exceeds the strike price by a minimum of 32%, with this percentage increasing by eight percentage points as of the fifth anniversary of the respective issue date and as of each subsequent anniversary date. The option rights can be exercised at the latest eight years after the allocation date. If they have not been exercised by that date, they will forfeit without compensation.

By way of shareholders' resolution of the general meeting on August 19, 2019, the authorization to issue such option rights was amended such that, in order for the options to be exercisable, the average closing price of the Company's shares or the average closing price of the right or certificate to be converted into an amount per share on the ten trading days immediately preceding the exercise must exceed the strike price by a minimum of 28%, with this percentage increasing by seven percentage points as of the fifth anniversary of the issue date and as of each subsequent anniversary date. Also, in addition to the aforementioned requirements, the exercise is only possible if the share price (calculated by reference to the price of the ordinary share underlying the ADS) has performed similar to or better than the Nasdaq Biotechnology Index. The changes made do not affect option rights already issued.

### *Chief Executive Officer Grant*

In September 2019, we granted Prof. Ugur Sahin, M.D., our co-founder and Chief Executive Officer, an option to purchase 4,374,963 of our ordinary shares, subject to Prof. Sahin's continuous employment with us. The option is subject to the terms, conditions, definitions and provisions of our ESOP and the applicable option agreement thereunder. The options' exercise price per share is the Euro translation of the public offering price from our initial public offering, €13.60 (\$15.00). The option will vest annually in equal installments after four years commencing on the first anniversary of our initial public offering and will be exercisable four years after our initial public offering. The option rights can be exercised up to ten years after the allocation date. If they have not been exercised by that date, they will lapse without compensation.

### *Management Board Grant*

From the beginning of 2020, the first year following the completion of our IPO, until the end of the term of the Management Board member's employment agreement, the service agreements with our Management Board provide for a long-term incentive compensation in terms of a yearly grant of options to purchase ordinary shares. The options allocated each year will be subject to the terms, conditions, definitions and provisions of the ESOP and the applicable option agreement thereunder. The allocation of the number of issued options in 2020 occurred as of February 13, 2020. As of December 31, 2020, the assessment about options expected to be granted in 2021 and 2022 was based on estimated allocation dates in the middle of the years 2021 and 2022, respectively. The per share exercise price of the options is the Euro equivalent of the arithmetic mean of the closing prices of the ten last trading days prior to the allocation date. For the award allocated as of February 13, 2020 the exercise price has been determined to be \$30.78 (€28.32). For the awards with estimated allocation dates the exercise prices and the numbers of options expected to be allocated have been derived from the Monte-Carlo simulation model. Those parameters will be adjusted until the actual allocation has occurred and the number of options granted and the exercise price has ultimately been determined. The options will vest annually in equal installments over four years commencing on the first anniversary of the allocation date and will be exercisable four years after the allocation date. The options expire ten years after the allocation date. If they have not been exercised by that date, they will lapse without compensation.

## C. Board Practices

### **Two-Tiered Board Structure**

We are a European public company with limited liability (*Societas Europaea* or SE) (also referred to as European stock corporation, and in the official terminology of the European legislation referred to as European public limited-liability company), having its seat in Germany. We have chosen to have a two-tiered structure. Hence, our corporate bodies are the Management Board (*Vorstand*), the Supervisory Board (*Aufsichtsrat*) and the shareholders' meeting

(Hauptversammlung). Our Management and Supervisory Boards are entirely separate, and, as a rule, no individual may simultaneously be a member of both boards.

Our Management Board is responsible for the day-to-day management of our business in accordance with applicable laws, our Articles of Association (*Satzung*) and the Management Board's internal rules of procedure (*Geschäftsordnung*). Our Management Board represents us in our dealings with third parties.

The principal function of our Supervisory Board is to supervise our Management Board. The Supervisory Board is also responsible for appointing and removing the members of our Management Board, representing us in connection with transactions between a current or former member of the Management Board and us, and granting approvals for certain significant matters.

Our Management Board and our Supervisory Board are solely responsible for and manage their own areas of competency (*Kompetenztrennung*); therefore, neither board may make decisions that, pursuant to applicable law, our Articles of Association or the internal rules of procedure are the responsibility of the other board. Members of both boards owe a duty of loyalty and care to us. In carrying out their duties, they are required to exercise the standard of care of a prudent and diligent businessperson. If they fail to observe the appropriate standard of care, they may become liable to us.

In carrying out their duties, the members of both boards must take into account a broad range of considerations when making decisions, including our interests and the interests of our shareholders, employees, creditors and, to a limited extent, the general public, while respecting the rights of our shareholders to be treated on equal terms. Additionally, the Management Board is responsible for implementing an internal monitoring system for risk management purposes.

Our Supervisory Board has comprehensive monitoring responsibilities. To ensure that our Supervisory Board can carry out these functions properly, our Management Board must, among other duties, regularly report to our Supervisory Board regarding our current business operations and future business planning (including financial, investment and personnel planning). In addition, our Supervisory Board or any of its members is entitled to request special reports from the Management Board on all matters regarding the Company, our legal and business relations with affiliated companies and any business transactions and matters at such affiliated companies that may have a significant impact on our position at any time.

Under German law, our shareholders have, as a general rule, no direct recourse against the members of our Management Board or the members of our Supervisory Board in the event that they are believed to have breached their duty of loyalty and care to us. Apart from when we are unable to fulfill our third party obligations, tortious conduct to board members or other special circumstances, only we have the right to claim damages against the members of our two boards.

We may waive these claims to damages or settle these claims only if at least three years have passed since a claim associated with any violation of a duty has arisen and only if our shareholders approve the waiver or settlement at a shareholders' meeting with a simple majority of the votes cast, provided that no shareholders who in the aggregate hold one-tenth or more of our share capital oppose the waiver or settlement and have their opposition formally recorded in the meeting's minutes.

#### **Supervisory Board**

German law requires that the Supervisory Board consists of at least three members, while a company's articles of association may stipulate a certain higher number. Our Supervisory Board currently consists of four members.

As we are not subject to co-determination, the members of our Supervisory Board are all elected by the shareholders' meeting in accordance with the provisions of the SE Regulation and the German Stock Corporation Act (*Aktengesetz*). German law does not require the majority of our Supervisory Board members to be independent and neither our Articles of Association (*Satzung*) nor the rules of procedure for our Supervisory Board provide otherwise. However, the rules of procedure for our Supervisory Board provide that the Supervisory Board should have an independent member with expertise in the field of accounting, internal control processes and auditing.

Under European law, a member of a supervisory board of an SE may be elected for a maximum term to be specified in the articles of association, which must not exceed six years. Re-election, including repeated re-election, is permissible. The shareholders' meeting may specify a term of office for individual members or all of the members of our Supervisory

Board which is shorter than the standard term of office and, subject to statutory limits, may set different start and end dates for the terms of members of our Supervisory Board. Our Articles of Association provide for a term of approximately five years, depending on the date of the annual general shareholders' meeting in the year in which the term of the relevant member is to expire.

The shareholders' meeting may, at the same time as it elects the members of the Supervisory Board, elect one or more substitute members. The substitute members replace members who cease to be members of our Supervisory Board and take their place for the remainder of their respective terms of office. Currently, no substitute members have been elected or have been proposed to be elected.

Members of our Supervisory Board may be dismissed at any time during their term of office by a resolution of the shareholders' meeting adopted by at least a simple majority of the votes cast. In addition, any member of our Supervisory Board may resign at any time by giving one month's written notice – or, in the event of cause, giving written notice with immediate effect – of his or her resignation to the Management Board.

Our Supervisory Board elects a chairperson and a deputy chairperson from its members. The deputy chairperson exercises the chairperson's rights and obligations whenever the chairperson is unable to do so. The members of our Supervisory Board have elected Mr. Helmut Jeggle as chairperson and Dr. Ulrich Wandschneider as deputy chairperson, each for the term of their respective membership on our Supervisory Board.

The Supervisory Board meets at least twice each calendar half-year. Our Articles of Association provide that a quorum of the Supervisory Board members is present if at least three of its members participate in the vote. Members of our Supervisory Board are deemed present if they attend the meeting via telephone or other (electronic) means of communication (including via video conference) or submit their written vote through another member. Additionally, our Articles of Association allow for resolutions to be taken via telephone or other (electronic) means of communications (including via video conference).

Resolutions of our Supervisory Board are passed by the vote of a simple majority of the votes cast unless otherwise required by law, our Articles of Association or the rules of procedure of our Supervisory Board. In the event of a tie, the chairperson of the Supervisory Board has the casting vote. Our Supervisory Board is not permitted to make management decisions, but in accordance with European and German law and in addition to its statutory responsibilities, it has determined that certain matters require its prior consent, including:

- entering into certain large transactions;
- creating or holding any interest in businesses (except wholly owned subsidiaries) or disposing of shares in businesses (except for a sale of JPT);
- issuing shares from authorized capital, unless the shares are issued pursuant to a redemption of stock appreciation rights; and
- acquiring treasury shares in return for valuable consideration.

#### **Supervisory Board Practices**

Decisions are generally made by our Supervisory Board as a whole, however decisions on certain matters may be delegated to committees of our Supervisory Board to the extent permitted by law. The chairperson, or if he or she is prevented from doing so, the deputy chairperson, chairs the meetings of the Supervisory Board and determines the order in which the agenda items are discussed, the method and order of voting, as well as any adjournment of the discussion and passing of resolutions on individual agenda items after a due assessment of the circumstances. Our Supervisory Board may designate further types of actions as requiring its approval.

In addition, each member of the Supervisory Board is obliged to carry out his or her duties and responsibilities personally, and such duties and responsibilities cannot be generally and permanently delegated to third parties. However, the Supervisory Board and its committees have the right to appoint independent experts for the review and analysis of specific circumstances in accordance with its control and supervision duties under applicable European and German law. We would bear the costs of any such independent experts that are retained by the Supervisory Board or any of its committees.

Pursuant to Section 107 para. 3 of the German Stock Corporation Act (*Aktiengesetz*), the supervisory board may form committees from among its members and charge them with the performance of specific tasks. The committees' tasks, authorizations and processes are determined by the supervisory board. Where permissible by law, important powers of the supervisory board may also be transferred to committees.

By resolution, the Supervisory Board has established an Audit Committee, a Compensation, Nominating and Governance Committee and a Capital Markets Committee. Set forth in the table below are the current members of the Audit Committee, the Compensation, Nominating and Corporate Governance Committee and the Capital Markets Committee.

Name of Committee	Current Members
Audit Committee Compensation, Nominating and Corporate Governance Committee	Dr. Ulrich Wandschneider, Michael Motschmann and Prof. Christoph Huber, M.D. Michael Motschmann, Prof. Christoph Huber, M.D. and Dr. Ulrich Wandschneider
Capital Markets Committee	Helmut Jeggle and Michael Motschmann

#### **Audit Committee**

Our Audit Committee consists of Dr. Ulrich Wandschneider, Michael Motschmann and Prof. Christoph Huber. Dr. Ulrich Wandschneider is the chair of the Audit Committee. The Audit Committee assists the Supervisory Board in overseeing the accuracy and integrity of our financial statements, our accounting and financial reporting processes and audits of our financial statements, the effective functioning of our internal control system, our risk management system, our compliance with legal and regulatory requirements, our independent auditor's qualifications and independence, the performance of the independent auditor and the effective functioning of our internal audit functions, and, subject to certain limitations, adopts and implements pertinent decisions on behalf of the Supervisory Board. The Audit Committee's duties and responsibilities to carry out its purpose, include, among others:

- considering the commissioning of the audit engagement, as well as the compensation, retention and oversight of the independent auditor;
- evaluating the qualifications, independence and performance of the independent auditor;
- reviewing and pre-approving the audit and non-audit services to be performed by the independent auditor;
- reviewing and discussing with the independent auditor and management the annual audit plan, as well as critical accounting policies and practices to be used;
- reviewing and discussing with the independent auditor and management the adequacy and effectiveness of our internal accounting controls and critical accounting policies;
- reviewing and discussing with the independent auditor and management the results of our annual audit;
- reviewing and discussing with the independent auditor and management any quarterly or annual earnings announcements;
- reviewing any related party transactions and reviewing and monitoring potential conflict of interest situations on an ongoing basis for compliance with our policies and procedures; and
- overseeing procedures for the receipt, retention and treatment of complaints received regarding accounting, internal accounting controls or auditing matters.

Within the limits of applicable European and German law, the Audit Committee shall have the resources and authority appropriate to discharge its duties and responsibilities, including the authority to select, retain, terminate, and approve the fees and other engagement terms of special or independent counsel, accountants or other experts and advisors, as it deems necessary or appropriate for so discharging its duties and responsibilities, without seeking approval of the Management Board or Supervisory Board.

All members of the Audit Committee qualify as "independent directors" as such term is defined in Rule 10A-3 under the Exchange Act and Nasdaq Rule 5605. Additionally, our Supervisory Board has determined that Dr. Ulrich Wandschneider qualifies as an "audit committee financial expert" as that term is defined under the Exchange Act.

#### ***Compensation, Nominating and Corporate Governance Committee***

Our Compensation, Nominating and Corporate Governance Committee consists of Michael Motschmann, Prof. Christoph Huber, M.D. and Dr. Ulrich Wandschneider. Mr. Motschmann is the chair of the committee. The Compensation, Nominating and Corporate Governance Committee's duties and responsibilities to carry out its purpose include, among others:

- preparing and discussing with management policies relating to the remuneration of the members of our Management Board;
- reviewing and supervising corporate goals and objectives for the remuneration of the members of the Management Board, including evaluation of the performance of the members of the Management Board in light of these goals and proposals to the Supervisory Board for remuneration based on such evaluations;
- reviewing all equity-based compensation plans and arrangements and making recommendations to the Supervisory Board regarding such plans;
- assisting with identifying and recruiting candidates to fill positions on the Management Board and the Supervisory Board;
- considering any corporate governance issue that arises and developing appropriate recommendations for the Supervisory Board; and
- overseeing the evaluation of the Supervisory Board and reporting on its performance and effectiveness.

#### ***Capital Markets Committee***

Our Capital Markets Committee consists of Helmut Jeggle and Michael Motschmann. Mr. Jeggle is the chair of the committee. The Capital Markets Committee advises the Supervisory Board on issues in connection with capital measures and takeover, merger and acquisition activities. Its responsibilities include the following tasks:

- overseeing the activities of the Company relating to its capital structure and capital raising, including preparation for and implementation of public offerings and share issuances; and
- overseeing the activities of the Company relating to takeovers, mergers and acquisitions activities.

#### **Management Board and Senior Management**

Our Management Board consists of at least two members. Our Supervisory Board determines the exact number of members of our Management Board. Pursuant to the Articles, the Supervisory Board may also appoint a chairperson or a spokesman of the Management Board. Prof. Ugur Sahin, M.D. has been appointed the chair of the Management Board.

The members of our Management Board are appointed by our Supervisory Board for a term of up to five years. They are eligible for reappointment or extension, including repeated re-appointment and extension, after the completion of their term in office, in each case again for up to an additional five years. Under certain circumstances, such as a serious breach of duty or a vote of no confidence by the shareholders in a shareholders' meeting, a member of the Management Board may be removed from office by our Supervisory Board prior to the expiration of his or her term.

The members of our Management Board conduct the daily business of the Company in accordance with applicable laws, our Articles of Association and the rules of procedure for the Management Board adopted by our Supervisory Board. They are generally responsible for the management of our company and for handling our daily business relations with third parties, the internal organization of our business and communications with our shareholders.

A member of the management board of an SE governed by German law may not deal with or vote on matters relating to proposals, arrangements or contractual agreements between himself or herself and the Company, and a member of our Management Board may be liable to us if he or she has a material interest in any contractual agreement between the Company and a third party which is not disclosed to and approved by our Supervisory Board.



The rules of procedure for our Management Board provide that certain matters require a resolution of the entire Management Board, in addition to transactions for which a resolution adopted by the entire Management Board is required by law or required by our Articles of Association. In particular, the entire Management Board shall decide on, among others:

- the budget plan for the following year, which is to be presented by the Management Board to the Supervisory Board by December 20 of each year;
- reporting to the Supervisory Board;
- all measures and transactions that require the Supervisory Board's approval;
- all measures and transactions relating to a business area that is of extraordinary importance to us or involving an extraordinary economic risk;
- taking on new lines of business or discontinuing existing lines of business;
- acquisitions or sales of interests or holdings; and
- certain large transactions.

#### **Code of Conduct and Conflicts of Interest Policy**

We have adopted a Code of Business Conduct & Ethics, or Code of Conduct, which outlines the principles of legal and ethical business conduct under which we do business. The Code of Conduct applies to all of our Supervisory Board members, Management Board members, directors of our subsidiaries and employees. The full text of the Code of Conduct is available on our website at <https://www.biontech.de>. The information and other content appearing on our website are not incorporated by reference into this Annual Report and our website address is included in this report as an inactive textual reference only. Any amendments or waivers from the provisions of the Code of Conduct for members of our Supervisory or Management Boards will be made only after approval by our Supervisory Board and will be disclosed on our website promptly following the date of such amendment or waiver.

We have also adopted a Conflicts of Interest Policy which sets forth the procedures by which we manage potential and actual conflicts of interest. Under the Conflicts of Interest Policy, which applies to all of our Supervisory Board Members, Management Board members, directors of our subsidiaries and employees, an actual, potential or perceived conflict of interest must be disclosed when it first arises. If the conflict is transactional in nature and involves a member of the Management Board or the Supervisory Board, the Management or Supervisory Board, as the case may be, with the abstention of the conflicted member, shall decide whether to approve the transaction.

In addition, we have implemented compliance policies that describe the compliance management systems that have been implemented for us and our subsidiaries. Our compliance policies are designed to ensure compliance with applicable legal requirements, while at the same time implementing high ethical standards that are mandatory for both management and each employee. The overall responsibility for the compliance management system lies with the Management Board. The Audit Committee will receive regular reports on the operation of the compliance management system.

**D. Employees**

As of December 31, 2020, we had 1,941 full-time equivalent employees working for BioNTech, of whom 440 hold a doctoral degree or higher. The following tables provide breakdowns of our full-time equivalent employees as of December 31, 2020 by function and by region:

<b>Function</b>	<b>December 31, 2020</b>
Clinical Research & Development	118
Scientific Research & Development	624
Operations	657
Quality	211
Supporting Functions	286
Commercial & Business Development	45
<b>Total</b>	<b>1,941</b>

<b>Region</b>	<b>December 31, 2020</b>
Mainz, Germany (Headquarters)	1,161
Munich, Germany	45
Idar-Oberstein, Germany	254
Halle, Germany	9
Berlin, Germany	109
Marburg, Germany	268
Cambridge, United States	95
<b>Total</b>	<b>1,941</b>

Since December 2016, our workforce has grown by 300%. Within the next several years, two further new production sites are planned to be built in Mainz and Idar-Oberstein.

None of our employees has engaged in any labor strikes. We have no collective bargaining agreements with our employees, but we maintain a company agreement (*Betriebsvereinbarungen*) with respect to certain topics at our Idar-Oberstein site. We have a workers' council at our Idar-Oberstein and Mainz sites. However, we consider our relationship with our employees to be positive and have not experienced any major labor disputes.

**E. Share Ownership**

The share ownership information with respect to Management Board and Supervisory Board members is presented in Item 7 below.

**Item 7. Major Shareholders and Related Party Transactions**

**A. Major Shareholders**

The following table presents information, as of December 31, 2020, regarding the beneficial ownership of our ordinary shares for:

- each person, or group of affiliated persons, known by us to own beneficially 5% or more of our outstanding shares;
- each member of our Supervisory Board;
- each member of our Management Board; and
- all members of our Supervisory Board and Management Board as a group.

The number of ordinary shares beneficially owned by each entity, person, and member of our Supervisory Board and our Management Board is determined in accordance with the rules of the SEC, and the information is not necessarily indicative of beneficial ownership for any other purpose. Under such rules, beneficial ownership includes any ordinary shares over which the individual has sole or shared voting power or investment power as well as any ordinary shares that the individual has the right to acquire within 60 days of December 31, 2020 through the exercise of any option, warrant or other right. Except as otherwise indicated, and subject to applicable community property laws, the persons named in the table have sole voting and investment power with respect to all ordinary shares held by that person. All of our ordinary shares and ADSs representing our ordinary shares vote on an equal basis.

The percentage of outstanding ordinary shares is computed on the basis of 241,521,065 ordinary shares outstanding as of December 31, 2020. This amount excludes 4,789,016 shares held in treasury. Amounts presented in this section include ordinary shares held in the form of ADSs. Unless otherwise indicated, the address for each beneficial owner is An der Goldgrube 12, D-55131 Mainz, Germany.

Name of Beneficial Owner	Number of Shares Beneficially Owned	Percentage Beneficially Owned
<b>5% Shareholders</b>		
AT Impf GmbH (1)	114,410,338	47.37%
Medine GmbH (2)	41,663,430	17.25%
<b>Members of the Supervisory Board and the Management Board</b>		
Prof. Ugur Sahin, M.D. (3)	41,663,430	17.25%
Sean Marett (4)	985,936	(9)
Dr. Sierk Poetting (5)	654,387	(9)
Dr. Özlem Türeci	-	-
Ryan Richardson	-	-
Helmut Jeggle (6)	116,687,524	48.31%
Michael Motschmann	-	-
Prof. Christoph Huber, M.D. (7)	2,202,040	(9)
Dr. Ulrich Wandschneider (8)	3,480	(9)
<b>All members of our Supervisory Board and Management Board, as a group</b>	<b>162,196,797</b>	<b>67.16%</b>

(1) Information herein is based upon a Schedule 13G jointly filed with the SEC on February 16, 2021 by ATHOS KG, AT Impf GmbH, Helmut Jeggle and Thomas Maier. Consists of 114,410,338 ordinary shares held by AT Impf GmbH. The sole member of AT Impf GmbH is ATHOS KG, and, as a result, ATHOS KG is deemed to be the beneficial owner of the securities held by AT Impf GmbH. Helmut Jeggle and Thomas Maier are each general partners (*Komplementär*) of ATHOS KG and may be deemed to be beneficial owners of the securities held by AT Impf KG. Each of Messrs. Jeggle and Maier disclaim beneficial ownership of such shares except to the extent of their pecuniary interest therein. We are also aware that, since December 31, 2020, AT Impf GmbH has sold 2,000,000 of the ordinary shares it held.

(2) Information herein is based upon a Schedule 13G jointly filed with the SEC on February 16, 2021 by Medine GmbH and Prof. Sahin. The sole shareholder of Medine GmbH is Prof. Sahin, and, as a result, Prof. Sahin is deemed to be the beneficial owner of the securities held by Medine GmbH. Consists of 41,663,430 ordinary shares held by Medine GmbH, 2,552,040 of which are held for the

benefit of a former colleague pursuant to a trust arrangement. Pursuant to this arrangement, Medine GmbH retains voting power, but not dispositive power, over such shares for so long as such shares are held in trust and accordingly Medine GmbH and Prof. Ugur Sahin, M.D. each may be deemed beneficially to own such shares.

- (3) Consists of the shares described in note 2 above. Prof. Sahin is the sole shareholder of Medine GmbH.
- (4) Consists of 985,936 ordinary shares held by RLG GmbH. Mr. Marett is the sole shareholder of RLG GmbH.
- (5) Consists of 654,387 ordinary shares held by Tofino GmbH. Dr. Poetting is sole shareholder of Tofino GmbH.
- (6) Consists of (a) the shares described in note 1 above, (b) 332,316 ordinary shares held directly by Mr. Jeggle, (c) 1,893,651 ordinary shares held by Salvia GmbH and (d) 51,219 ordinary shares held by Nils GmbH. Mr. Jeggle has no voting or dispositive power with regard to such shares described in note 1 above and disclaims beneficial ownership of such shares except to the extent of his pecuniary interest therein.
- (7) Consists of 2,202,040 ordinary shares held by CHuber 2008 GmbH. Prof. Huber is the majority shareholder of CHuber 2008 GmbH.
- (8) Consists of 3,480 ordinary shares held by beebusy capital gmbh.
- (9) Less than one percent.

#### **Holdings by U.S. Shareholders**

We estimate that as of December 31, 2020, 30.46% of our outstanding ordinary shares are held by 2 U.S. record holders.

#### **B. Related Party Transactions**

##### **Agreements with TRON**

We have a longstanding relationship with Translational Oncology at the University Medical Center of the Johannes Gutenberg University Mainz (*Translationale Onkologie an der Universitätsmedizin der Johannes Gutenberg Universität Mainz gemeinnützige GmbH*), or TRON. TRON is a non-profit limited liability company engaged in biopharmaceutical research. Prof. Ugur Sahin, M.D., our co-founder and Chief Executive Officer, co-founded TRON and served as Managing Director for Science and Research at TRON, until his resignation September 10, 2019, and is currently serving as a scientific advisor of TRON. Additionally, Prof. Christoph Huber, a member of our Supervisory Board, served on TRON's supervisory board until his resignation in April 2019. Prof. Ugur Sahin, M.D., our co-founder and Chief Executive Officer, owns a significant amount of shares in TRON.

On January 1, 2015, we and certain of our subsidiaries entered into both a Master Agreement for Research Services and a License Agreement with TRON. During the year ended December 31, 2020, the aggregate value of transactions related to these agreements with TRON amounted to €10.1 million pursuant to these agreements (€10.0 million during the year ended December 31, 2019).

##### **Agreements with Santo Service GmbH**

We have several agreements with Santo Service GmbH, or Santo Service, pursuant to which Santo Service provides us with certain real property and custodial services. Santo Service is wholly owned by AT Impf GmbH, one of our major shareholders. During the year ended December 31, 2020, the aggregate value of transactions with Santo Service amounted to €4.6 million pursuant to these agreements (€2.1 million during the year ended December 31, 2019).

##### **Agreement with Medine GmbH**

On August 29, 2019, we entered into an agreement with Medine GmbH, or Medine, pursuant to which we acquired from Prof. Dr. Ugur Sahin, M.D. all of the outstanding shares of reBOOST Management GmbH (subsequently renamed to reSano GmbH), or reBOOST, which owned certain intellectual property, in exchange for a total consideration of €0.3 million. Medine is wholly-owned by Prof. Ugur Sahin, M.D., our co-founder and Chief Executive Officer, who was also the Managing Director of reBOOST at the time of the acquisition and is the Managing Director of Medine.

##### **Series A 2018 Financing**

In February 2018, we issued an aggregate of 22,587,912 of our ordinary shares to certain new and existing shareholders at a price of \$11.99 per share for aggregate proceeds of \$270.9 million.

The following table sets forth the aggregate number of ordinary shares that we issued and sold in this transaction to our related parties and the aggregate purchase price for such shares:

Participant	Number of Ordinary Shares	Aggregate Purchase Price (\$)
AT Impf GmbH (1)	5,002,812	59,997,612.58

(1) See "Major Shareholders" under this Item 7 for additional information about ordinary shares held by this entity or the parent company of this entity.

#### Series B 2019 Financing

In June and August 2019, we issued an aggregate of 12,465,288 ordinary shares (excluding 5,524,506 ordinary shares which were issued to a Hong Kong-based investor and subsequently transferred to us for no consideration) to certain new and existing shareholders at a price of \$18.10 per share for aggregate proceeds of €198.6 million (\$225.6 million).

The following table sets forth the aggregate number of ordinary shares that we issued and sold in this transaction to our related parties and the aggregate purchase price for such shares:

Participant	Number of Ordinary Shares	Aggregate Purchase Price (\$)
AT Impf GmbH (1)	1,657,332	29,999,550.68

(1) See "Major Shareholders" under this Item 7 for additional information about ordinary shares held by this entity or the parent company of this entity.

#### Initial Public Offering

In October 2019, we sold 10,517,408 ADSs representing 10,517,408 of our ordinary shares to certain new and existing shareholders at a price of \$15.00 per ADS for proceeds of €135.4 million (\$149.1 million) in our initial public offering. The following table sets forth the aggregate number of ADSs that we issued and sold in this transaction to our related parties and the aggregate purchase price for such shares:

Participant	Number of ADS representing Ordinary Shares	Aggregate Purchase Price (\$)
AT Impf GmbH (1)	2,800,000	42,000,000.00
Helmut Jeggler (1)	51,219	768,285.00

(1) See "Major Shareholders" under this Item 7 for additional information about ordinary shares held by this entity, the parent company of this entity or Supervisory Board member.

#### Global Offering

On July 27, 2020 we issued 5,500,000 ADS each representing one of our ordinary shares at a public offering price of \$93.00 per ADS for proceeds of €5.5 million (\$6.4 million), which we refer to as the Underwritten Offering. On August 27, 2020, following the Underwritten Offering, we issued 16,124 ADS each representing one of our ordinary shares at a public offering price of \$93.00 per ADS for proceeds of €16 thousand (\$19 thousand), which we refer to as the Rights Offering.

Participant	Number of ADS representing Ordinary Shares	Aggregate Purchase Price (\$)
AT Impf GmbH (1)	268,818	25,000,074.00

(1) See "Major Shareholders" under this Item 7 for additional information about ordinary shares held by this entity, the parent company of this entity.

**C. Interests of Experts and Counsel**

Not applicable.

**Item 8. Financial Information**

**A. Consolidated Statements and Other Financial Information**

See Item 18.

**B. Significant Changes**

Not applicable.

**Item 9. The Offer and Listing**

**A. Offer Listing Details**

Not applicable.

**B. Plan of Distribution**

Not applicable.

**C. Markets**

ADSs representing our ordinary shares have been listed on the Nasdaq Global Select Market under the symbol "BNTX" since October 10, 2019.

**D. Selling Shareholders**

Not applicable.

**E. Dilution**

Not applicable.

**F. Expenses of the Issue**

Not applicable.

**Item 10. Additional Information**

**A. Share Capital**

Not applicable.

**B. Memorandum and Articles of Association**

**General**

We were incorporated as a German stock corporation (*Aktiengesellschaft*) with the legal name Petersberg 91. V AG under the laws of the Federal Republic of Germany on June 2, 2008. We changed our name to BioNTech AG on December 11, 2008. Effective as of March 8, 2019, the date on which the change of legal form and company was registered with the commercial register (*Handelsregister*) of the local court (*Amtsgericht*) of Mainz, Germany, we converted to a *Societas Europaea* with the legal name BioNTech SE. We completed our initial public offering in October 2019. The principal legislation under which we operate and our shares are issued are the Council Regulation (EC) No 2157/2001 of October 8, 2001 on the Statute for a European company (SE), the German Law on the Implementation of Council Regulation (EC) No 2157/2001 of October 8, 2001 on the Statute for a European company (SE) (*Gesetz zur Ausführung der Verordnung (EG)*)

We are registered with the commercial register (*Handelsregister*) of the local court (*Amtsgericht*) in Mainz, Germany, under number HRB 48720. Our statutory seat is in Mainz, Germany, and our registered office is An der Goldgrube 12, 55131 Mainz, Germany. Copies of our Articles of Association (*Satzung*) will be publicly available from the commercial register (*Handelsregister*) at the local court of Mainz, Germany, electronically at [www.unternehmensregister.de](http://www.unternehmensregister.de) and as an exhibit to this Annual Report.

#### Share Capital

We have share capital registered in the commercial register (*Handelsregister*) in the amount of €246,310,081, which is divided into 246,310,081 registered shares (*Namensaktien*). All shares are shares with no par value (*Stückaktien ohne Nennbetrag*) with a notional amount attributable to each ordinary share of €1. Each issued ordinary share is fully paid.

#### Form, Certification and Transferability of Shares

The form and contents of our share certificates, collective share certificates and global share certificates are determined by our Management Board. A shareholder's right to certification of its shares is excluded, to the extent permitted by law and to the extent that certification is not required by the stock exchange on which the shares or rights or certificates representing them are admitted to trading. We are permitted to issue collective share certificates and global share certificates that represent multiple or all of our shares.

Our shares are freely transferable under German law.

#### Changes in Our Share Capital During the Last Three Fiscal Years

Our share capital as registered with the commercial register (*Handelsregister*) amounts to €246,310,081, including an amount of €4,789,016 relating to 4,789,016 ordinary shares held in treasury. Since January 1, 2018, our share capital has changed as follows:

- On February 1, 2018, our share capital as registered with the commercial register (*Handelsregister*) was increased by issuing 1,254,884 shares;
- On September 12, 2018, our share capital as registered with the commercial register (*Handelsregister*) was increased by issuing 32,373 shares;
- On October 18, 2018, our share capital as registered with the commercial register (*Handelsregister*) was increased by issuing 186,715 shares;
- On January 29, 2019, our share capital as registered with the commercial register (*Handelsregister*) was increased by issuing 282,678 shares;
- On April 24, 2019, our share capital as registered with the commercial register (*Handelsregister*) was increased by issuing 131,933 shares against contributions in kind (swap of shares in our company against shares in one of our subsidiary companies);
- On June 26, 2019, our share capital as registered with the commercial register (*Handelsregister*) was increased by issuing 666,123 shares;
- On August 16, 2019, our share capital as registered with the commercial register (*Handelsregister*) was increased by issuing 333,310 shares;
- On September 18, 2019, our share capital as registered with the commercial register (*Handelsregister*) was increased by issuing 206,595,492 shares by way of a capital increase from our funds; thus, no contribution by investors was made;
- On September 26, 2019, our share capital as registered with the commercial register (*Handelsregister*) was increased by issuing 3,038,674 shares;
- On October 14, 2019, our share capital as registered with the commercial register (*Handelsregister*) was increased by issuing 10,000,000 shares;

- On November 6, 2019, our share capital as registered with the commercial register (*Handelsregister*) was increased by issuing 517,408 shares;
- On April 23, 2020, our share capital as registered with the commercial register (*Handelsregister*) was increased by issuing 1,580,777 shares;
- On May 5, 2020, our share capital as registered with the commercial register (*Handelsregister*) was increased by issuing 2,377,446 shares;
- On May 8, 2020, our share capital as registered with the commercial register (*Handelsregister*) was increased by issuing 1,935,488 shares;
- On July 24, 2020, our share capital as registered with the commercial register (*Handelsregister*) was increased by issuing 5,500,000 shares;
- On August 24, 2020, our share capital as registered with the commercial register (*Handelsregister*) was increased by issuing 16,124 shares; and
- On September 8, 2020, our share capital as registered with the commercial register (*Handelsregister*) was increased by issuing 2,595,996 shares.

#### **Anti-takeover Provisions of Our Charter Documents**

Our Articles of Association (*Satzung*) do not include any provisions that would have a direct effect of delaying, deferring or preventing a change of control. However, in the event of a hostile takeover, we could use our authorized capital to increase our share capital to issue new shares to an investor at a premium. An increase in the number of shares outstanding could have a negative effect on a party's ability to carry out a hostile takeover. The provisions of German law relating to public bids and takeovers that require any such bids to be carried out in a manner designed to safeguard equal and fair treatment to all shareholders and give them a right to be bought out at an adequate compensation where a party acquires "control" (as such term is defined in such provisions) over the relevant company do not apply.

#### **Future Changes to the Share Capital**

##### ***Authorized Capital***

Under the relevant law, the general meeting of a European stock corporation (*Societas Europaea*) governed by German law can authorize the Management Board, with the consent of the Supervisory Board, to issue shares in a specified aggregate nominal amount of up to 50% of the issued share capital of such company at the time the resolution becomes effective. The shareholders' authorization becomes effective upon registration in the commercial register (*Handelsregister*) and may extend for a period of no more than five years thereafter. Under § 4(5) of our Articles of Association (*Satzung*), the Management Board is authorized to increase our share capital, on one or more occasions, by a total of up to €91,812,171 by issuing, on one or more occasions, up to 91,812,171 new, registered shares with no par value (*Genehmigtes Kapital*), in each case with consent of the Supervisory Board. This authorization expires on August 18, 2024.

Any new shares issued from the authorized capital will participate in the profits starting with the fiscal year for which the annual financial statements have not yet been submitted to the general meeting at the time of registration of the implementation of the capital increase. Further details of a capital increase from the authorized capital may be specified by the Management Board.

##### ***Conditional Capital***

Pursuant to § 4(6) of our Articles of Association (*Satzung*), our share capital is conditionally increased by €21,874,806 through issuance of new, registered shares with no par value (*Bedingtes Kapital ESOP 2017/2019*). The conditional capital may only be used to issue shares to the holders of option rights granted under our ESOP to members of our Management Board and to certain of our employees.

The conditional capital increase will only be implemented to the extent that stock options under our ESOP are exercised and such stock options are not serviced by our providing treasury shares or through cash payments. Any new shares issued under the conditional capital pursuant to the said § 4(6) of our Articles of Association (*Satzung*) shall be entitled to dividends from the beginning of the previous financial year in case they are created by the exercise of



subscription rights until the start of the annual general meeting of the Company and otherwise from the beginning of the financial year in which they are created as a result of the exercise of the stock options.

Pursuant to § 4(7) of our Articles of Association (*Satzung*), our share capital is conditionally increased by €87,499,260 through issuance of new, registered shares with no par value (*Bedingtes Kapital WSV 2019*). The conditional capital may only be used to issue shares to the holders or creditors of option rights or conversion rights or those under an obligation to convert under warrant-linked or convertible bonds avail of their option rights or conversion rights or where they are under an obligation to convert, to the extent they satisfy their obligation to convert, or to the extent that we exercise a right to choose to grant our shares, in whole or in part instead of paying a monetary amount due, and to the extent cash compensation is not granted in each relevant case or treasury shares or shares of another stock-listed company are not utilized for servicing.

Any new shares issued under the said conditional capital pursuant to the said § 4(7) of our Articles of Association shall carry an entitlement to dividends from the beginning of the financial year in which they are created; however, as far as the law permits, the Management Board can confer dividend rights for new shares in derogation of the foregoing.

#### **Preemptive Rights**

German law generally provides shareholders with preemptive rights when new shares convertible bonds, bonds with warrants, profit participation rights or participating bonds are issued. This requirement, however, may also be satisfied by way of a credit institution subscribing for the securities and then offering them to the shareholders for purchase (*mittelbares Bezugsrecht*).

Further, it is possible for a shareholder resolution approved by three-quarters of the share capital voting on the resolution to exclude preemptive rights both where the general meeting itself resolves that the new securities to be issued and in relation to the authorized capital, *i.e.*, an authorization to the Management Board to, with the consent of the Supervisory Board, resolve on the issuance of new securities; provided, however, that in each case the exclusion or the authorization to so exclude preemptive rights, respectively, must be justified by specific facts, in accordance with established case law of the German Federal Court of Justice (*BGH*). The German Federal Court of Justice (*BGH*) considers the exclusion of subscription rights justified if it (i) serves a purpose in the company's interests, (ii) is suitable for attaining such purpose, and (iii) is necessary and appropriate. Additionally, the management board must submit a written report to the shareholders' meeting in which it presents the reasons for the exclusion of the subscription rights.

Accordingly, under our Articles of Association (*Satzung*), the Management Board may, with the consent of the Supervisory Board, exclude such preemptive rights in a capital increase from the authorized capital in the following circumstances:

- to exclude fractional amounts from the subscription right;
- in the case of a capital increase against cash contributions, if the issue price of the new shares is not significantly lower than the market price of the company's shares already listed on the stock exchange at the time the issue price is finally determined. However, this authorization shall only apply subject to the provision that the shares issued excluding subscription rights in accordance with Section 186(3) Sentence 4 AktG may not exceed a total of 10% of the share capital either at the time this authorization takes effect or, if this amount is lower, at the time this authorization is exercised. This limit of 10% of the share capital includes shares which are issued or disposed of during the term of this authorization until the date of its exercise in direct or equivalent application of Section 186(3) Sentence 4 AktG. Shares which are used to service bonds with convertible or option rights or convertible obligations are to be offset against the 10% limit if these bonds were issued under exclusion of shareholder subscription rights in accordance with Section 186(3) Sentence 4 AktG during the entitlement period. Treasury shares are to be offset against the 10% limit, where they were disposed of by the company during the term of this authorization with the exclusion of subscription rights pursuant to or in analogous application of Section 186(3) Sentence 4 AktG;
- in the case of capital increases in exchange for contributions in kind, in particular in order to be able to offer the shares to third parties when purchasing companies, parts of companies or interests in companies as well as licenses or industrial property rights;
- in order to grant subscription rights to new shares to holders of conversion or option rights in respect of bonds issued by the company or its subordinated domestic or foreign Group companies, to the extent to which they

- would be entitled after exercising their conversion or option rights or after fulfilling an agreed conversion obligation;
- to implement an election dividend by which shareholders are given the option to contribute their dividend entitlements (either in whole or part) as a contribution in kind against issuance of our new shares;
- in capital increases, in each case if excluding subscription rights, according to the assessment by the Management Board, is expedient to the shares' successful placement in view of the requirements of eligible investors and if the discount by which the issue price of the shares may be below the current stock ex-change price at the time the Management Board adopts the resolution on using authorized capital, according to the assessment by the Management Board, does not exceed the extent necessary for a successful placement and in any case does not exceed 10% of either the latest available closing price at the time when the issue price is fixed or the volume-weighted average price over a period of up to five trading days ending on the day on which the issue price is so fixed;
- in case shares are to be issued to a member of our Management Board or to another person who is employed by us or one of our affiliates and a minimum holding period of at least one year and the obligation to transfer back the shares in the event that the beneficiary is not employed by us or one of our affiliated companies for the entire duration of the holding period or any other agreed period is agreed upon. Additional restrictions with regard to the shares issued may be agreed upon; and
- in order to be able to satisfy an option to acquire additional ordinary shares or American Depositary Shares that has been agreed with the issuing banks in connection with a public offering of our shares in the form of American Depositary Shares.

The total number of new shares issued from the authorized capital and under exclusion of subscription rights pursuant to bullets one through three and six above may not exceed 20% of the share capital, either at the time that the amendment to the Articles of Association (*Satzung*), resolved upon by the general meeting of June 26, 2020, came into effect or, if lower, at the time of utilization of the authorization. To be counted against the aforementioned 20% limit are: (i) those shares issued or to be issued to service conversion or option rights or conversion or option obligations or tender rights of the issuer under bonds, if the bonds have been issued during the term of this authorization up to the time of its exercise, excluding the subscription rights of shareholders, as well as, to a certain extent (ii) treasury shares that have been disposed under exclusion of subscription rights during the term of this authorization (except in the case of certain exceptions of the resolution to item no. 8 of the general meeting of August 19, 2019).

#### **Corporate Purpose of our Company**

Our business objective, as described in § 2 of our Articles of Association (*Satzung*), is to research and develop, as well as to manufacture and market immunological and RNA-based drugs and test methods for the diagnosis, prevention and treatment of cancer, infectious diseases and other serious diseases.

#### **Shareholders' Meetings and Voting Rights**

Pursuant to our Articles of Association (*Satzung*), shareholders' meetings may be held at our seat or in any municipality in Germany with more than 500,000 inhabitants. Generally, shareholders' meetings are convened by our Management Board, or our Supervisory Board. Shareholders representing in the aggregate at least five percent of our ordinary shares may, subject to certain formal prerequisites, request that a shareholders' meeting be convened. Shareholders representing in the aggregate at least five percent of our ordinary shares or owning shares with an aggregate nominal value of at least €500,000 may request the addition of one or several items to the agenda of any shareholders' meeting. Shareholders' meetings may be summoned either via publication in the German Federal Gazette (*Bundesanzeiger*) or via mail or email, in each case generally at least 36 days before the meeting.

Shareholders may participate and vote in the shareholders' meeting if they are registered as a shareholder with the Company's share register. A shareholder who wishes to attend the shareholders' meeting—either in person or by proxy, which may also be appointed by us (*Stimmrechtsvertreter*)—must register for the meeting, which registration must occur no later than six days before the meeting (or at a later date, if so determined by our Management Board).

Each share carries one vote at a shareholders' meeting. Resolutions are, in accordance with our Articles of Association (*Satzung*), generally taken by simple majority of the votes cast. However, under applicable German and European law, a number of resolutions must be passed by either a three-quarter majority of the votes cast or a three-quarter

majority of the share capital represented at the meeting. The fact that in these cases the quorum is determined in relation to the share capital or shares present (as opposed to, for example, all shares eligible to vote) means that holders of a minority of our shares could potentially control the outcome of resolutions.

#### **Claims against Directors and Shareholders' Derivative Actions**

Under German law, generally, the company, rather than its shareholders, is the proper claimant in an action with respect to a wrong committed against the company, or in cases where there is an irregularity in the company's internal management or supervision. Therefore, such claims may only be raised by the company represented by its management board, or, in the case of a wrong committed by a member of the Management Board, by the Supervisory Board. This concerns, in particular, claims against members of the Management Board or the Supervisory Board.

However, pursuant to German case law, the Supervisory Board is obliged to pursue the company's claims against the Management Board, unless the interest of the company keeps them from doing so. Further, the Management Board, or, if a claim is against a member of the Management Board, the Supervisory Board, is obliged to pursue the company's claims against the designated individuals if so resolved by a simple majority of votes cast during a shareholders' meeting. With a simple majority of votes, shareholders can also request that a representative pursue the claim on behalf of the company. The court may appoint such a representative upon the request of shareholders holding at least 10% of the company's share capital or a participation of at least €1,000,000 in the share capital.

If the company is unable to fulfill its third-party obligations, the company's creditors may pursue the company's damage claims against members of the Management Board for certain wrongdoings.

Under certain circumstances, shareholders can bring forward damage claims of the company against its management on their own behalf. In order to bring forward such a claim one shareholder alone or together with other shareholders needs to hold at least 1% of the company's share capital or a participation of €100,000 in the share capital. Additionally, the claimant(s) must comply with special claim approval procedures conducted before a competent court which will allow the pertinent request only if there are circumstances justifying the assumption that damage has been afflicted on the company by improper conduct or a gross breach of the law or the articles of association.

#### **Dividend Rights**

Under German law, distributions of dividends on shares for a given fiscal year are generally determined by a process in which the management board and supervisory board submit a proposal to the company's annual general shareholders' meeting held in the subsequent fiscal year and such annual general shareholders' meeting adopts a resolution.

German law provides that a resolution concerning dividends and distribution thereof may be adopted only if the company's unconsolidated financial statements prepared in accordance with German law show net retained profits. In determining the profit available for distribution, the result for the relevant year must be adjusted for profits and losses brought forward from the previous year and for withdrawals from or transfers to reserves. Certain reserves are required by law and must be deducted when calculating the profit available for distribution.

Shareholders generally participate in profit distributions in proportion to the number of shares they hold. Dividends on shares resolved by the general shareholders' meeting are paid annually, shortly after the general shareholders' meeting, in compliance with the rules of the respective clearing system. Dividend payment claims are subject to a three-year statute of limitation in the company's favor.

#### **Authorization to Purchase and Sell Our Own Shares**

We may not purchase our own shares unless authorized by the shareholders' meeting or in other very limited circumstances as set out in the German Stock Corporation Act. The Company's shareholders' meeting held on August 19, 2019 authorized the Management Board until August 18, 2024, provided it complies with the legal requirement of equal treatment, to acquire treasury shares up to a total of 10% of the Company's share capital at the time of the relevant resolution or at the time the authorization is exercised. These shares held by the Company (including shares attributable to it pursuant to the AktG) must never exceed 10% of the share capital. The shares may be purchased (i) through the stock exchange, (ii) by means of a public offer directed to all shareholders of the Company, (iii) by means of a public invitation to the shareholders to make a sales offer or (iv) from the Bill & Melinda Gates Foundation under very limited circumstances as specified in the authorization. Such shares may not be purchased for trading purposes. The Management Board is authorized to use the shares only as specified in the authorization.

### **Squeeze-Out of Minority Shareholders**

Under German law, the shareholders' meeting of a stock corporation may resolve, upon request of a shareholder that holds at least 95% of the share capital, that the shares held by any remaining minority shareholders be transferred to the majority shareholder against payment of "adequate cash compensation" (*Ausschluss von Minderheitsaktionären*). This amount must take into account the full value of the company at the time of the resolution, which is generally determined using the future earnings value method (*Ertragswertmethode*).

A squeeze-out in the context of a merger (*umwandlungsrechtlicher Squeeze-Out*) only requires a majority shareholder to hold at least 90% of the share capital.

### **Liquidation Rights**

Apart from liquidation, e.g., as a result of insolvency proceedings, we may be liquidated with a vote of the holders of at least three-quarters of the share capital represented at the shareholders' meeting at which such a vote is taken. If we are liquidated, any assets remaining after all of our liabilities have been paid off would be distributed among our shareholders in proportion to their holdings in accordance with German statutory law. The German Stock Corporation Act provides certain protections for creditors, which must be observed in the event of liquidation.

### **C. Material Contracts**

Except as otherwise disclosed in this Annual Report (including the exhibits thereto), we are not currently, and have not been in the last two years, party to any material contract, other than contracts entered into in the ordinary course of our business.

### **D. Exchange Controls**

There are currently no legal restrictions in the Federal Republic of Germany on international capital movements and foreign exchange transactions, except in limited embargo circumstances (*Teilembargo*) relating to certain areas, entities or persons as a result of applicable resolutions adopted by the United Nations and the European Union. Restrictions currently exist with respect to, among others, Belarus, Congo, Egypt, Eritrea, Guinea, Guinea-Bissau, Iran, Iraq, Lebanon, Libya, North Korea, Somalia, South Sudan, Sudan, Syria, Tunisia and Zimbabwe.

For statistical purposes, there are, however, limited notification requirements regarding transactions involving cross-border monetary transfers. With some exceptions, every corporation or individual residing in the Federal Republic of Germany must report to the German Central Bank (*Deutsche Bundesbank*) (i) any payment received from, or made to, a non-resident corporation or individual that exceeds €12,500 (or the equivalent in a foreign currency) and (ii) (with the exception of individuals residing in the Federal Republic of Germany) in case the sum of claims against, or liabilities payable to, non-resident corporations or individuals exceeds €5,000,000 (or the equivalent in a foreign currency) at the end of any calendar month. Payments include cash payments made by means of direct debit, checks and bills, remittances denominated in euros and other currencies made through financial institutions, as well as netting and clearing arrangements.

### **E. Taxation**

#### **German Taxation**

The following discussion addresses certain German tax consequences of acquiring, owning or disposing of the ADSs. With the exception of "—Taxation of Holders Tax Resident in Germany" below, which provides an overview of dividend taxation and of capital gains taxation with respect to holders that are residents of Germany, this discussion applies only to U.S. treaty beneficiaries (defined below) that acquire the ADSs representing our ordinary shares.

This discussion is based on domestic German tax laws, including, but not limited to, circulars issued by German tax authorities, which, e.g., are not binding on the German courts, and the Treaty (defined below). It is based upon tax laws in effect at the time of filing of this report. These laws are subject to change, possibly with retroactive effect. For example, certain member states of the European Union are considering introducing a financial transaction tax (*Finanztransaktionssteuer*) which, if introduced, may also be applicable on sales and/or transfer of ADSs. In addition, in Germany, for example, there are currently ongoing discussions on an increase of the top tax rate, which may also have an effect on the German tax consequences of acquiring, owning and disposing of the ADSs. There is no assurance that German tax authorities will not challenge one or more of the tax consequences described in this section.

In addition, this discussion is based upon the assumption that each obligation in the deposit agreement and any related agreement will be performed in accordance with its terms. It does not purport to be a comprehensive or exhaustive description of all German tax considerations that may be of relevance in the context of acquiring, owning and disposing of ADSs.

The tax information presented in this report is not a substitute for tax advice. Prospective holders of ADSs should consult their own tax advisors regarding the German tax consequences of the purchase, ownership, disposition, donation or inheritance of ADSs in light of their particular circumstances, including the effect of any state, local, or other foreign or domestic laws or changes in tax law or interpretation. The same applies with respect to the rules governing the refund of any German dividend withholding tax (*Kapitalertragsteuer*) withheld. Only an individual tax consultation can appropriately account for the particular tax situation of each investor.

#### **General**

Based on the circular issued by the German Federal Ministry of Finance (*BMF-Schreiben*), dated May 24, 2013, reference number IV C 1-S2204/12/10003, as amended by the circular dated December 18, 2018 (reference number IV C 1 – S 2204/12/10003), in respect of the taxation of American Depositary Receipts, or ADRs, on domestic shares, or the ADR Tax Circular, for German tax purposes, the ADSs should, in light of the ADR Tax Circular, represent a beneficial ownership interest in the underlying shares of BioNTech and qualify as ADRs for the purpose of the ADR Tax Circular. If the ADSs qualify as ADRs under the ADR Tax Circular, dividends would accordingly be attributable to holders of the ADSs for German tax purposes, and not to the legal owner of the ordinary shares (*i.e.*, the financial institution on behalf of which the ordinary shares are stored at a domestic depository for the ADS holders). Furthermore, holders of the ADSs should be treated as beneficial owners of the capital of BioNTech with respect to capital gains (see below in section “—German Taxation of Capital Gains of the U.S. Treaty Beneficiaries of the ADSs”). However, investors should note that circulars published by the German tax authorities (including the ADR Tax Circular) are not, e.g., binding on German courts, including German tax courts, and it is unclear whether a German court would follow the ADR Tax Circular in determining the German tax treatment of the ADSs. For the purpose of this German tax section, it is assumed that the ADSs qualify as ADRs within the meaning of the ADR Tax Circular.

#### **Taxation of Holders Not Tax Resident in Germany**

The following discussion describes selected German tax consequences of acquiring the ADSs, owning the ADSs and disposing of the ADSs to a holder that is a U.S. treaty beneficiary. For purposes of this discussion, a “U.S. treaty beneficiary” is a resident of the United States for purposes of the Convention between the Federal Republic of Germany and United States of America for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with respect to Taxes on Income and Capital and Certain Other Taxes of 1989, as amended by the Protocol as of June 4, 2008 (*Abkommen zwischen der Bundesrepublik Deutschland und den Vereinigten Staaten von Amerika zur Vermeidung der Doppelbesteuerung und zur Verhinderung der Steuerverkürzung auf dem Gebiet der Steuern vom Einkommen und vom Vermögen und einiger anderer Steuern in der Fassung vom 4. Juni 2008*), hereinafter referred to as the “Treaty,” who is eligible for relevant benefits under the Treaty.

A holder will be a U.S. treaty beneficiary entitled to full Treaty benefits in respect of the ADSs if it is, *inter alia*:

- the beneficial owner of the ADSs (and the dividends paid with respect thereto);
- a U.S. tax resident corporation or individual;
- not also a resident of Germany for German tax purposes; and
- not subject to the limitation on benefits (*i.e.*, anti-treaty shopping) article of the Treaty that applies in limited circumstances.

Special rules apply to pension funds and certain other tax-exempt investors.

This discussion does not address the treatment of ADSs that are (i) held in connection with a permanent establishment or fixed base through which a U.S. treaty beneficiary carries on business or performs personal services in Germany or (ii) part of business assets for which a permanent representative in Germany has been appointed.

### General Rules for the Taxation of Holders Not Tax Resident in Germany

Non-German resident holders of ADSs are subject to German taxation with respect to German source income (*beschränkte Steuerpflicht*). According to the ADR Tax Circular, income from the shares should be attributed to the holder of the ADSs for German tax purposes. As a consequence, income from the ADSs should be treated as German source income.

#### German Withholding Taxation of Dividends of the U.S. Treaty Beneficiaries of the ADSs

Generally, the full amount of a dividend distributed by BioNTech to a non-German resident holder, which does not maintain a permanent establishment or other taxable presence in Germany, is subject to (final) German withholding tax at an aggregate rate of 26.375% (that amount consists of 25% on dividends distributed plus solidarity surcharge of 5.5% on the amount of the withholding tax). The basis for the withholding tax is generally the dividend approved for distribution by our general shareholder's meeting. German withholding tax is withheld and remitted to the German tax authorities by (i) the disbursing agent (*i.e.*, the German credit institution, financial services institution, securities trading enterprise or securities trading bank (each as defined in the German Banking Act (*Kreditwesengesetz*) and in each case including a German branch of a foreign enterprise, but excluding a foreign branch of a German enterprise)) that holds or administers the underlying shares in custody and (a) disburses or credits the dividend income from the underlying shares, (b) disburses or credits the dividend income from the underlying shares on delivery of the dividend coupons or (c) disburses such dividend income to a foreign agent; or (ii) the central securities depository (*Wertpapiersammelbank*) in terms of the German Depository Act (*Depotgesetz*) holding the underlying shares in a collective deposit, if such central securities depository disburses the dividend income from the underlying shares to a foreign agent, regardless of whether a holder must report the dividend for tax purposes and regardless of whether or not a holder is a resident of Germany. Dividend payments, to the extent funded from BioNTech's tax-recognized contribution account (*steuerliches Einlagekonto*), subject to certain prerequisites, do not form part of the taxable dividend income but should lower the holder's acquisition costs for the ADSs.

Pursuant to the Treaty, the German withholding tax may generally not exceed (i) 15% of the gross amount of the dividends received by a U.S. treaty beneficiary other than a company holding ADSs which represent 10% or more of the voting shares in BioNTech, and (ii) 5% of the gross amount of the dividends received by a U.S. treaty beneficiary that is a company holding ADSs which represent 10% or more of the voting shares in BioNTech. The excess of the total withholding tax, including the solidarity surcharge, over the maximum rate of withholding tax permitted by the Treaty is refunded to U.S. treaty beneficiaries upon application. For example, for a declared dividend of 100, a U.S. treaty beneficiary initially receives 73,625 (100 minus the 26.375% withholding tax including solidarity surcharge). A U.S. treaty beneficiary other than a company holding ADSs which represent 10% or more of the voting shares in BioNTech is entitled to a partial refund from the German tax authorities in the amount of 11.375% of the gross dividend (of 100). As a result, the U.S. treaty beneficiary ultimately receives a total of 85 (85% of the declared dividend) following the refund of the excess withholding. However, it should be noted that there is uncertainty as to how the German tax authorities will apply the refund process to dividends on the ADSs with respect to non-German resident holders. Further, such refund is subject to the German anti-avoidance treaty shopping rule (as described below in "Withholding Tax Refund for U.S. Treaty Beneficiaries").

#### German Withholding Taxation of Capital Gains of the U.S. Treaty Beneficiaries of the ADSs

The capital gains from the disposition of the ADSs realized by a non-German resident holder, which does not maintain a permanent establishment or other taxable presence in Germany, would be treated as German source income and be subject to German tax if the ADSs qualify as a Qualifying Participation. A Qualifying Participation exists if a holder at any time during the five years preceding the disposition, directly or indirectly, owned at least 1% of BioNTech's share capital, irrespective of whether through the ADSs or shares of BioNTech. If such holder had acquired the ADSs without consideration, the previous owner's holding period and quota would be taken into account.

Pursuant to the Treaty, capital gains from the disposal of a Qualifying Participation realized by a U.S. treaty beneficiary are, however, generally exempt from German taxation. Pursuant to the Treaty, U.S. treaty beneficiaries are not subject to German tax in relation to capital gains from the disposal of a Qualifying Participation even under the circumstances described in the preceding paragraph and therefore should not be subject to German taxation on capital gains from the disposition of the ADSs.

German statutory law requires the disbursing agent to levy withholding tax on capital gains from the sale of ADSs or other securities held in a custodial account in Germany. With regard to the German taxation of capital gains, disbursing

agent means a German credit institution, financial services institution, securities trading enterprise or securities trading bank (each as defined in the German Banking Act and, in each case including a German branch if a foreign enterprise, but excluding a foreign branch of a German enterprise) that holds the ADSs in custody or administers the ADSs for the investor or conducts sales or other dispositions and disburses or credits the income from the ADSs to the holder of the ADSs. The German statutory law does not explicitly condition the obligation to withhold taxes on capital gains being subject to taxation in Germany under German statutory law or on an applicable income tax treaty permitting Germany to tax such capital gains.

However, a circular issued by the German Federal Ministry of Finance, dated January 18, 2016, reference number IV C 1-S2252/08/10004 :017, as most recently amended by circular dated September 16, 2019, reference number IV C 1-S2252/08/10004 :027, provides that taxes need not be withheld when the holder of the custody account is not a resident of Germany for tax purposes and the income is not subject to German taxation. The circular further states that there is no obligation to withhold such tax even if the non-resident holder owns at least 1% of the share capital of a German corporation. While circulars issued by the German Federal Ministry of Finance are generally only to be adhered to by the German tax authorities but are, for example, not binding on the German courts, in practice, the disbursing agents nevertheless typically rely on guidance contained in such circulars. Therefore, a disbursing agent would only withhold tax at 26.375% on capital gains derived by a U.S. treaty beneficiary from the sale of ADSs held in a custodial account in Germany in the event that the disbursing agent did not follow the abovementioned guidance. In this case, the U.S. treaty beneficiary may be entitled to claim a refund of the withholding tax from the German tax authorities under the Treaty, as described below in “—Withholding Tax Refund for U.S. Treaty Beneficiaries.” A refund of taxes withheld on capital gains from the disposition of the ADSs which do not qualify as Qualifying Participations may also be claimed based on German statutory domestic law.

#### **Withholding Tax Refund for U.S. Treaty Beneficiaries**

U.S. treaty beneficiaries are generally eligible for treaty benefits under the Treaty, as described above in “—Taxation of Holders Not Tax Resident in Germany.” Accordingly, U.S. treaty beneficiaries are in general entitled to claim a refund of (i) the portion of the otherwise applicable 26.375% German withholding tax (*Kapitalertragsteuer*) on dividends that exceeds the applicable Treaty rate and (ii) the full amount of German withholding tax (*Kapitalertragsteuer*) on capital gains from the disposition of ADSs. The application for such claim is generally to be filed with the Federal Central Office of Taxation (*Bundeszentralamt für Steuern*) within four years after the end of the calendar year in which the capital gains or dividends have been received (*bezogen*).

However, in respect of dividends, the refund described in the preceding paragraph is only possible if, due to special rules on the restriction of withholding tax credit, the following three cumulative requirements are met: (i) the holder must qualify as beneficial owner of the ADSs for an uninterrupted minimum holding period of 45 days within a period starting 45 days prior to and ending 45 days after the due date of the dividends, (ii) the holder has to bear at least 70% of the change in value risk related to the ADSs during the minimum holding period as described under (i) of this paragraph and has not entered into (acting by itself or through a related party) hedging transactions which lower the change in value risk by more than 30%, and (iii) the holder must not be obliged to fully or largely compensate directly or indirectly the dividends to third parties. If these requirements are not met, then for a holder not being tax-resident in Germany who applied for a full or partial refund of the withholding tax pursuant to a double taxation treaty, no refund is available. This restriction generally does only apply if (a) the German tax underlying the refund application is below a tax rate of 15% based on the gross amount of the dividends and (b) the holder does not directly own 10% or more of the shares of BioNTech and is subject to income taxes in its state of residence, without being tax-exempt. The restriction of the withholding tax credit does not apply if the holder has beneficially owned the ADSs for at least one uninterrupted year until receipt (*Zufluss*) of the dividends.

In general, as previously discussed, investors should note that it is unclear how the German tax administration will apply the refund process to dividends on the ADSs. Further, such refund is subject to the German anti treaty shopping rule. Generally, this rule requires that the U.S. treaty beneficiary (in case it is a non-German resident company) maintains its own administrative substance and conducts its own business activities. In particular, a foreign company has no right to a full or partial refund to the extent persons holding ownership interests in BioNTech would not be entitled to the refund if they derived the income directly and the gross income realized by the foreign company is not caused by the business activities of the foreign company, and there are either no economic or other considerable reasons for the interposition of the foreign company, or the foreign company does not participate in general commerce by means of a business organization with resources appropriate to its business purpose. However, this shall not apply if the foreign company's principal class of stock is regularly traded in substantial volume on a recognized stock exchange, or if the foreign company is subject to the provisions of the German Investment Tax Act (*Investmentsteuergesetz*). Whether or not and to which extent the anti-treaty

shopping rule applies to the ADSs has to be analyzed on a case by case basis taking into account all relevant tests. In addition, the interpretation of these tests is disputed and to date no published decisions of the German Federal Finance Court exist in this regard. It should be noted that a draft bill containing reforms to the German anti-treaty shopping rule is currently in the legislative process and might be passed into law still in 2021.

Due to the legal structure of the ADSs, only limited guidance from the German tax authorities exists on the practical application of the refund process with respect to the ADSs and the respective limitations. Recently, the German tax authorities have indicated that for ADR programs (which are considered comparable to ADS programs) a collective tax certificate in connection with a withholding of tax amounts may no longer be issued by the domestic depository of the shares upon request of the foreign depository agents. Rather, individual tax certificates need to be issued which might delay a potential refund procedure. Moreover, the simplified refund procedure based on electronic data exchange (*Datenträgerverfahren*) for claims for reimbursement based on ADRs has been suspended temporarily by the tax authorities.

#### **Taxation of Holders Tax Resident in Germany**

This subsection provides an overview of dividend taxation and of capital gains taxation with regard to the general principles applicable to ADS holders that are tax resident in Germany. A holder is a German tax resident if, in case of an individual, he or she maintains a domicile (*Wohnsitz*) or a usual residence (*gewöhnlicher Aufenthalt*) in Germany or if, in case of a corporation, it has its place of management (*Geschäftsleitung*) or registered seat (*Sitz*) in Germany.

The German dividend and capital gains taxation rules applicable to German tax residents require a distinction between ADSs held as private assets (*Privatvermögen*) and ADSs held as business assets (*Betriebsvermögen*).

#### **ADSs as Private Assets (*Privatvermögen*)**

If the ADSs are held as private assets by a German tax resident, dividends and capital gains (other than capital gains from the disposition of a Qualifying Participation) are taxed as investment income and are principally subject to 25% German flat income tax on capital income (*Abgeltungsteuer*) (plus a 5.5% solidarity surcharge (*Solidaritätszuschlag*) thereon, resulting in an aggregate rate of 26.375%), which is levied in the form of withholding tax (*Kapitalertragsteuer*). In other words, once deducted, the holder's income tax liability on the dividends will be settled. Dividend payments to the extent funded from BioNTech's tax-recognized contribution account (*steuerliches Einlagekonto*), subject to certain prerequisites, do not form part of the taxable dividend income but should lower the holder's acquisition costs for the ADSs.

Holders of ADSs may apply to have their capital investment income assessed in accordance with the general rules and with an individual's personal income tax rate if this would result in a lower tax burden in which case actually incurred expenses are not deductible. The holder would be taxed on gross personal investment income (including dividends or gains with respect to ADSs), less the saver's allowance of €801 for an individual or €1,602 for a married couple and a registered civil union (*eingetragene Lebenspartnerschaft*) filing taxes jointly. The deduction of expenses related to the investment income (including dividends or gains with respect to ADSs) is generally not possible for private investors.

Losses resulting from the disposal of ADSs can only be offset against capital gains from the sale of any shares (*Aktien*) and other ADSs. If, however, a holder holds a Qualifying Participation, 60% of any capital gains resulting from the sale and transfer are taxable at the holder's personal income tax rate (plus 5.5% solidarity surcharge thereon). Conversely, 60% of any capital losses are recognized for tax purposes.

Since 2021, the basis for the calculation of the solidarity surcharge (*Solidaritätszuschlag*) has been reduced for certain individual persons being subject to tax assessments (other than withholding taxes), and in certain cases, the solidarity surcharge has been abolished. However, the abolition or reduction of the solidarity surcharge is not applicable to corporations. In addition, the abolition or reduction of the solidarity surcharge will not affect withholding taxes. Solidarity surcharge will still be levied at 5.5% on the full withholding tax amount and withheld accordingly. There will not be any separate refund of such withheld solidarity surcharge (regardless of the aforementioned exemption limits) in case the withholding tax cannot be refunded either.

Church tax generally has to be withheld, if applicable, based on an automatic data access procedure, unless the holder of ADSs has filed a blocking notice (*Sperrvermerk*) with the Federal Central Tax Office. Where church tax is not levied by way of withholding, it is determined by means of income tax assessment.



#### ADSs as Business Assets (*Betriebsvermögen*)

In case the ADSs are held as business assets, the taxation depends on the legal form of the holder (*i.e.*, whether the holder is a corporation or an individual).

Irrespective of the legal form of the holder, dividends are subject to the aggregate withholding tax rate of 26.375%. The withholding tax is generally creditable against the respective holder's corporate income tax or income tax liability. Due to special rules on the restriction of withholding tax credits in respect of dividends, a full withholding tax credit requires that the following three cumulative requirements are met: (i) the holder must qualify as beneficial owner of the ADSs for an uninterrupted minimum holding period of 45 days occurring within a period starting 45 days prior to and ending 45 days after the due date of the dividends, (ii) the holder has to bear at least 70% of the change in value risk related to the ADSs during the minimum holding period as described under (i) of this paragraph and has not entered into (acting by itself or through a related party) hedging transactions which lower the change in value risk for more than 30%, and (iii) the holder must not be obliged to fully or largely compensate directly or indirectly the dividends to third parties. If these requirements are not met, three-fifths of the withholding tax imposed on the dividends must not be credited against the holder's corporate income tax or income tax liability, but may, upon application, be deducted from the holder's tax base for the relevant tax assessment period. A holder that is generally subject to German income tax or corporate income tax and that has received gross dividends without any deduction of withholding tax due to a tax exemption without qualifying for a full tax credit under the aforementioned requirements has to notify the competent local tax office accordingly, has to file withholding tax returns for a withholding tax of 15% in accordance with statutory formal requirements and has to make a payment in the amount of the omitted withholding tax deduction. The special rules on the restriction of withholding tax credit (and the corresponding notification and payment obligations) do not apply to a holder whose overall dividend earnings within an assessment period do not exceed €20,000 or that has been the beneficial owner of the ADSs for at least one uninterrupted year until receipt (*Zufluss*) of the dividends.

To the extent the amount withheld exceeds the income tax liability, the withholding tax will be refunded, provided that certain requirements are met (including the aforementioned requirements).

Special rules apply to credit institutions (*Kreditinstitute*), financial services institutions (*Finanzdienstleistungsinstitute*), financial enterprises (*Finanzunternehmen*), life insurance and health insurance companies, and pension funds.

In principle, dividends that a corporation receives from German or foreign corporations are subject to corporate income tax (and solidarity surcharge thereon) at a rate of 15.825% and also subject to trade tax of between 7.0% and 19.0% depending on the multiplier applied by the relevant municipality. However, with regard to holders in the legal form of a corporation, capital gains are in general effectively 95% tax exempt from corporate income tax (including solidarity surcharge). Dividends are also generally 95% tax exempt from corporate income tax (including solidarity surcharge), *inter alia*, if the holder held at least 10% of the registered share capital (*Grundkapital oder Stammkapital*) of BioNTech at the beginning of the calendar year, or Qualifying Dividends. Five percent of the capital gains and five percent of the Qualifying Dividends are treated as non-deductible business expenses, respectively, and, as such, are subject to corporate income tax (including solidarity surcharge); actual business expenses incurred to generate dividends may be deducted. The acquisition of a participation of at least 10% in the course of a calendar year is deemed to have occurred at the beginning of such calendar year for the determination of whether a dividend is a Qualifying Dividend. Participations in the share capital of BioNTech held through a partnership, including co-entrepreneurships (*Mitunternehmenschaften*), are attributable to the respective partner only on a pro rata basis at the ratio of its entitlement to the profits of the partnership.

Capital gains and dividend income of a German tax resident corporation are generally subject to German trade tax of between 7.0% and 19.0% depending on the multiplier applied by the relevant municipality. The aforementioned 95% exemption for capital gains generally applies also for trade tax purposes. However, the amount of any dividends after deducting business expenses related to the dividends is not subject to trade tax if the corporation held at least 15% of BioNTech's registered share capital at the beginning of the relevant tax assessment period. In this case, the aforementioned exemption of 95% of the dividend income also applies for trade tax purposes. Losses from the sale of ADSs are generally not tax deductible for corporate income tax and trade tax purposes.

With regard to individuals holding ADSs as business assets, 60% of dividends and capital gains are taxed at the individual's personal income tax rate (plus 5.5% solidarity surcharge thereon). Correspondingly, only 60% of business expenses related to the dividends and capital gains as well as losses from the sale of ADSs are principally deductible for income tax purposes. Since 2021, the basis for the calculation of the solidarity surcharge (*Solidaritätszuschlag*) has been

reduced for certain individual persons being subject to tax assessments (other than withholding taxes), and in certain cases, the solidarity surcharge has been abolished, subject to the limitations described above in “—ADSs as Private Assets (*Privatvermögen*)”. The dividend income and 60% of the capital gains are generally subject to trade tax, which is fully or partly creditable against the individual’s personal income tax by a lump-sum method. Dividends (after deduction of business expenses economically related thereto) are exempt from trade tax if the holder held at least 15% of BioNTech’s registered share capital at the beginning of the relevant tax assessment period.

#### **German Inheritance and Gift Tax (*Erbschaft- und Schenkungsteuer*)**

The transfer of ADSs to another person by inheritance or gift generally should be subject to German inheritance and gift tax only if:

- (i) the decedent or donor or heir, beneficiary or other transferee (a) maintained his or her domicile or a usual residence in Germany, (b) had its place of management or registered office in Germany at the time of the transfer, (c) is a German citizen who has spent no more than five consecutive years outside of Germany without maintaining a domicile in Germany or (d) is a German citizen who serves for a German entity established under public law and is remunerated for his or her service from German public funds (including family members who form part of such person’s household, if they are German citizens) and is only subject to estate or inheritance tax in his or her country of domicile or usual residence with respect to assets located in such country (special rules apply to certain former German citizens who neither maintain a domicile nor have their usual residence in Germany);
- (ii) at the time of the transfer, the ADSs are held by the decedent or donor as business assets forming part of a permanent establishment in Germany or for which a permanent representative in Germany has been appointed; or
- (iii) the ADSs subject to such transfer form part of a portfolio that represents at the time of the transfer 10% or more of the registered share capital of BioNTech and that has been held directly or indirectly by the decedent or donor, either alone or together with related persons.

The Agreement between the Federal Republic of Germany and the United States of America for the avoidance of double taxation with respect to taxes on inheritances and gifts as of December 21, 2000 (*Abkommen zwischen der Bundesrepublik Deutschland und den Vereinigten Staaten von Amerika zur Vermeidung der Doppelbesteuerung auf dem Gebiet der Nachlass-, Erbschaft- und Schenkungssteuern in der Fassung vom 21. Dezember 2000*), hereinafter referred to as the “United States-Germany Inheritance and Gifts Tax Treaty,” provides that the German inheritance tax or gift tax can, with certain restrictions, only be levied in the cases of (i) and (ii) above. Special provisions apply to certain German citizens living outside of Germany and former German citizens.

#### **Other Taxes**

No German transfer tax, value-added tax, stamp duty or similar taxes are assessed on the purchase, sale or other transfer of ADSs. Provided that certain requirements are met, an entrepreneur may, however, opt for value-added tax on transactions that are otherwise tax-exempt. Net wealth tax (*Vermögensteuer*) is not imposed currently in Germany.

#### **Material United States Federal Income Tax Considerations**

The following discussion describes material U.S. federal income tax considerations relating to the acquisition, ownership and disposition of ADSs by a U.S. Holder (as defined below) that acquires our ADSs and holds them as a capital asset. This discussion is based on the tax laws of the United States, including the Internal Revenue Code of 1986, as amended, or the Code, Treasury regulations promulgated or proposed thereunder, and administrative and judicial interpretations thereof, all as in effect on the date hereof. These tax laws are subject to change, possibly with retroactive effect, and subject to differing interpretations that could affect the tax consequences described herein. This section does not address the treatment of a non-U.S. holder, nor does it address the tax treatment under the laws of any state, local or foreign taxing jurisdiction.

For purposes of this discussion, a “U.S. Holder” is a beneficial owner of our ADSs that, for U.S. federal income tax purposes, is:

- an individual who is a citizen or resident of the United States;
- a domestic corporation (or other entity taxable as a corporation);

- an estate the income of which is subject to U.S. federal income taxation regardless of its source; or
- a trust if (i) a court within the United States is able to exercise primary supervision over the trust's administration and one or more U.S. persons have the authority to control all substantial decisions of the trust or (ii) a valid election under the Treasury regulations is in effect for the trust to be treated as a U.S. person.

This discussion does not address all aspects of U.S. federal income taxation that may be applicable to U.S. Holders in light of their particular circumstances or status (including, for example, banks and other financial institutions, insurance companies, broker and dealers in securities or currencies, traders that have elected to mark securities to market, regulated investment companies, real estate investment trusts, partnerships or other pass-through entities, corporations that accumulate earnings to avoid U.S. federal income tax, tax-exempt organizations, pension plans, persons that hold our shares as part of a straddle, hedge or other integrated investment, persons subject to alternative minimum tax or whose "functional currency" is not the U.S. dollar).

If a partnership (including any entity or arrangement treated as a partnership for U.S. federal income tax purposes) holds our ADSs, the tax treatment of a person treated as a partner in the partnership for U.S. federal income tax purposes generally will depend on the status of the partner and the activities of the partnership. Partnerships (and other entities or arrangements so treated for U.S. federal income tax purposes) and their partners should consult their own tax advisors.

In general, and taking into account the earlier assumptions, for U.S. federal income and German tax purposes, a holder of ADSs will be treated as the owner of the shares represented by those ADSs. Exchanges of shares for ADSs, and ADSs for shares, generally will not be subject to U.S. federal income or to German tax.

***This discussion addresses only U.S. Holders and does not discuss any tax considerations other than U.S. federal income tax considerations. Prospective investors are urged to consult their own tax advisors regarding the U.S. federal, state and local, and foreign tax consequences of the purchase, ownership, and disposition of ADSs.***

#### ***Dividends***

Under the U.S. federal income tax laws, and subject to the passive foreign investment company, or PFIC, rules discussed below, the gross amount of any dividend we pay out of our current or accumulated earnings and profits (as determined for U.S. federal income tax purposes) is includible in income for a U.S. Holder and subject to U.S. federal income taxation. Dividends paid to a noncorporate U.S. Holder that constitute qualified dividend income will be taxable at a preferential tax rate applicable to long-term capital gains, provided that the U.S. Holder holds the ADSs for more than 60 days during the 121-day period beginning 60 days before the ex-dividend date and meets other holding period requirements. Dividends we pay with respect to the ADSs generally will be qualified dividend income.

A U.S. Holder must include any German tax withheld from the dividend payment, as described above under "—German Taxation—General Rules for the Taxation of Holders Not Tax Resident in Germany," in the gross amount of dividend paid even though the holder does not in fact receive it. The dividend is taxable to the holder when the depository receives the dividend, actually or constructively. Because we are not a U.S. corporation, the dividend will not be eligible for the dividends-received deduction generally allowed to U.S. corporations in respect of dividends received from other U.S. corporations. The amount of the dividend distribution includible in U.S. Holder's income will be the U.S. dollar value of the Euro payments made, determined at the spot Euro/U.S. dollar rate on the date the dividend distribution is includible in income, regardless of whether the payment is in fact converted into U.S. dollars. Generally, any gain or loss resulting from currency exchange fluctuations during the period from the date the dividend payment is included in income to the date the payment is converted into U.S. dollars will be treated as ordinary income or loss and will not be eligible for the special tax rate applicable to qualified dividend income. The gain or loss generally will be income or loss from sources within the United States for foreign tax credit limitation purposes.

To the extent a distribution with respect to ADSs exceeds our current or accumulated earnings and profits, as determined under U.S. federal income tax principles, the distribution will be treated, first, as a tax-free return of the U.S. Holder's investment, up to the holder's adjusted tax basis in its ADSs, and, thereafter, as capital gain, which is subject to the tax treatment described below in "—Gain on Sale, Exchange or Other Taxable Disposition."

Subject to certain limitations, the German tax withheld in accordance with the Treaty and paid over to the German taxing authority will be creditable or deductible against a U.S. Holder's U.S. federal income tax liability. To the extent a refund of the tax withheld is available to a U.S. Holder under German law or under the Treaty, the amount of tax withheld

that is refundable will not be eligible for credit against a U.S. Holder's U.S. federal income tax liability. See “—German Taxation—Withholding Tax Refund for U.S. Treaty Beneficiaries” above for the procedures for obtaining a tax refund.

#### ***Gain On Sale, Exchange or Other Taxable Disposition***

Subject to the PFIC rules described below under “—Passive Foreign Investment Company Considerations”, a U.S. Holder that sells, exchanges or otherwise disposes of ADSs in a taxable disposition generally will recognize capital gain or loss for U.S. federal income tax purposes equal to the difference between the U.S. dollar value of the amount realized and the holder's tax basis, determined in U.S. dollars, in the ADSs. Gain or loss recognized on such a sale, exchange or other disposition of ADSs generally will be long-term capital gain if the U.S. Holder's holding period in the ADSs exceeds one year. Long-term capital gains of non-corporate U.S. Holders are taxed generally at preferential rates. The gain or loss generally will be income or loss from sources within the United States for foreign tax credit limitation purposes. A U.S. Holder's ability to deduct capital losses is subject to limitations.

#### ***Passive Foreign Investment Company Considerations***

We do not believe that we should be treated as, and do not expect to become, a PFIC. Because the determination of our PFIC status is made annually based on the factual tests described below, however, we cannot provide any assurances regarding our PFIC status for the current or future taxable years or that the IRS will agree with our conclusion regarding our PFIC status.

If we were classified as a PFIC in any taxable year, a U.S. Holder would be subject to special rules with respect to distributions on and sales, exchanges and other dispositions of the ADSs. We will be treated as a PFIC for any taxable year in which at least 75% of our gross income is “passive income” or at least 50% of our gross assets during the taxable year (based on the average of the fair market values of the assets determined at the end of each quarterly period) are assets that produce or are held for the production of passive income. Passive income for this purpose generally includes, among other things, dividends, interest, rents, royalties, gains from commodities and securities transactions, and gains from assets that produce passive income. However, rents and royalties received from unrelated parties in connection with the active conduct of a trade or business are not considered passive income for purposes of the PFIC test. In determining whether we are a PFIC, a pro rata portion of the income and assets of each corporation in which we own, directly or indirectly, at least a 25% interest (by value) is taken into account.

If we were a PFIC with respect to a U.S. Holder, then unless such U.S. Holder makes one of the elections described below, a special tax regime would apply to the U.S. Holder with respect to (i) any “excess distribution” (generally, aggregate distributions in any year that are greater than 125% of the average annual distribution received by the holder in the shorter of the three preceding years or the holder's holding period for the ADSs) and (ii) any gain realized on the sale or other disposition of the ADSs. Under this regime, any excess distribution and realized gain will be treated as ordinary income and will be subject to tax as if (a) the excess distribution or gain had been realized ratably over the U.S. Holder's holding period, (b) the amount deemed realized in each year had been subject to tax in each year of that holding period at the highest marginal rate for such year (other than income allocated to the current period or any taxable period before we became a PFIC, which would be subject to tax at the U.S. Holder's regular ordinary income rate for the current year and would not be subject to the interest charge discussed below), and (c) the interest charge generally applicable to underpayments of tax had been imposed on the taxes deemed to have been payable in those years. If we were determined to be a PFIC, this tax treatment for U.S. Holders would apply also to indirect distributions and gains deemed realized by U.S. Holders in respect of stock of any of our subsidiaries determined to be PFICs. In addition, dividend distributions would not qualify for the lower rates of taxation applicable to long-term capital gains discussed above under “—Taxation of Dividends.”

A U.S. Holder that holds the ADSs at any time during a taxable year in which we are classified as a PFIC generally will continue to treat such ADSs as ADSs in a PFIC, even if we no longer satisfy the income and asset tests described above, unless the U.S. Holder elects to recognize gain, which will be taxed under the excess distribution rules as if such ADSs had been sold on the last day of the last taxable year for which we were a PFIC.

Certain elections by a U.S. Holder would alleviate some of the adverse consequences of PFIC status and would result in an alternative treatment of the ADSs, as described below.

If we were a PFIC, the rules above would not apply to a U.S. Holder that makes an election to treat ADSs as stock of a “qualified electing fund” or QEF. However, we do not expect that a U.S. Holder would be able to make this election because we do not intend to provide to U.S. Holders the required information to make a valid QEF election.

If we were a PFIC, the rules above also would not apply to a U.S. Holder that makes a “mark-to-market” election with respect to the ADSs, but this election will be available with respect to the ADSs only if they meet certain minimum trading requirements to be considered “marketable stock” for purposes of the PFIC rules. Generally, shares of ADSs will be treated as marketable stock if they are “regularly traded” on a “qualified exchange” within the meaning of applicable U.S. Treasury Regulations. ADSs generally will be considered regularly traded during any calendar year during which they are traded, other than in *de minimis* quantities, on at least 15 days during each calendar quarter. Any trades that have as their principal purpose meeting this requirement will be disregarded. Our ADSs will be marketable stock as long as they remain listed on the Nasdaq Global Select Market and are traded regularly.

A U.S. Holder that makes a valid mark-to-market election for the first tax year in which the holder holds (or is deemed to hold) ADSs and for which we are a PFIC will be required to include each year an amount equal to the excess, if any, of the fair market value of such ADSs the holder owns as of the close of the taxable year over the holder’s adjusted tax basis in such ADSs. The U.S. Holder will be entitled to a deduction for the excess, if any, of the holder’s adjusted tax basis in the ADSs over the fair market value of such ADSs as of the close of the taxable year, but only to the extent of any net mark-to-market gains with respect to such ADSs included by the U.S. Holder under the election for prior taxable years. The U.S. Holder’s basis in such ADSs will be adjusted to reflect the amounts included or deducted pursuant to the election. Amounts included in income pursuant to a mark-to-market election, as well as gain on the sale, exchange or other taxable disposition of such ADSs, will be treated as ordinary income. The deductible portion of any mark-to-market loss, as well as loss on a sale, exchange or other disposition of ADSs to the extent that the amount of such loss does not exceed net mark-to-market gains previously included in income, will be treated as ordinary loss.

The mark-to-market election applies to the taxable year for which the election is made and all subsequent taxable years, unless the shares cease to be treated as marketable stock for purposes of the PFIC rules or the IRS consents to its revocation. The excess distribution rules described above generally will not apply to a U.S. Holder for tax years for which a mark-to-market election is in effect. However, if we were a PFIC for any year in which the U.S. Holder owns the ADSs but before a mark-to-market election is made, the interest charge rules described above would apply to any mark-to-market gain recognized in the year the election is made.

A U.S. Holder of PFIC shares must generally file an annual information return on IRS Form 8621 (Information Return by a Shareholder of a Passive Foreign Investment Company or Qualified Electing Fund). The failure to file IRS Form 8621 could result in the imposition of penalties and the extension of the statute of limitations with respect to U.S. federal income tax.

***U.S. Holders are urged to consult their tax advisors as to our status as a PFIC, and the tax consequences to them if we were a PFIC, including the reporting requirements and the desirability of making, and the availability of, a QEF election or a mark-to-market election with respect to the ADSs.***

#### ***Medicare Tax***

Non-corporate U.S. Holders that are individuals, estates or trusts and whose income exceeds certain thresholds generally are subject to a 3.8% tax on all or a portion of their net investment income, which may include their gross dividend income and net gains from the disposition of ADSs. A U.S. person that is an individual, estate or trust is encouraged to consult its tax advisors regarding the applicability of this Medicare tax to its income and gains in respect of any investment in ADSs.

#### ***Information Reporting with Respect to Foreign Financial Assets***

Individual U.S. Holders may be subject to certain reporting obligations on IRS Form 8938 (Statement of Specified Foreign Financial Assets) with respect to the ADSs for any taxable year during which the U.S. Holder’s aggregate value of these and certain other “specified foreign financial assets” exceed a threshold amount that varies with the filing status of the individual. This reporting obligation also applies to domestic entities formed or availed of to hold, directly or indirectly, specified foreign financial assets, including the ADSs. Significant penalties can apply if U.S. Holders are required to make this disclosure and fail to do so.

U.S. Holders who acquire ADSs for cash may be required to file IRS Form 926 (Return by a U.S. Transferor of Property to a Foreign Corporation) with the IRS and to supply certain additional information to the IRS if (i) immediately after the transfer, the U.S. Holder owns directly or indirectly (or by attribution) at least 10% of our total voting power or value or (ii) the amount of cash transferred to us in exchange for ADSs, when aggregated with all related transfers under

applicable regulations, exceeds \$100,000. Substantial penalties may be imposed on a U.S. Holder that fails to comply with this reporting requirement.

**Information Reporting and Backup Withholding**

In general, information reporting, on IRS Form 1099, will apply to dividends in respect of ADSs and the proceeds from the sale, exchange or redemption of ADSs that are paid to a holder of ADSs within the United States (and in certain cases, outside the United States), unless such holder is an exempt recipient such as a corporation. Backup withholding (currently at a 24% rate) may apply to such payments if a holder of ADSs fails to provide a taxpayer identification number (generally on an IRS Form W-9) or certification of other exempt status or fails to report in full dividend and interest income.

Backup withholding is not an additional tax. A U.S. Holder generally may obtain a refund of any amounts withheld under the backup withholding rules that exceed the U.S. Holder's income tax liability by filing a refund claim with the IRS.

**F. Dividends and Paying Agents**

Not applicable.

**G. Statement by Experts**

Not applicable.

**H. Documents on Display**

We are subject to the informational requirements of the Exchange Act. Accordingly, we are required to file reports and other information with the SEC, including annual reports on Form 20-F and reports on Form 6-K. The SEC maintains an Internet website that contains reports and other information about issuers, like us, that file electronically with the SEC. The address of that website is [www.sec.gov](http://www.sec.gov).

We also make available on our website, free of charge, our Annual Report and the text of our reports on Form 6-K, including any amendments to these reports, as well as certain other SEC filings, as soon as reasonably practicable after they are electronically filed with or furnished to the SEC. Our website address is [www.biontech.de](http://www.biontech.de). The information contained on our website is not incorporated by reference in this Annual Report and our website address is included in this Annual Report as an inactive textual reference only.

Statements contained in this Annual Report regarding the contents of any contract or other document are not necessarily complete, and, where the contract or other document is an exhibit to the Annual Report, each of these statements is qualified in all respects by the provisions of the actual contract or other documents.

**I. Subsidiary Information**

Not applicable.

**Item 11. Quantitative and Qualitative Disclosures About Market Risk**

We are exposed to various risks in relation to financial instruments, including currency risk. Our risk management is coordinated by our Management Board. We do not engage in the trading of financial assets for speculative purposes. The most significant financial risks to which we are exposed include the risks discussed below.

**Currency Risk**

We are subject to currency risk, as our income and expenditures are denominated in Euro and the U.S. dollar. As such, we are exposed to exchange rate fluctuations between these currencies. Cash inflows denominated in U.S. dollar occurred from issuing ordinary shares in connection with public financing transaction, which includes our initial public offering in 2019 and the global offering in 2020 as well as from generating proceeds under our collaboration agreements. We aim to match U.S. dollar cash inflows with U.S. dollar cash outflows where possible, and we do not hedge this exposure. Under our collaboration agreement with Pfizer, significant increases in cash balances, revenues and sales and

marketing expenses denominated in U.S. dollars may occur with respect to commercializing our COVID-19 vaccine, while we would expect our development and operating expenses to remain, at least some extent, denominated in Euro.

We publish our consolidated financial statements in Euro. Revenue and expenses incurred in U.S. dollars will be translated into Euro when they are reported in our consolidated financial statements. As a result, any substantial future appreciation or decline of the U.S. dollar against the Euro could have a material effect on our revenue and profitability. As an example, if the U.S. dollar weakens by 5% against the Euro, monetary assets and monetary liabilities denominated in U.S. dollar as of December 31, 2020 would decrease by €32.7 million, or 5%.

For additional information about our quantitative and qualitative risks, see Note 12 to the consolidated financial statements.

#### Item 12. Description of Securities Other than Equity Securities

##### A. Debt Securities

Not applicable.

##### B. Warrants and Rights

Not applicable.

##### C. Other Securities

Not applicable.

##### D. American Depositary Shares

###### Fees and Expenses

###### *Persons depositing or withdrawing shares or ADS holders must pay:*

\$5.00 (or less) per 100 ADSs (or portion of 100 ADSs)

\$.05 (or less) per ADS

A fee equivalent to the fee that would be payable if securities distributed to an ADS holder had been shares and the shares had been deposited for issuance of ADSs

\$.05 (or less) per ADS per calendar year

Registration or transfer fees

Expenses of the depository

Taxes and other governmental charges the depository or the custodian has to pay on any ADSs or shares underlying ADSs, such as stock transfer taxes, stamp duty or withholding taxes

###### *For:*

Issuance of ADSs, including issuances resulting from a distribution of shares or rights or other property

Cancellation of ADSs for the purpose of withdrawal, including if the deposit agreement terminates

Any cash distribution to ADS holders

Distribution of securities distributed to holders of deposited securities (including rights) that are distributed by the depository to ADS holders

Depository services

Transfer and registration of shares on our share register to or from the name of the depository or its agent when an ADS holder deposits or withdraws shares

Cable and facsimile transmissions (when expressly provided in the deposit agreement)

Converting foreign currency to U.S. dollars

As necessary

Any charges incurred by the depositary or its agents for servicing the deposited securities

As necessary

The depositary collects its fees for delivery and surrender of ADSs directly from investors depositing shares or surrendering ADSs for the purpose of withdrawal or from intermediaries acting for them. The depositary collects fees for making distributions to investors by deducting those fees from the amounts distributed or by selling a portion of distributable property to pay the fees. The depositary may collect its annual fee for depositary services by deduction from cash distributions or by directly billing investors or by charging the book-entry system accounts of participants acting for them. The depositary may collect any of its fees by deduction from any cash distribution payable (or by selling a portion of securities or other property distributable) to ADS holders that are obligated to pay those fees. The depositary may generally refuse to provide fee-attracting services until its fees for those services are paid.

From time to time, the depositary may make payments to us to reimburse us for costs and expenses generally arising out of establishment and maintenance of the ADS program, waive fees and expenses for services provided to us by the depositary or share revenue from the fees collected from ADS holders. In performing its duties under the deposit agreement, the depositary may use brokers, dealers, foreign currency dealers or other service providers that are owned by, or affiliated with, the depositary and that may earn or share fees, spreads or commissions.

The depositary may convert currency itself or through any of its affiliates and, in those cases, acts as principal for its own account and not as agent, advisor, broker or fiduciary on behalf of any other person and earns revenue, including, without limitation, transaction spreads, that it will retain for its own account. The revenue is based on, among other things, the difference between the exchange rate assigned to the currency conversion made under the deposit agreement and the rate that the depositary or its affiliate receives when buying or selling foreign currency for its own account. The depositary makes no representation that the exchange rate used or obtained in any currency conversion under the deposit agreement will be the most favorable rate that could be obtained at the time or that the method by which that rate will be determined will be the most favorable to ADS holders, subject to the depositary's obligations under the deposit agreement. The methodology used to determine exchange rates used in currency conversions is available upon request.

#### **Payment of Taxes**

ADS holders will be responsible for any taxes or other governmental charges payable on their ADSs or on the deposited securities represented by any of their ADSs. The depositary may refuse to register any transfer of ADS holders ADSs or allow him or her to withdraw the deposited securities represented by his or her ADSs until those taxes or other charges are paid. It may apply payments owed to you or sell deposited securities represented by his or her ADSs to pay any taxes owed and you will remain liable for any deficiency. If the depositary sells deposited securities, if appropriate, it will reduce the number of ADSs to reflect the sale and pay to ADS holders any proceeds, or send to ADS holders any property, remaining after it has paid the taxes.



**Item 13. Defaults, Dividend Arrearages and Delinquencies**

Not applicable.

**Item 14. Material Modifications to the Rights of Security Holders and Use of Proceeds**

Not applicable.

**Item 15. Controls and Procedures**

**Disclosure Controls and Procedures**

As required by Rule 13a-15 under the Exchange Act, management, including our Chief Executive Officer (CEO) and our Chief Financial Officer (CFO), has performed an evaluation of the effectiveness of our disclosure controls and procedures. Disclosure controls and procedures refer to controls and other procedures designed to ensure that information required to be disclosed in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. Disclosure controls and procedures include, without limitations, controls and procedures designed to ensure that information required to be disclosed by us in our reports that we file or submit under the Exchange Act is accumulated and communicated to management, including our principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding our required disclosures.

Based on the foregoing, our CEO and CFO have concluded that, as of the end of the period covered by this annual report, our disclosure controls and procedures were effective in ensuring that the information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in by the SEC's rules and forms, and that the information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management to allow timely decisions regarding required disclosure.

**Management's Annual Report on Internal Control over Financial Reporting**

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f). Our internal control over financial reporting is a process designed by or under the supervision of the Chief Financial Officer, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of our financial statements for external reporting purposes in accordance with International Financial Reporting Standards as issued by the IASB.

No system of internal control over financial reporting, including one determined to be effective, may prevent or detect all misstatements. It can provide only reasonable assurance regarding financial statement preparation and presentation. Also, projections of the results of any evaluation of the effectiveness of internal control over financial reporting into future periods are subject to inherent risk. The relevant controls may become inadequate due to changes in circumstances or the degree of compliance with the underlying policies or procedures may deteriorate.

Our management assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2020. In making this assessment, it used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in "Internal Control - Integrated Framework (2013)".

As permitted by the SEC, the Company has elected to exclude an assessment of the internal controls of acquisitions made during the year ended December 31, 2020, namely the acquisitions of BioNTech US Inc. as well as BioNTech Manufacturing Marburg GmbH. The acquired entities did not contribute to the Group's revenues, they contributed €28.5 million and €6.7 million of operating loss, respectively, which are included within the €15.2 million of profit of the Group during the year ended December 31, 2020 and constituted 3.9% and 5.7% of the Group's total assets as of December 31, 2020.

Based on this assessment, our management has determined that the Company's internal control over financial reporting as of December 31, 2020 is effective.

## Attestation Report of the Registered Public Accounting Firm

The effectiveness of our internal control over financial reporting as of December 31, 2020 has been audited by Ernst & Young GmbH Wirtschaftsprüfungsgesellschaft, an independent registered public accounting firm. Their report is included on page F-2. Ernst & Young GmbH Wirtschaftsprüfungsgesellschaft is a member of the Chamber of Public Accountants (*Wirtschaftsprüferkammer*), Berlin, Germany.

### Changes in Control over Financial Reporting

There were no changes to our internal control over financial reporting (as defined in Rule 13a-15(f) and 15d-15(f) under the Securities and Exchange Act of 1934) that occurred during the period covered by this form 20-F that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

### Item 16A. Audit Committee Financial Expert

Our Audit Committee consists of Dr. Ulrich Wandschneider, Michael Motschmann and Prof. Christoph Huber. Dr. Ulrich Wandschneider is the chair of the Audit Committee. All members of the Audit Committee qualify as “independent directors” as such term is defined in Rule 10A-3 under the Exchange Act and Nasdaq Rule 5605. Additionally, our Supervisory Board has determined that Dr. Ulrich Wandschneider qualifies as an “audit committee financial expert” as that term is defined under the Exchange Act.

### Item 16B. Code of Ethics

We have adopted a Code of Business Conduct & Ethics, or Code of Conduct, which outlines the principles of legal and ethical business conduct under which we do business. The Code of Conduct applies to all of our Supervisory Board members, Management Board members, directors of our subsidiaries and employees. The full text of the Code of Conduct is available on our website at <https://www.biontech.de>. The information and other content appearing on our website are not part of this Annual Report and our website address is included in this Annual Report as an inactive textual reference only. Any amendments or waivers from the provisions of the Code of Conduct for members of our Supervisory or Management Boards will be made only after approval by our Supervisory Board and will be disclosed on our website promptly following the date of such amendment or waiver.

### Item 16C. Principal Accountant Fees and Services

Ernst & Young GmbH Wirtschaftsprüfungsgesellschaft, or EY, has served as our independent registered public accounting firm for the years ended December 31, 2020, December 31, 2019 and December 31, 2018 for which audited financial statements appear in this Annual Report.

The following table sets out the aggregate fees for professional audit services and other services rendered by EY in the periods indicated:

<i>(in thousands)</i>	Years ended	
	December 31, 2020	2019
Audit fees	€1,354	€578
Audit-related fees	444	721
Tax fees	255	132
All other fees	419	49
<b>Total fees for professional audit services and other services</b>	<b>€2,472</b>	<b>€1,480</b>

Audit fees relate to the audit of the financial statements as set out in this Annual Report, certain procedures on our quarterly results, fees for testing our internal controls over financial reporting during the six months ended December 31, 2020 and services related to our statutory and regulatory filings for our subsidiaries.

Audit-related fees billed for assurance and related services are related mainly to the issuance of comfort letters in connection with our financing transactions.

Tax service fees were billed for services in conjunction with transactions, especially with our financing and deal transactions.

Other fees comprised fees for testing the implementation of our internal controls over financial reporting during the six months ended June 30, 2020.

The Audit Committee evaluates the qualifications, independence and performance of the independent auditor as well as pre-approves and reviews the audit and non-audit services to be performed by the independent auditor. The external audit plan and fees for professional audit services and other services rendered by EY for the years ended December 31, 2020 and 2019 were approved by the Audit Committee. The Audit Committee monitors compliance with the German and U.S. rules on non-audit services provided by an independent registered public accounting firm.

**Item 16D. Exemptions from the Listing Standards for Audit Committees**

Please see “Board Practices—Supervisory Board Practices—Audit Committee” in Item 6C in this Annual Report for the information required by this Item 16D.

**Item 16E. Purchases of Equity Securities by the Issuer and Affiliated Purchasers**

Not applicable.

**Item 16F. Change in Registrant’s Certifying Accountant**

Not applicable.

**Item 16G. Corporate Governance**

**German Corporate Governance Code**

The German Corporate Governance Code, or the Corporate Governance Code, was originally published by the German Federal Ministry of Justice (*Bundesministerium der Justiz*) in 2002. The version currently in effect, dated December 16, 2019, was published in the German Federal Gazette (*Bundesanzeiger*) on March 20, 2020. The Corporate Governance Code contains recommendations (*Empfehlungen*) and suggestions (*Anregungen*) relating to the management and supervision of German companies that are listed on a stock exchange. It follows internationally and nationally recognized standards for good and responsible corporate governance. The purpose of the Corporate Governance Code is to make the German system of corporate governance transparent for investors. The Corporate Governance Code includes corporate governance recommendations and suggestions with respect to shareholders and shareholders’ meetings, the management and supervisory boards, transparency, accounting policies and auditing.

There is no obligation to comply with the recommendations or suggestions of the Corporate Governance Code. The German Stock Corporation Act (*Aktengesetz*) requires only that the management board and supervisory board of a German company listed on a trading facility (such as a stock exchange) which is regulated and supervised by government authorities issue an annual declaration that either (i) states that the company has complied with the recommendations of the Corporate Governance Code or (ii) lists the recommendations that the company has not complied with and explains its reasons for deviating from the recommendations of the Corporate Governance Code (*Entsprechenserklärung*). In addition, a listed company is also required to state in this annual declaration whether it intends to comply with the recommendations or list the recommendations it does not plan to comply with in the future. These declarations must be made accessible to shareholders at all times. If the company changes its policy on certain recommendations between such annual declarations, it must disclose this fact and explain its reasons for deviating from the recommendations. Non-compliance with suggestions contained in the Corporate Governance Code need not be disclosed.

While in our opinion it is doubtful whether the above legal requirements and hence the Corporate Governance Code currently apply to us as a company listing on the Nasdaq Global Select Market, we issue the annual declaration described above on a voluntary basis. Therefore, our Management Board and Supervisory Board comply with the Corporate Governance Code except for such provisions which are listed explicitly in the annual declaration and for which they provide an explanation of non-compliance.

## Differences in Corporate Law

The applicable provisions of the SE Regulation in conjunction with the German Stock Corporation Act as applied to a European stock corporation that has its legal seat in Germany differ from laws applicable to U.S. corporations and their shareholders. Set forth below is a summary of certain differences between the provisions of the SE Regulation in conjunction with the German Stock Corporation Act applicable to us and the General Corporation Law of the State of Delaware relating to shareholders' rights and protections. This summary is not intended to be a complete discussion of the respective rights and it is qualified in its entirety by reference to Delaware law and European and German law.

### *European Union/Federal Republic of Germany*

#### Board System

A European stock corporation may choose to have a two-tier board structure composed of the Management Board (*Vorstand*) and the Supervisory Board (*Aufsichtsrat*). We have chosen this structure.

The Management Board is responsible for running the company's affairs and representing the company in dealings with third parties.

The Supervisory Board of a European stock corporation under German law has a control and supervisory function. The Supervisory Board does not actively manage the company but certain Management Board actions require the approval of the Supervisory Board.

### *Delaware*

Under Delaware law, a corporation has a unitary board structure, and it is the responsibility of the board of directors to appoint and oversee the management of the corporation on behalf of and in the best interests of the stockholders of the corporation.

Management is responsible for running the corporation and overseeing its day-to-day operations.

Under applicable European and German law, a European stock corporation governed by German law with a share capital of at least €3 million generally must have at least two members on its Management Board and the number of members shall be determined by or in the manner provided in the company's articles of association.

The Supervisory Board must consist of at least three but—depending on the share capital—no more than 21 Supervisory Board members, whereby the number of Supervisory Board members must be divisible by three if this is necessary for the fulfilment of co-determination requirements. The articles of association of the company must specify if the Supervisory Board has more than three members.

Supervisory Board members are either appointed by the shareholders' meeting or delegated by one or more individual shareholders if so provided for in the company's articles of association. If the Supervisory Board consists of fewer members than is required to meet the quorum for resolutions (either statutory or pursuant to the company's articles of association), a competent court may appoint additional members as needed to meet the quorum. The provisions of German law in relation to employees' co-determination do not apply to the Company.

Under Delaware law, a corporation must have at least one director and the number of directors shall be fixed by or in the manner provided in the bylaws.

Removal of Directors

Members of the Management Board of a European stock corporation are appointed by the Supervisory Board for a maximum period of six years with an opportunity to be reelected. The articles of association may provide for a shorter term, which in our case is up to five years. The members of the Management Board may be reelected, even repeatedly. The Supervisory Board may remove a member of the Management Board prior to the expiration of his or her term only for cause, such as gross breach of duties (*grobe Pflichtverletzung*), the inability to manage the business properly (*Unfähigkeit zur ordnungsgemäßen Pflichtausübung*) or a vote of no-confidence during the shareholders' meeting (*Vertrauensentzug*). The shareholders themselves are not entitled to appoint or dismiss the members of the Management Board.

Under European law, a member of the Supervisory Board of a company may be elected for a term of up to six years. The articles of association may provide for a shorter term. Our Supervisory Board members are, if the general meeting does not resolve on a shorter term, elected for a period up to the end of the general meeting deciding on the discharge for the fourth financial year after the election. Reelection, including repeated reelection, is permissible. Members of the Supervisory Board may be removed with or without cause by way of a general meeting resolution, with the applicable majority requirement depending on the relevant company's articles of association.

Vacancies on the Board of Directors

Under the law, vacant positions on the Management Board are filled by the Supervisory Board in accordance with the general rules of appointment, which provide that vacancies are filled by the simple majority of votes of Supervisory Board members present or represented by proxy at the vote (with, under certain circumstances, the chairman having a casting vote), unless otherwise provided by the company's articles of association. In case of emergencies, a vacant position on the Management Board may be filled by an individual appointed by the court. Vacant positions on the Supervisory Board are filled in accordance with the general rules of appointment.

Under Delaware law, any director or the entire board of directors may be removed, with or without cause, by the holders of a majority of the shares then entitled to vote at an election of directors, except (i) unless the certificate of incorporation provides otherwise, in the case of a corporation whose board of directors is classified, stockholders may effect such removal only for cause; or (ii) in the case of a corporation having cumulative voting, if less than the entire board of directors is to be removed, no director may be removed without cause if the votes cast against his removal would be sufficient to elect him if then cumulatively voted at an election of the entire board of directors, or, if there are classes of directors, at an election of the class of directors of which he is a part.

Under Delaware law, vacancies and newly created directorships may be filled by a majority of the directors then in office (even though less than a quorum) or by a sole remaining director unless (i) otherwise provided in the certificate of incorporation or by-laws of the corporation or (ii) the certificate of incorporation directs that a particular class of stock is to elect such director, in which case a majority of the other directors elected by such class, or a sole remaining director elected by such class, will fill such vacancy.

Annual General Meeting	<p>A European stock corporation, which is governed by German law, must hold an annual shareholders' meeting within six months of the end of its fiscal year. The annual shareholders' meeting must be held at a location determined by the articles of association. If the articles of association do not provide for a specific location, the shareholders' meeting shall be held at the company's seat or, if applicable, at the venue (in Germany) where its shares are listed.</p>	<p>Under Delaware law, the annual meeting of stockholders shall be held at such place, on such date and at such time as may be designated from time to time by the board of directors or as provided in the certificate of incorporation or by the bylaws.</p>
General Meeting	<p>Under the law, extraordinary shareholders' meetings, in addition to the annual shareholders' meetings, may be called either by the Management Board, or the Supervisory Board. Shareholders holding at least 5% of the company's share capital are entitled to request that an extraordinary shareholders' meeting be convened. In the event that the meeting is not then so convened, a competent court may order that the meeting be convened or authorize the shareholders or their representative to convene the meeting themselves.</p>	<p>Under Delaware law, special meetings of the stockholders may be called by the board of directors or by such person or persons as may be authorized by the certificate of incorporation or by the bylaws.</p>
Notice of General Meetings	<p>Under applicable European and German law, unless a longer period is otherwise provided for in the articles of association or applies because of registration requirements stipulated in the articles of association, the shareholders must be given at least 30 days' advance notice of the shareholders' meeting. Such notices must at least specify the name of the company, the statutory seat of the company, and the location, date and time of the shareholders' meeting. In addition, the invitation must contain the agenda items as well as the Management Board's and the Supervisory Board's voting proposal for each agenda item and, depending on the circumstances, certain further information.</p> <p>If all shareholders entitled to attend the shareholders' meeting are present or represented and do not object to the meeting being held, the formalities of calling and holding of a shareholders' meeting do not apply.</p>	<p>Under Delaware law, unless otherwise provided in the certificate of incorporation or bylaws, written notice of any meeting of the stockholders must be given to each stockholder entitled to vote at the meeting not less than ten nor more than 60 days before the date of the meeting and shall specify the place, date, hour, and purpose or purposes of the meeting.</p>

Proxy	<p>A shareholder may designate another person to attend, speak and vote at a shareholders' meeting of the company on such shareholder's behalf by proxy.</p> <p>With respect to Management Board meetings, a Management Board member may transmit its (written or verbal) vote via another Management Board member.</p> <p>With respect to Supervisory Board meetings, a Supervisory Board member may participate in voting by issuing a written vote to another Supervisory Board member or any third party entitled to attend the Supervisory Board meeting.</p>	<p>Under Delaware law, at any meeting of stockholders, a stockholder may designate another person to act for such stockholder by proxy, but no such proxy shall be voted or acted upon after three years from its date, unless the proxy provides for a longer period. A director of a Delaware corporation may not issue a proxy representing the director's voting rights as a director.</p>
Preemptive Rights	<p>Under the law applicable to European stock corporations governed by German law, existing shareholders have a statutory subscription right for any additional issue of shares or any security convertible into shares pro rata to the nominal value of their respective holdings in the company, unless (i) shareholders representing three-quarters of the registered share capital present at the shareholders' meeting have resolved upon the whole or partial exclusion of the subscription right and (ii) there exists good and objective cause for such exclusion. No separate resolution on the exclusion of subscription rights is required if all shareholders waive their statutory subscription rights.</p>	<p>Under Delaware law, stockholders have no preemptive rights to subscribe to additional issues of stock or to any security convertible into such stock unless, and except to the extent that, such rights are expressly provided for in the certificate of incorporation.</p>
Authority to Allot	<p>Under applicable European and German law, the Management Board may not allot shares, grant rights to subscribe for or to convert any security into shares unless a shareholder resolution to that effect has been passed at the company's shareholders' meeting granting the Management Board with such authority—subject to the approval of the Supervisory Board—in each case in accordance with the provisions of the German Stock Corporation Act.</p>	<p>Under Delaware law, if the corporation's certificate of incorporation so provides, the board of directors has the power to authorize the issuance of stock. It may authorize capital stock to be issued for consideration consisting of cash, any tangible or intangible property or any benefit to the corporation or any combination thereof. It may determine the amount of such consideration by approving a formula. In the absence of actual fraud in the transaction, the judgment of the directors as to the value of such consideration is conclusive.</p>



Liability of Directors and Officers	<p>Under German law, any provision, whether contained in the company's articles of association or any contract or otherwise, that purports to exempt a Management or Supervisory Board member from any liability that would otherwise attach to such board member in connection with any negligence, default, breach of duty or breach of trust in relation to the company is void.</p> <p>Under German law, members of both the Management Board and members of the Supervisory Board are liable to the company, and in certain cases to third parties or shareholders, for any damage caused to them due to a breach of such member's duty of care. Apart from insolvency or special circumstances, only the company has the right to claim damages from members of either board. The company may waive claims for damages against a negligent Management or Supervisory Board member only after the expiry of three years.</p>	<p>Under Delaware law, a corporation's certificate of incorporation may include a provision eliminating or limiting the personal liability of a director to the corporation and its stockholders for damages arising from a breach of fiduciary duty as a director. However, no provision can limit the liability of a director for:</p> <ul style="list-style-type: none"> <li>• any breach of the director's duty of loyalty to the corporation or its stockholders;</li> <li>• acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law;</li> <li>• intentional or negligent payment of unlawful dividends or stock purchases or redemptions; or</li> <li>• any transaction from which the director derives an improper personal benefit.</li> </ul>
Voting Rights	<p>Under the relevant European and German law, each share, except for statutory non-voting preferred shares (<i>nicht stimmberechtigte Vorzugsaktien</i>), entitles its holder to vote at the shareholders' meeting with, in the case of no-par value shares, each share conferring one vote. While German law does not provide for a minimum attendance quorum for shareholders' meetings, the company's articles of association may so provide. In general, resolutions adopted at a shareholders' meeting may be passed by a simple majority of votes cast, unless a higher majority is required by law or under the company's articles of association.</p>	<p>Delaware law provides that, unless otherwise provided in the certificate of incorporation, each stockholder is entitled to one vote for each share of capital stock held by such stockholder.</p>
Shareholder Vote on Certain Transactions	<p>Under applicable European and German law, certain shareholders' resolutions of fundamental importance require the vote of at least three-quarters of the share capital present or represented in the voting at the time of adoption of the resolution. Resolutions of fundamental importance include, in particular, capital increases with exclusion of subscription rights, capital decreases, the creation of authorized or conditional share capital, the dissolution of a company, a merger into or with another company, split-offs and split-ups, the conclusion of inter-company agreements (<i>Unternehmensverträge</i>), in particular domination agreements (<i>Beherrschungsverträge</i>) and profit and loss transfer agreements (<i>Ergebnisabführungsverträge</i>).</p>	<p>Generally, under Delaware law, unless the certificate of incorporation provides for the vote of a larger portion of the stock, completion of a merger, consolidation, sale, lease or exchange of all or substantially all of a corporation's assets or dissolution requires:</p> <ul style="list-style-type: none"> <li>• the approval of the board of directors; and</li> <li>• approval by the vote of the holders of a majority of the outstanding stock or, if the certificate of incorporation provides for more or less than one vote per share, a majority of the votes of the outstanding stock of a corporation entitled to vote on the matter.</li> </ul>

Under applicable European and German law, both Management and Supervisory Board members must conduct their affairs with "the care and diligence of a prudent business man" and act in the best interest of the company. The scope of the fiduciary duties of Management and Supervisory Board members is generally determined by European and German legislation and by the courts.

Statutory and fiduciary duties of members of the Management Board to the company include, among others:

- to act in accordance with the law, the company's articles of association and the rules of procedure for the Management Board, if any;
- to report to the Supervisory Board on a regular basis as well as on certain important occasions;
- to exercise reasonable care, skill and diligence;
- to maintain a proper accounting system;
- to not compete, directly or indirectly, with the company without permission by the supervisory board; and
- to secure that no further transactions are made in case of insolvency.

Statutory and fiduciary duties of members of the Supervisory Board to the company include, among others:

- to effectively supervise the Management Board's handling of the company's affairs;
- to evaluate and issue a resolution on certain transactions which can only be conducted by the Management Board after approval of the Supervisory Board;
- to approve the company's financial statements;
- to appoint the Management Board members and to represent the company in transactions between the company and members of the Management Board; and
- to approve service contracts between individual members of the Supervisory Board and the company.

Delaware law does not contain specific provisions setting forth the standard of conduct of a director. The scope of the fiduciary duties of directors is generally determined by the courts of the State of Delaware. In general, directors have a duty to act without self-interest, on a well-informed basis and in a manner they reasonably believe to be in the best interest of the stockholders.

Directors of a Delaware corporation owe fiduciary duties of care and loyalty to the corporation and to its stockholders. The duty of care generally requires that a director act in good faith, with the care that an ordinarily prudent person would exercise under similar circumstances. Under this duty, a director must inform himself of all material information reasonably available regarding a significant transaction. The duty of loyalty requires that a director act in a manner he reasonably believes to be in the best interests of the corporation. He must not use his corporate position for personal gain or advantage. In general, but subject to certain exceptions, actions of a director are presumed to have been made on an informed basis, in good faith and in the honest belief that the action taken was in the best interests of the corporation. However, this presumption may be rebutted by evidence of a breach of one of the fiduciary duties. Delaware courts have also imposed a heightened standard of conduct upon directors of a Delaware corporation who take any action designed to defeat a threatened change in control of the corporation.

In addition, under Delaware law, when the board of directors of a Delaware corporation approves the sale or break-up of a corporation, the board of directors may, in certain circumstances, have a duty to obtain the highest value reasonably available to the stockholders.

Under German law, generally, the company, rather than its shareholders, is the proper claimant in an action with respect to a wrong committed against the company, or in cases where there is an irregularity in the company's internal management or supervision. Therefore, such claims may only be raised by the company represented by its Management Board, or, in the case of a wrong committed by a member of the Management Board, by the Supervisory Board.

Additionally, pursuant to German case law, the Supervisory Board is obliged to pursue the company's claims against the Management Board, unless the interest of the company keeps them from doing so.

The Management Board, or, if a claim is against a member of the Management Board, the Supervisory Board, is obliged to pursue the company's claims against the designated individuals if so resolved by a simple majority of votes cast during a shareholders' meeting. With a simple majority of votes, shareholders can request that a representative pursues the claim on behalf of the company.

If the company is unable to fulfill its third-party obligations, the company's creditors may pursue the company's damage claims against members of the Management Board for certain wrongdoings.

Under certain circumstances, shareholders can bring forward damage claims of the company against its management on their own behalf. In order to bring forward such a claim one shareholder alone or together with other shareholders needs to hold at least one percent of the company's share capital or a participation of €100,000 in the share capital. Additionally, the claimant(s) need(s) to pass through special claim approval procedures.

#### Foreign Private Issuer Exemptions

As a "foreign private issuer," as defined by the SEC, although we are permitted to follow certain corporate governance practices of the Federal Republic of Germany, instead of those otherwise required under the rules of the Nasdaq Stock Market LLC, or Nasdaq, for domestic issuers, we follow the Nasdaq corporate governance rules applicable to foreign private issuers. While we voluntarily follow most Nasdaq corporate governance rules, we intend to take advantage of the following limited exemptions:

- exemption from filing quarterly reports on Form 10-Q and providing current reports on Form 8-K disclosing significant events within four days of their occurrence (however, we intend to furnish quarterly financial information under cover of Form 6-K);
- exemption from compliance with Regulation FD, which generally requires that when a company intentionally discloses material-non public information, it do so through a public disclosure that is broadly available to all members of the public at the same time. However, we do furnish quarterly financial information and other

Under Delaware law, a stockholder may initiate a derivative action to enforce a right of a corporation if the corporation fails to enforce the right itself. The complaint must:

- state that the plaintiff was a stockholder at the time of the transaction of which the plaintiff complains or that the plaintiff's shares thereafter devolved on the plaintiff by operation of law; and
- either (i) allege with particularity the efforts made by the plaintiff to obtain the action the plaintiff desires from the directors and the reasons for the plaintiff's failure to obtain the action, or (ii) or state the reasons for not making the effort.

Additionally, the plaintiff must remain a stockholder through the duration of the derivative suit. The action will not be dismissed or compromised without the approval of the Delaware Court of Chancery.

information on a more frequent basis under cover of Form 6-K, and intend to continue doing so. Moreover, we comply with other other securities laws, such as rule 10b-5 (rule targeting securities fraud), among others;

- exemption from Section 16 rules regarding sales of ordinary shares by insiders, which will provide less data in this regard than the data provided to shareholders of U.S. companies that are subject to the Exchange Act; and
- exemption from the Nasdaq rules applicable to domestic issuers requiring disclosure within four business days of any determination to grant a waiver of the code of business conduct and ethics to directors and officers. Although we will require board approval of any such waiver, we may choose not to disclose the waiver in the manner set forth in the Nasdaq rules, as permitted by the foreign private issuer exemption.

Furthermore, Nasdaq Rule 5615(a)(3) provides that a foreign private issuer, such as we, may rely on home country corporate governance practices in lieu of certain of the rules in the Nasdaq Rule 5600 Series and Rule 5250(d), provided that we nevertheless comply with Nasdaq's Notification of Noncompliance requirement (Rule 5625) and the Voting Rights requirement (Rule 5640) and that we have an audit committee that satisfies Rule 5605(c)(3), consisting of committee members that meet the independence requirements of Rule 5605(c)(2)(A)(ii). Although we are permitted to follow certain corporate governance rules that conform to German requirements in lieu of many of the Nasdaq corporate governance rules, we comply with the Nasdaq corporate governance rules applicable to foreign private issuers. We may utilize these exemptions for as long as we continue to qualify as a foreign private issuer.

**Item 16H. Mine Safety Disclosure**

Not applicable.

PART III

Item 17. Financial Statements

See Item 18.

Item 18. Financial Statements

The financial statements are filed as part of this Annual Report beginning on page F-1.

Item 19. Exhibits

Exhibit Number	Description
1.1*	<a href="#">Articles of Association of the Registrant</a>
2.1	<a href="#">Form of Specimen American Depositary Receipt (included in Exhibit 2.3)</a>
2.2	<a href="#">Registrant's Specimen Certificate for Ordinary Shares (incorporated herein by reference to Exhibit 4.2 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019).</a>
2.3	<a href="#">Form of Deposit Agreement among the Registrant, the depository and holders and beneficial owners of the American Depositary Shares (incorporated herein by reference to Exhibit 1 to the Registration Statement on Form F-6 (File No. 333-233898), filed with the SEC on September 23, 2019)</a>
2.4*	<a href="#">Description of Securities of the Registrant</a>
4.1†	<a href="#">Master Agreement for Research Services by and among the Registrant, BioNTech RNA Pharmaceuticals GmbH, BioNTech Diagnostics GmbH, BioNTech Protein Therapeutics GmbH, BioNTech Cell &amp; Gene Therapies GmbH, Eufets GmbH, JPT Peptide Technologies GmbH and TRON-Translationale Onkologie an der Universitätsmedizin der Johannes Gutenberg Universität Mainz gemeinnützige GmbH, dated January 1, 2015 (incorporated herein by reference to Exhibit 10.1 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019).</a>
4.2†	<a href="#">Confirmation Letter by and among the Registrant, BioNTech RNA Pharmaceuticals GmbH and TRON-Translationale Onkologie an der Universitätsmedizin der Johannes Gutenberg Universität Mainz gemeinnützige GmbH dated September 15, 2016 (incorporated herein by reference to Exhibit 10.2 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019).</a>
4.3†	<a href="#">Supplementary Agreement for IVAC Developments to the Master Agreement for Research Services by and among the Registrant, BioNTech RNA Pharmaceuticals GmbH, BioNTech Diagnostics GmbH, BioNTech Protein Therapeutics GmbH, BioNTech Cell &amp; Gene Therapies GmbH, BioNTech Innovative Manufacturing Services GmbH (f/k/a Eufets GmbH), JPT Peptide Technologies GmbH and TRON-Translationale Onkologie an der Universitätsmedizin der Johannes Gutenberg Universität Mainz gemeinnützige GmbH, dated November 28, 2017 (incorporated herein by reference to Exhibit 10.3 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)</a>
4.4†	<a href="#">License Agreement by and among the Registrant, TRON-Translationale Onkologie an der Universitätsmedizin der Johannes Gutenberg Universität Mainz gemeinnützige GmbH, Johannes Gutenberg-Universität Mainz, Universitätsmedizin der Johannes Gutenberg-Universität and Ganymed Pharmaceuticals AG, dated January 1, 2015 (incorporated herein by reference to Exhibit 10.4 to the Registrant's Registration Statement on Form F-1 (File No. 333-233688), filed with the SEC on September 9, 2019)</a>

- 4.5† [Framework Collaboration Agreement by and among the Registrant, BioNTech RNA Pharmaceuticals GmbH, BioNTech Diagnostics GmbH, BioNTech Protein Therapeutics GmbH, BioNTech Cell & Gene Therapies GmbH, BioNTech Innovative Manufacturing Services GmbH, IPT Peptide Technologies GmbH and TRON-Translationale Onkologie an der Universitätsmedizin der Johannes Gutenberg Universität Mainz gemeinnützige GmbH, dated August 29, 2019 \(incorporated herein by reference to Exhibit 10.5 to the Registrant's Registration Statement on Form F-1 \(File No. 333-233688\), filed with the SEC on September 9, 2019\)](#)
- 4.6† [Amended Patent License Agreement by and among the Registrant, the Board of Supervisors of Louisiana State University and Agricultural and Mechanical College and Uniwersytet Warszawski, dated May 12, 2015 \(incorporated herein by reference to Exhibit 10.6 to the Registrant's Registration Statement on Form F-1 \(File No. 333-233688\), filed with the SEC on September 9, 2019\)](#)
- 4.7† [License and Collaboration Agreement by and between the Registrant and Genmab A/S, dated May 19, 2015 \(incorporated herein by reference to Exhibit 10.7 to the Registrant's Registration Statement on Form F-1 \(File No. 333-233688\), filed with the SEC on September 9, 2019\)](#)
- 4.8† [Amendment No. 1 to License and Collaboration Agreement by and between the Registrant and Genmab A/S, dated May 18, 2017 \(incorporated herein by reference to Exhibit 10.8 to the Registrant's Registration Statement on Form F-1 \(File No. 333-233688\), filed with the SEC on September 9, 2019\)](#)
- 4.9† [Amendment No. 2 to License and Collaboration Agreement by and between the Registrant and Genmab A/S, dated August 4, 2017 \(incorporated herein by reference to Exhibit 10.9 to the Registrant's Registration Statement on Form F-1 \(File No. 333-233688\), filed with the SEC on September 9, 2019\)](#)
- 4.10† [Amendment No. 3 to License and Collaboration Agreement by and between the Registrant and Genmab A/S, dated May 18, 2018 \(incorporated herein by reference to Exhibit 10.10 to the Registrant's Registration Statement on Form F-1 \(File No. 333-233688\), filed with the SEC on September 9, 2019\)](#)
- 4.11† [Collaboration and License Agreement by and between Sanofi S.A. and BioNTech RNA Pharmaceuticals GmbH, dated November 2, 2015 \(incorporated herein by reference to Exhibit 10.11 to the Registrant's Registration Statement on Form F-1 \(File No. 333-233688\), filed with the SEC on September 9, 2019\)](#)
- 4.12† [Amendment to Collaboration and License Agreement by and between Sanofi S.A. and BioNTech RNA Pharmaceuticals GmbH, dated December 22, 2018 \(incorporated herein by reference to Exhibit 10.12 to the Registrant's Registration Statement on Form F-1 \(File No. 333-233688\), filed with the SEC on September 9, 2019\)](#)
- 4.13† [Development Agreement by and between Sanofi S.A. and BioNTech RNA Pharmaceuticals GmbH, dated March 29, 2018 \(incorporated herein by reference to Exhibit 10.13 to the Registrant's Registration Statement on Form F-1 \(File No. 333-233688\), filed with the SEC on September 9, 2019\)](#)
- 4.14† [Collaboration Agreement by and among the Registrant, BioNTech RNA Pharmaceuticals GmbH, Genentech, Inc. and F. Hoffman-La Roche Ltd, dated September 20, 2016 \(incorporated herein by reference to Exhibit 10.14 to the Registrant's Registration Statement on Form F-1 \(File No. 333-233688\), filed with the SEC on September 9, 2019\)](#)
- 4.15\*† [First Amendment to the Collaboration Agreement by and among the Registrant, BioNTech RNA Pharmaceuticals GmbH, Genentech, Inc. and F. Hoffman-La Roche Ltd, dated June 1, 2018 \(incorporated herein by reference to Exhibit 10.17 to the Registrant's Registration Statement on Form F-1 \(File No. 333-239970\), filed with the SEC on July 21, 2020\)](#)
- 4.16\*† [Second Amendment to the Collaboration Agreement by and among the Registrant, BioNTech RNA Pharmaceuticals GmbH, Genentech, Inc. and F. Hoffman-La Roche Ltd, dated December 6, 2019 \(incorporated herein by reference to Exhibit 10.18 to the Registrant's Registration Statement on Form F-1 \(File No. 333-239970\), filed with the SEC on July 21, 2020\)](#)
- 4.17\* [Joinder and Third Amendment to the Collaboration Agreement by and among the Registrant, BioNTech RNA Pharmaceuticals GmbH, BioNTech Manufacturing GmbH, Genentech, Inc. and F. Hoffman-La Roche Ltd, effective as of October 1, 2020](#)

- 4.18\*† [Fourth Amendment to the Collaboration Agreement by and among the Registrant, BioNTech RNA Pharmaceuticals GmbH, BioNTech Manufacturing GmbH, Genentech, Inc. and E. Hoffman-La Roche Ltd, effective as of October 26, 2020](#)
- 4.19† [Patent Sublicense Agreement by and between CellScript, LLC and BioNTech RNA Pharmaceuticals GmbH, dated July 14, 2017 \(incorporated herein by reference to Exhibit 10.15 to the Registrant's Registration Statement on Form F-1 \(File No. 333-233688\), filed with the SEC on September 9, 2019\)](#)
- 4.20\*† [Second Amendment to Patent Sublicense Agreement by and between CellScript, LLC and BioNTech RNA Pharmaceuticals GmbH, effective as of August 1, 2020](#)
- 4.21† [Patent Sublicense Agreement by and between mRNA RiboTherapeutics, Inc. and BioNTech RNA Pharmaceuticals GmbH, dated July 14, 2017 \(incorporated herein by reference to Exhibit 10.16 to the Registrant's Registration Statement on Form F-1 \(File No. 333-233688\), filed with the SEC on September 9, 2019\)](#)
- 4.22\*† [Second Amendment to Patent Sublicense Agreement by and between mRNA RiboTherapeutics, Inc. and BioNTech RNA Pharmaceuticals GmbH, effective as of August 1, 2020](#)
- 4.23† [Research Collaboration and License Agreement by and among the Registrant, BioNTech RNA Pharmaceuticals GmbH and Pfizer, Inc., dated July 20, 2018 \(incorporated herein by reference to Exhibit 10.18 to the Registrant's Registration Statement on Form F-1 \(File No. 333-233688\), filed with the SEC on September 9, 2019\)](#)
- 4.24† [Collaboration and License Agreement by and between the Trustees of the University of Pennsylvania and BioNTech RNA Pharmaceuticals GmbH, dated October 9, 2018 \(incorporated herein by reference to Exhibit 10.19 to the Registrant's Registration Statement on Form F-1 \(File No. 333-233688\), filed with the SEC on September 9, 2019\)](#)
- 4.25† [Sublease Agreement by and among the Registrant and Universitätsmedizin der Johannes Gutenberg-Universität Mainz, dated January 14, 2013 \(incorporated herein by reference to Exhibit 10.21 to the Registrant's Registration Statement on Form F-1 \(File No. 333-233688\), filed with the SEC on September 9, 2019\)](#)
- 4.26† [Amendment to Sublease Agreement by and among the Registrant and Universitätsmedizin der Johannes Gutenberg-Universität Mainz, dated July 5, 2014 \(incorporated herein by reference to Exhibit 10.22 to the Registrant's Registration Statement on Form F-1 \(File No. 333-233688\), filed with the SEC on September 9, 2019\)](#)
- 4.27† [Amendment to Sublease Agreement by and among the Registrant and Universitätsmedizin der Johannes Gutenberg-Universität Mainz, dated June 8, 2015 \(incorporated herein by reference to Exhibit 10.23 to the Registrant's Registration Statement on Form F-1 \(File No. 333-233688\), filed with the SEC on September 9, 2019\)](#)
- 4.28† [Amendment to Sublease Agreement by and among the Registrant and Universitätsmedizin der Johannes Gutenberg-Universität Mainz, dated January 18, 2017 \(incorporated herein by reference to Exhibit 10.24 to the Registrant's Registration Statement on Form F-1 \(File No. 333-233688\), filed with the SEC on September 9, 2019\)](#)
- 4.29† [Lease Agreement by and among the Registrant and Wolfram Richter, dated August 17, 2011 \(incorporated herein by reference to Exhibit 10.25 to the Registrant's Registration Statement on Form F-1 \(File No. 333-233688\), filed with the SEC on September 9, 2019\)](#)
- 4.30† [Amendment No. 1 to Lease Agreement by and among the Registrant and Wolfram Richter, dated February 17, 2012 \(incorporated herein by reference to Exhibit 10.26 to the Registrant's Registration Statement on Form F-1 \(File No. 333-233688\), filed with the SEC on September 9, 2019\)](#)
- 4.31† [Amendment No. 2 to Lease Agreement by and among the Registrant and Wolfram Richter, dated February 1, 2013 \(incorporated herein by reference to Exhibit 10.27 to the Registrant's Registration Statement on Form F-1 \(File No. 333-233688\), filed with the SEC on September 9, 2019\)](#)
- 4.32† [Amendment No. 3 to Lease Agreement by and among the Registrant and Wolfram Richter, dated March 6, 2013 \(incorporated herein by reference to Exhibit 10.28 to the Registrant's Registration Statement on Form F-1 \(File No. 333-233688\), filed with the SEC on September 9, 2019\)](#)

4.33† [Amendment No. 4 to Lease Agreement by and among the Registrant and Wolfram Richter, dated December 10, 2013 \(incorporated herein by reference to Exhibit 10.29 to the Registrant's Registration Statement on Form F-1 \(File No. 333-233688\), filed with the SEC on September 9, 2019\)](#)

4.34† [Amendment No. 5 to Lease Agreement by and among the Registrant and Wolfram Richter, dated March 29, 2016 \(incorporated herein by reference to Exhibit 10.30 to the Registrant's Registration Statement on Form F-1 \(File No. 333-233688\), filed with the SEC on September 9, 2019\)](#)

4.35† [Amendment No. 6 to Lease Agreement by and among the Registrant and Wolfram Richter, dated October 6, 2017 \(incorporated herein by reference to Exhibit 10.31 to the Registrant's Registration Statement on Form F-1 \(File No. 333-233688\), filed with the SEC on September 9, 2019\)](#)

4.36† [Lease Agreement by and among the Registrant and Wista-Management GmbH, dated April 12, 2005 \(incorporated herein by reference to Exhibit 10.32 to the Registrant's Registration Statement on Form F-1 \(File No. 333-233688\), filed with the SEC on September 9, 2019\)](#)

4.37† [Amendment to Lease Agreement by and among the Registrant and Wista-Management GmbH, dated December 27, 2018 \(incorporated herein by reference to Exhibit 10.33 to the Registrant's Registration Statement on Form F-1 \(File No. 333-233688\), filed with the SEC on September 9, 2019\)](#)

4.38† [Amendment to Lease Agreement by and among the Registrant and Wista-Management GmbH, dated October 24, 2019 \(incorporated herein by reference to Exhibit 4.35 to the Registrant's Annual Report on Form 20-F for the year ended December 31, 2019\)](#)

4.39† [Amendment to Lease Agreement by and among the Registrant and Wista-Management GmbH, dated June 1, 2020 \(incorporated herein by reference to Exhibit 10.38 to the Registrant's Registration Statement on Form F-1 \(File No. 333-233970\), filed with the SEC on July 21, 2020\)](#)

4.40† [Loan Agreement by and between BioNTech Innovative Manufacturing Services GmbH and Deutsche Bank AG dated November 21, 2017 \(incorporated herein by reference to Exhibit 10.34 to the Registrant's Registration Statement on Form F-1 \(File No. 333-233688\), filed with the SEC on September 9, 2019\)](#)

4.41† [Loan Agreement by and between JPT Peptides Technologies GmbH and Deutsche Bank AG dated July 18, 2018 \(incorporated herein by reference to Exhibit 10.35 to the Registrant's Registration Statement on Form F-1 \(File No. 333-233688\), filed with the SEC on September 9, 2019\)](#)

4.42† [Finance Contract by and between the Registrant and the European Investment Bank, dated December 12, 2019 \(incorporated herein by reference to Exhibit 10.43 to the Registrant's Registration Statement on Form F-1 \(File No. 333-233970\), filed with the SEC on July 21, 2020\)](#)

4.43† [Finance Fee Letter by and between the Registrant and the European Investment Bank, dated December 12, 2019 \(incorporated herein by reference to Exhibit 10.44 to the Registrant's Registration Statement on Form F-1 \(File No. 333-233970\), filed with the SEC on July 21, 2020\)](#)

4.44\*† [Amended and Restated Collaboration Agreement by and between the Registrant and Pfizer Inc., dated March 17, 2020](#)

4.45† [Antiviral Vaccine RDI Finance Contract by and between the European Investment Bank and the Registrant, dated as of June 10, 2020 \(incorporated herein by reference to Exhibit 10.46 to the Registrant's Registration Statement on Form F-1 \(File No. 333-233970\), filed with the SEC on July 21, 2020\)](#)

4.46† [Finance Fee Letter by and between the Registrant and the European Investment Bank, dated June 10, 2020 \(incorporated herein by reference to Exhibit 10.47 to the Registrant's Registration Statement on Form F-1 \(File No. 333-233970\), filed with the SEC on July 21, 2020\)](#)

4.47† [License Agreement by and between the Broad Institute, Inc. and BioNTech US Inc. \(as successor-by-merger to Neon Therapeutics, Inc.\), dated as of November 13, 2015 \(incorporated herein by reference to Exhibit 10.48 to the Registrant's Registration Statement on Form F-1 \(File No. 333-233970\), filed with the SEC on July 21, 2020\)](#)

4.48† [First Amendment to the License Agreement by and between the Broad Institute, Inc. and BioNTech US Inc. \(as successor-by-merger to Neon Therapeutics, Inc.\), dated as of January 18, 2018 \(incorporated herein by reference to Exhibit 10.49 to the Registrant's Registration Statement on Form F-1 \(File No. 333-233970\), filed with the SEC on July 21, 2020\)](#)



4.49†	<a href="#">Second Amendment to the License Agreement by and between the Broad Institute, Inc. and BioNTech US Inc. (as successor-by-merger to Neon Therapeutics, Inc.), dated as of November 14, 2018 (incorporated herein by reference to Exhibit 10.50 to the Registrant's Registration Statement on Form F-1 (File No. 333-233970), filed with the SEC on July 21, 2020</a>
4.50†	<a href="#">Sales Agreement by and among the Registrant, Jefferies LLC and SVB Leerink LLC, dated November 9, 2020 (incorporated herein by reference to Exhibit 1.2 to the Registrant's Registration Statement on Form F-3 (File No. 333-249991), filed with the SEC on November 10, 2020)</a>
4.51*†	<a href="#">Advance Purchase Agreement by and among BioNTech Manufacturing GmbH, Pfizer Inc., and the European Commission, dated November 20, 2020</a>
4.52*†	<a href="#">Purchase Agreement by and among BioNTech Manufacturing GmbH, Pfizer Inc., and the European Commission, dated February 17, 2021</a>
4.53*†	<a href="#">Lease by and between the Pharmserv GmbH and Novartis Manufacturing GmbH</a>
8*	<a href="#">List of Subsidiaries of the Registrant</a>
12.1*	<a href="#">Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</a>
12.2*	<a href="#">Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</a>
13.1*	<a href="#">Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</a>
13.2*	<a href="#">Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</a>
15.1	<a href="#">Consent of Ernst &amp; Young GmbH Wirtschaftsprüfungsgesellschaft</a>
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

\* Filed herewith.

† Certain information has been excluded from the exhibit because it both (i) is not material and (ii) would likely cause competitive harm to the Registrant if publicly disclosed.

SIGNATURES

The Registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this Annual Report on Form 20-F on its behalf.

BioNTech SE

Date: March 30, 2021

By: \_\_\_\_\_  
/s/ Prof. Ugur Sahin, M.D.  
**Prof. Ugur Sahin, M.D.**  
**Chief Executive Officer**

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To the Shareholders and the Management and Supervisory Boards of BioNTech SE

### Opinion on the Financial Statements

We have audited the accompanying consolidated statements of financial position of BioNTech SE and subsidiaries (the Company) as of December 31, 2020 and 2019, the related consolidated statements of operations, comprehensive income, changes in equity and cash flows for each of the three years in the period ended December 31, 2020, and the related notes (collectively referred to as the “(consolidated) financial statements”). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2020 and 2019, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2020, in conformity with International Financial Reporting Standards as issued by the International Accounting Standard Board.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company’s internal control over financial reporting as of December 31, 2020, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission “(2013 framework),” and our report dated March 30, 2021 expressed an unqualified opinion thereon.

### Basis for Opinion

These financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

### Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

### Accounting for cost-sharing and related revenue recognition under Genentech and Pfizer Collaboration Agreements

#### Description of the Matter

The Company has been engaged in collaboration agreements (“agreements”) with Genentech and Pfizer. Upon entering into the agreements, the Company has recognized a contract liability. As of December 31, 2020, the Company has a contract liability of €82.3 million related to the Genentech agreement and no remaining contract liability related to the Pfizer agreement. Additionally, the Company recognized €49.2 million of revenue from the Genentech agreement and €118.0 million from the Pfizer agreement.

The Company, Genentech, and Pfizer conduct research and development activities under these agreements. Revenue for both agreements is recognized based upon incurred costs as a measurement basis in the cost-sharing models. As explained in note 6 to the consolidated financial statements, the Company, Genentech, and Pfizer share certain internal and external research and development costs under the agreements. The Company’s research and development costs include external actual and estimated Clinical Research Organizations costs (“CRO”), external actual and estimated Contract Manufacturing Organization (“CMO”) costs, and internal employee costs.

Auditing the cost-sharing under the agreements was challenging because of the complexity of determining the eligible research and development costs under the respective agreements. The research and development costs include management’s judgment specifically for estimated third party CRO and CMO costs incurred during the reporting period. Additionally, management evaluates the research and development costs incurred and activities performed by Genentech and Pfizer to assess the eligibility for reimbursement through cost-sharing under the agreements.

We obtained an understanding, evaluated the design and tested the operating effectiveness of controls over the accounting for the cost-sharing conducted under the agreements. We tested management's evaluation of the agreements to determine eligible research & development costs, tested their review of completeness and accuracy of those costs and tested their review of the underlying calculations. We also tested management's controls of reviewing third party CMO and CRO costs incurred and eligibility to be included under the terms of the agreements.

Our audit procedures included, among others, conducting interviews with program management, clinical operations and manufacturing personnel to determine the progress to date under the agreements and testing the eligibility of the Company's research and development costs against the terms of the agreements. We met with Company personnel and reviewed meeting minutes to understand discussions held with Genentech and Pfizer during various committee meetings to test the completeness and accuracy of information obtained. Further, we tested the research and development activities reported by the Company, Genentech, and Pfizer for appropriate classification and disclosure by comparing the cost categories reported to those included in the agreements. Lastly, we obtained external confirmations from Genentech and Pfizer for the research and development costs incurred and evaluated the adequacy of the Company's related disclosures.

#### **Valuation of IPR&D acquired within Business Combinations of Neon**

*Description of the Matter* As described in more detail in Note 5 to the consolidated financial statements, in May 2020, the Company completed its acquisition of Neon Therapeutics Inc. (Neon) for a purchase price of €89.9 million. As a result of the acquisition, the Company acquired in-process research and development (IPR&D) assets including a neoantigen-targeting T cell platform that can be utilized to develop product candidates across several neoantigen-targeting non-engineered and engineered T cell therapies with BNT221 (NEO-PTC-01) being the most advanced program acquired. The lead program acquired is BNT222 (NEO-STC-01) a T-cell therapy candidate targeting shared RAS neoantigens. NEO-PTC-01 and NEO-STC-01 IPR&D assets were accounted for as definite-lived intangible assets and valued at €28.8 million and €0.6 million, respectively.

Auditing the valuation of the IPR&D assets was complex because of the significant estimation uncertainty in determining the fair value of the intangible assets. The fair value determination is based on a discounted cash flow model using certain assumptions containing high subjectivity, such as revenue growth, probability of technical success and discount rates. These significant assumptions are forward-looking and could be affected by future economic and market conditions. Further, the estimated fair value of the IPR&D assets was sensitive to changes in these assumptions.

*How We Addressed the Matter in Our Audit* We evaluated the design and tested the operating effectiveness of the Company's controls related to the valuation of the IPR&D assets. For example, we tested controls over management's review of the significant assumptions used to calculate the valuation of the intangible assets acquired including forecasts of future cash flows, discount rate and review of the valuation model.

Our audit procedures included, among others, obtaining an understanding of management's approach to developing the probability of technical success and evaluating the reasonableness by comparing to analyst expectations, historical results of similar products in development and industry trends. In addition, to evaluating the probability of technical success, we considered the phase of development of the IPR&D project and third-party data regarding clinical trial success rates. We evaluated the reasonableness of the projected revenue growth used in the valuation by comparing assumptions to industry trends, such as patient population, market studies, and price ranges for similar drugs. Our procedures also included sensitivity analysis of the significant assumptions to evaluate the change in the fair value of the IPR&D assets resulting from changing the assumptions.

Further, we involved our valuation specialists to evaluate the discounted cash flow model used by the Company and to test the discount rate utilized in the Company's valuation. Lastly, we evaluated the adequacy of the Company's related disclosures.

/s/ Ernst & Young GmbH Wirtschaftsprüfungsgesellschaft

We have served as the Company's auditor since 2018

Cologne, Germany  
March 30, 2021

To the Shareholders and the Management and Supervisory Boards of BioNTech SE

**Opinion on Internal Control Over Financial Reporting**

We have audited BioNTech SE's and subsidiaries' internal control over financial reporting as of December 31, 2020, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission “(2013 framework),” (the COSO criteria). In our opinion, BioNTech SE and subsidiaries (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2020, based on the COSO criteria.

As indicated in the accompanying Management's Annual Report on Internal Control over Financial Reporting, management's assessment of and conclusion on the effectiveness of internal control over financial reporting did not include the internal controls of BioNTech US Inc. and BioNTech Manufacturing Marburg GmbH, which are included in the 2020 consolidated financial statements of the Company and constituted 10% and 6% of total assets and net assets, respectively, as of December 31, 2020 and 0% of revenues and constituted €35.7 million of net loss included within the €15.2 million total profit for the year then ended. Our audit of internal control over financial reporting of the Company also did not include an evaluation of the internal control over financial reporting of BioNTech US Inc. and BioNTech Manufacturing Marburg GmbH.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated statements of financial position of the Company as of December 31, 2020 and 2019, the related consolidated statements of operations, comprehensive income, changes in equity and cash flows for each of the three years in the period ended December 31, 2020, and the related notes and our report dated March 30, 2021 expressed an unqualified opinion thereon.

**Basis for Opinion**

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Annual Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

**Definition and Limitations of Internal Control Over Financial Reporting**

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Ernst & Young GmbH Wirtschaftsprüfungsgesellschaft

Cologne, Germany  
March 30, 2021



**Consolidated Statements of Financial Position**

<i>(in thousands)</i>		<b>December 31, 2020</b>	<b>December 31, 2019</b>
<b>Assets</b>	<b>Note</b>		
<b>Non-current assets</b>			
Intangible assets	11	€163,490	€89,434
Property, plant and equipment	10	226,968	93,044
Right-of-use assets	19	98,988	55,018
Other assets	14	1,045	-
Deferred tax assets	8	161,233	-
<b>Total non-current assets</b>		<b>€651,724</b>	<b>€237,496</b>
<b>Current assets</b>			
Inventories	13	64,120	11,722
Trade receivables	12	165,468	11,913
Other financial assets	12	137,234	1,680
Other assets	14	60,966	9,069
Income tax assets		898	756
Deferred expenses	15	28,001	5,862
Cash and cash equivalents	12	1,210,209	519,149
<b>Total current assets</b>		<b>€1,666,896</b>	<b>€560,151</b>
<b>Total assets</b>		<b>€2,318,620</b>	<b>€797,647</b>
<b>Equity and liabilities</b>			
<b>Equity</b>			
Share capital	16	246,310	232,304
Capital reserve	16	1,514,451	686,714
Treasury shares	16	(4,789)	(5,525)
Accumulated losses		(409,629)	(424,827)
Other reserves	17	25,503	4,826
<b>Total equity</b>		<b>€1,371,846</b>	<b>€493,492</b>
<b>Non-current liabilities</b>			
Interest-bearing loans and borrowings	12	231,047	68,904
Other financial liabilities	12	31,476	-
Provisions	20	5,498	-
Contract liabilities	6	71,892	97,109
Other liabilities	18	566	-
Deferred tax liabilities		281	-
<b>Total non-current liabilities</b>		<b>€340,760</b>	<b>€166,013</b>
<b>Current liabilities</b>			
Interest-bearing loans and borrowings	12	9,142	5,307
Trade payables	12	102,288	20,498
Other financial liabilities	12	74,075	10,352
Government grants	7.5	91,951	-
Tax provisions		11	150
Other provisions		903	762
Contract liabilities	6	299,583	93,583
Other liabilities	18	28,061	7,490
<b>Total current liabilities</b>		<b>€606,014</b>	<b>€138,142</b>
<b>Total liabilities</b>		<b>€946,774</b>	<b>€304,155</b>
<b>Total equity and liabilities</b>		<b>€2,318,620</b>	<b>€797,647</b>

The accompanying notes form an integral part of these consolidated financial statements.

Consolidated Statements of Operations

	Note	Years ended December 31,		
		2020	2019	2018
<i>(in thousands, except per share data)</i>				
Revenues				
Research & development revenues	6	€178,849	€84,428	€101,837
Commercial revenues	6	303,476	24,161	25,738
<b>Total revenues</b>		<b>482,325</b>	<b>108,589</b>	<b>127,575</b>
Cost of sales	7.1	(59,333)	(17,361)	(13,690)
Research and development expenses	7.2	(645,029)	(226,466)	(143,040)
Sales and marketing expenses	7.3	(14,512)	(2,718)	(3,041)
General and administrative expenses	7.4	(94,049)	(45,547)	(26,334)
Other operating expenses		(2,358)	(739)	(720)
Other operating income	7.5	250,539	2,724	5,396
<b>Operating loss</b>		<b>€(82,417)</b>	<b>€(181,518)</b>	<b>€(53,854)</b>
Finance income*	7.6	1,564	4,122	8,046
Finance expenses*	7.7	(62,946)	(326)	(48)
Interest expenses related to lease liabilities	19	(2,003)	(1,718)	(1,721)
Share of loss of equity method investees		-	-	(84)
<b>Loss before tax</b>		<b>€(145,802)</b>	<b>€(179,440)</b>	<b>€(47,662)</b>
Income taxes	8	161,000	268	(600)
<b>Profit / (Loss) for the period</b>		<b>€15,198</b>	<b>€(179,172)</b>	<b>€(48,262)</b>
Attributable to:				
Equity holders of the parent		15,198	(179,056)	(48,019)
Non-controlling interests		-	(116)	(243)
<b>Profit / (Loss) for the period</b>		<b>€15,198</b>	<b>€(179,172)</b>	<b>€(48,262)</b>
<b>Earnings per share</b>				
Basic and diluted, profit / (loss) for the period attributable to ordinary equity holders of the parent**		€0.06	€(0.85)	€(0.25)

\* Foreign exchange differences on a cumulative basis are shown either as finance income or expenses and might switch between those two positions during the year-to-date reporting periods.

\*\* Numbers of shares for calculating the earnings per share for the years ended December 31, 2019 and December 31, 2018 have been adjusted to reflect capital increase due to 1:18 share split, which occurred on September 18, 2019.

The accompanying notes form an integral part of these consolidated financial statements.

**Consolidated Statements of Comprehensive Income / (Loss)**

<i>(in thousands)</i>	Note	Years ended December 31,		2018
		2020	2019	
<b>Profit / (Loss) for the period</b>		<b>€15,198</b>	<b>€(179,172)</b>	<b>€(48,262)</b>
<b>Other comprehensive income / (loss)</b>				
<i>Other comprehensive income / (loss) that may be reclassified to profit or loss in subsequent periods, net of tax</i>				
Exchange differences on translation of foreign operations		(11,096)	77	10
<b>Net other comprehensive income / (loss) that may be reclassified to profit or loss in subsequent periods</b>		<b>(11,096)</b>	<b>77</b>	<b>10</b>
<i>Other comprehensive loss that will not be reclassified to profit or loss in subsequent periods, net of tax</i>				
Remeasurement loss on defined benefit plans		(273)	-	-
<b>Net other comprehensive loss that will not be reclassified to profit or loss in subsequent periods</b>		<b>(273)</b>	<b>-</b>	<b>-</b>
<b>Other comprehensive income / (loss) for the period, net of tax</b>		<b>(11,369)</b>	<b>77</b>	<b>10</b>
<b>Comprehensive income / (loss) for the period, net of tax</b>		<b>€3,829</b>	<b>€(179,095)</b>	<b>€(48,252)</b>
Attributable to:				
Equity holders of the parent		3,829	(178,979)	(48,009)
Non-controlling interests		-	(116)	(243)
<b>Comprehensive income / (loss) for the period, net of tax</b>		<b>€3,829</b>	<b>€(179,095)</b>	<b>€(48,252)</b>

The accompanying notes form an integral part of these consolidated financial statements.

**Consolidated Statements of Changes in Stockholders' Equity**

(in thousands)	Note	Equity attributable to equity holders of the parent					Foreign currency translation reserve	Total	Non-controlling interest	Total equity
		Share capital	Capital reserve	Treasury shares	Accumulated losses	Other reserves				
<b>As of January 1, 2018</b>		<b>€166,764</b>	<b>€8,922</b>	-	<b>€(197,753)</b>	<b>€(27,206)</b>	<b>€(23)</b>	<b>€(49,296)</b>	<b>€1,090</b>	<b>€(48,206)</b>
Loss for the period		-	-	-	(48,019)	-	-	(48,019)	(243)	(48,262)
Other comprehensive income		-	-	-	-	-	10	10	-	10
<b>Total comprehensive income</b>		-	-	-	<b>(48,019)</b>	-	<b>10</b>	<b>(48,009)</b>	<b>(243)</b>	<b>(48,252)</b>
Issuance of share capital	16	25,949	329,867	-	-	-	-	355,816	-	355,816
Share based payments	17	-	-	-	-	7,641	-	7,641	-	7,641
Settlement of share-based payment plan		583	5,326	-	-	(5,909)	-	-	-	-
<b>As of December 31, 2018</b>		<b>€193,296</b>	<b>€344,115</b>	-	<b>€(245,771)</b>	<b>€(25,474)</b>	<b>€(13)</b>	<b>€266,153</b>	<b>€847</b>	<b>€267,000</b>
Loss for the period		-	-	-	(179,056)	-	-	(179,056)	(116)	(179,172)
Other comprehensive income		-	-	-	-	-	77	77	-	77
<b>Total comprehensive income</b>		-	-	-	<b>(179,056)</b>	-	<b>77</b>	<b>(178,979)</b>	<b>(116)</b>	<b>(179,095)</b>
Issuance of share capital	16	8,126	41,748	-	-	-	-	49,874	-	49,874
Capital increase Series B	16	17,990	186,390	(5,525)	-	-	-	198,855	-	198,855
Capital increase initial public offering (referred to as IPO)	16	10,517	132,743	-	-	-	-	143,260	-	143,260
Acquisition of non-controlling interest	16	2,375	(1,644)	-	-	-	-	731	(731)	-
Transaction costs	16	-	(16,638)	-	-	-	-	(16,638)	-	(16,638)
Share based payments	17	-	-	-	-	30,236	-	30,236	-	30,236
<b>As of December 31, 2019</b>		<b>€232,304</b>	<b>€686,714</b>	<b>€(5,525)</b>	<b>€(424,827)</b>	<b>€4,762</b>	<b>€64</b>	<b>€493,492</b>	-	<b>€493,492</b>
Profit for the period		-	-	-	15,198	-	-	15,198	-	15,198
Other comprehensive loss		-	-	-	-	(273)	(11,096)	(11,369)	-	(11,369)
<b>Total comprehensive income</b>		-	-	-	<b>15,198</b>	<b>(273)</b>	<b>(11,096)</b>	<b>3,829</b>	-	<b>3,829</b>
Issuance of share capital	16	14,006	860,960	736	-	-	-	875,702	-	875,702
Transaction costs	16	-	(33,223)	-	-	-	-	(33,223)	-	(33,223)
Share-based payments	17	-	-	-	-	32,046	-	32,046	-	32,046
<b>As of December 31, 2020</b>		<b>€246,310</b>	<b>€1,514,451</b>	<b>€(4,789)</b>	<b>€(409,629)</b>	<b>€36,535</b>	<b>€(11,032)</b>	<b>€1,371,846</b>	-	<b>€1,371,846</b>

\* Numbers as of January 1, 2019 have been adjusted to reflect capital increase due to 1:18 share split which occurred on September 18, 2019.

The accompanying notes form an integral part of these consolidated financial statements.

Consolidated Statements of Cash Flows

<i>(in thousands)</i>	Years ended December 31,		
	2020	2019	2018
<b>Operating activities</b>			
Profit / (Loss) for the period	€15,198	€(179,172)	€(48,262)
Income taxes	(161,000)	(268)	600
Loss before tax	<b>€(145,802)</b>	<b>€(179,440)</b>	<b>€(47,662)</b>
Adjustments to reconcile loss before tax to net cash flows:			
Depreciation and amortization of property, plant, equipment and intangible assets	38,744	33,896	21,984
Share-based payment expense	32,142	30,236	7,641
Net foreign exchange differences	41,275	70	459
(Gain) / Loss on disposal of property, plant and equipment	595	542	(14)
Finance income	(1,564)	(1,782)	(1,996)
Interest on lease liability	2,003	1,717	1,721
Finance expense	20,336	326	48
Movements in government grants	91,951	-	-
Share of loss of an associate and a joint venture	-	-	84
Other non-cash income	1,749	-	-
Working capital adjustments:			
Decrease / (Increase) in trade receivable and contract assets	(247,886)	2,939	(18,732)
Decrease / (Increase) in inventories	(49,794)	(5,798)	(1,253)
(Decrease) / Increase in trade payables, other liabilities, contract liabilities and provisions	204,583	(80,577)	(21,080)
Interest received	1,444	1,256	1,996
Interest paid	(3,628)	(2,044)	(1,769)
Income tax received (paid), net	378	122	(304)
<b>Net cash flows used in operating activities</b>	<b>€(13,474)</b>	<b>€(198,537)</b>	<b>€(58,877)</b>
<b>Investing activities</b>			
Purchase of property, plant and equipment	(66,033)	(38,592)	(29,901)
Proceeds from sale of property, plant and equipment	1,241	21	705
Purchase of intangibles assets and right-of-use assets	(19,413)	(32,488)	(37,256)
Acquisition of subsidiaries and businesses, net of cash acquired	(60,643)	(6,056)	-
<b>Net cash flows used in investing activities</b>	<b>€(144,848)</b>	<b>€(77,115)</b>	<b>€(66,452)</b>
<b>Financing activities</b>			
Proceeds from issuance of share capital, net of costs	753,007	375,351	361,725
Proceeds from loans and borrowings	156,027	11,000	5,600
Repayment of loans and borrowings	(1,566)	-	-
Payments related to lease liabilities	(12,743)	(3,061)	(2,148)
<b>Net cash flows from financing activities</b>	<b>€894,725</b>	<b>€383,290</b>	<b>€365,177</b>
Net increase in cash and cash equivalents	736,403	107,638	239,848
Change in cash and cash equivalents resulting from exchange rate differences	(45,343)	16	(459)
Cash and cash equivalents at January 1	519,149	411,495	172,106
<b>Cash and cash equivalents at December 31</b>	<b>€1,210,209</b>	<b>€519,149</b>	<b>€411,495</b>

The accompanying notes form an integral part of these consolidated financial statements.

## Notes to the Consolidated Financial Statements

### 1 Corporate Information

BioNTech SE is a limited company incorporated and domiciled in Germany. American Depositary Shares (ADS) representing BioNTech SE's ordinary shares have been publicly traded on Nasdaq Global Select Market since October 10, 2019. The registered office is located in Mainz, Germany (An der Goldgrube 12, 55131 Mainz). The accompanying International Financial Reporting Standards (IFRS) consolidated financial statements present the financial position and the results of operation of BioNTech SE and its subsidiaries, hereinafter also referred to as "BioNTech" or the "Group".

During the year ended December 31, 2020 the following changes to the Group structure occurred:

- On February 16, 2020, BioNTech Protein Therapeutics GmbH was renamed to BioNTech Delivery Technologies GmbH and the company's registered office was changed from Mainz to Halle.
- On May 6, 2020, BioNTech SE acquired Neon Therapeutics, Inc., Cambridge, Massachusetts, United States (formerly Nasdaq: NTGN), or Neon. Under the merger agreement by and among BioNTech, Neon and BioNTech's wholly-owned subsidiary, Endor Lights, Inc., New York, United States, Endor Lights, Inc. merged with and into Neon. The new subsidiary operates under the name BioNTech US Inc., is held indirectly via BioNTech USA Holding, LLC. as a wholly-owned subsidiary and serves as BioNTech's headquarters in the United States.
- On July 17, 2020, BioNTech IVAC GmbH was renamed to BioNTech Manufacturing GmbH and on August 7, 2020, BioNTech Small Molecules GmbH was renamed to BioNTech Europe GmbH.
- On September 17, 2020, the liquidation process for BioNTech Austria Beteiligungen GmbH was initiated by a resolution of the shareholders.
- On October 15, 2020, BioNTech Pharmaceuticals Asia Pacific Pte. Ltd. was founded and is a wholly-owned subsidiary of BioNTech SE.
- Three new real estate entities have been founded in Germany: BioNTech Real Estate An der Goldgrube GmbH & Co. KG, BioNTech Real Estate Adam-Opel-Straße GmbH & Co. KG and BioNTech Real Estate Haus Vier GmbH & Co. KG, all Holzkirchen. All are partnerships wholly-owned by its limited partner BioNTech Real Estate Holding GmbH, a wholly-owned subsidiary of BioNTech SE.
- On October 31, 2020, BioNTech SE acquired Novartis Manufacturing GmbH, Marburg, Germany. The new production site operates under the name BioNTech Manufacturing Marburg GmbH, a wholly-owned subsidiary of BioNTech SE.
- On November 11, 2020, BioNTech UK Limited was founded and is a wholly-owned subsidiary of BioNTech SE.
- On December 15, 2020, reBOOST Management GmbH was renamed to reSano GmbH.

All entities listed above are included in the Group's consolidated financial statements.

Information on the Group's structure is provided in Note 4.

The consolidated financial statements of the Group for the year ended December 31, 2020 were authorized for issue in accordance with a resolution of the Supervisory Board on March 30, 2021.

### 2 Significant Accounting Policies

#### 2.1 Basis of Preparation

##### General

The consolidated financial statements have been prepared on a going concern basis in accordance with the IFRS as issued by the International Accounting Standards Board (IASB).

BioNTech prepares and publishes its consolidated financial statements in Euros and rounds numbers to thousands or millions of Euros, respectively. Accordingly, numerical figures shown as totals in some tables may not be exact arithmetic aggregations of the figures that preceded them and figures presented in the explanatory notes may not add up to the rounded arithmetic aggregations.

### Segment Information

Historically BioNTech reported four segments: Clinical, Technology Platform, Manufacturing and Product Sales & External Services. In the course of the year ended December 31, 2020, BioNTech leveraged the breadth of its immunotherapy technologies and used its expertise to mobilize these rapidly to address the COVID-19 pandemic. In December 2020, BioNTech's COVID-19 vaccine was authorized or approved for emergency or temporary use or granted conditional marketing authorization in over 65 countries worldwide. Beginning in the fourth quarter, given the financial and operational significance of the activities to develop and then market, produce and transport the COVID-19 vaccine, BioNTech's Management Board, as the chief operating decision maker (CODM), reviewed financial information presented on a consolidated basis. Decisions with respect to business operations and resource allocations are made by the CODM based on BioNTech as a whole. Accordingly, BioNTech operates and makes decisions as a single operating segment, which is also its reporting segment.

## 2.2 Basis of Consolidation

The consolidated financial statements comprise the financial statements of BioNTech SE and its controlled investees (subsidiaries).

The Group controls an investee if, and only if, the Group has

- power over the investee (*i.e.*, existing rights that give it the current ability to direct the relevant activities of the investee);
- exposure, or rights, to variable returns from its involvement with the investee; and
- the ability to use its power over the investee to affect its returns.

Generally, there is a presumption that a majority of voting rights results in control.

The Group re-assesses whether it controls an investee if facts and circumstances indicate that there are changes to one or more of the three elements of control. Consolidation of a subsidiary begins when the Group obtains control over the subsidiary and ceases when the Group loses control of the subsidiary.

The profit / (loss) and each component of other comprehensive income / (loss) for the period are attributed to the equity holders of the parent of the Group and to the non-controlling interests, even if this results in the non-controlling interests having a deficit balance. When necessary, adjustments are made to the consolidated financial statements of subsidiaries to bring their accounting policies in line with the Group's accounting policies. All intra-group assets and liabilities, equity, income, expenses and cash flows relating to transactions between members of the Group are eliminated on consolidation.

A change in the ownership interest of a subsidiary, without a loss of control, is accounted for as an equity transaction.

If the Group loses control over a subsidiary, it derecognizes the related assets (including goodwill), liabilities, non-controlling interests and other components of equity, while any resultant gain or loss is recognized in the consolidated statements of operations. Any investment retained is recognized at fair value.

## 2.3 Summary of Significant Accounting Policies

### 2.3.1 Business combinations and Goodwill

Business combinations are accounted for using the acquisition method. The cost of an acquisition is measured as the aggregate of the consideration transferred, which is measured at acquisition date fair value, and the amount of any non-controlling interests in the acquiree.

Goodwill is initially measured at cost as the excess of the aggregate of the consideration transferred and the amount recognized for non-controlling interests and any previous interest held over the net identifiable assets acquired and liabilities assumed.

After initial recognition, goodwill is tested at least annually or when there is an indication for impairment. See Note 2.3.13. For the purpose of impairment testing, goodwill acquired in a business combination is, from the acquisition date, allocated to each of the Group's cash-generating units that are expected to benefit from the combination, irrespective of whether other assets or liabilities of the acquiree are assigned to those units.

Where goodwill has been allocated to a cash-generating unit (CGU) and part of the operation within that unit is disposed of, the goodwill associated with the disposed operation is included in the carrying amount of the operation when determining the gain or loss on disposal. Goodwill disposed in these circumstances is measured based on the relative values of the disposed operation and the portion of the cash-generating unit retained.

### 2.3.2 Current versus Non-Current Classifications

The Group presents assets and liabilities in the consolidated statements of financial position based on current or non-current classification. An asset is current when it is either: (i) expected to be realized within 12 months after the reporting period or (ii) cash or cash equivalents, unless it is restricted from being exchanged or used to settle a liability for at least 12 months after the reporting period. All other assets are classified as non-current. A liability is current when it is due to be settled within 12 months after the reporting period. The Group classifies all other liabilities as non-current.

Deferred tax assets and liabilities are classified as non-current assets and liabilities, respectively.

### 2.3.3 Fair Value Measurement

Fair value is a market-based measurement. For some assets and liabilities, observable market transactions or market information is available. For other assets and liabilities, observable market transactions or market information might not be available. When a price for an identical asset or liability is not observable, another valuation technique is used. To increase consistency and comparability in fair value measurements, there are three levels of the fair value hierarchy:

- Level 1 contains the use of quoted prices in active markets for identical assets or liabilities.
- Level 2 inputs are inputs other than quoted prices included within Level 1 that are observable for the asset or liability either directly or indirectly.
- Level 3 inputs are unobservable.

Within this hierarchy, estimated values are made by management based on reasonable assumptions, including other fair value methods.

For assets and liabilities that are recognized in the financial statements at fair value on a recurring basis, the Group determines whether transfers have occurred between levels in the fair value hierarchy by re-assessing categorization (based on the lowest level input that is significant to the fair value measurement as a whole) at the end of each reporting period.

For the purpose of fair value disclosures, the Group has determined classes of assets and liabilities on the basis of the nature, characteristics and risks of the asset or liability and the level of the fair value hierarchy, as explained above.

### 2.3.4 Revenue from Contracts with Customers

#### Revenue Recognition

BioNTech generates revenues from collaboration and license agreements under which BioNTech grants licenses to use, research, develop, manufacture and commercialize product candidates and products. BioNTech determined that those collaboration and license agreements qualify as contracts with its customers. If the grant of a license is bundled together with the rendering of services, it is assessed whether these agreements are comprised of more than one performance obligation. A performance obligation is only accounted for as the grant of a license if the grant of a license is the sole or the predominant promise of the performance obligation.

If the consideration in an agreement includes a variable amount, BioNTech estimates the amount of consideration to which BioNTech will be entitled in exchange for transferring the goods to the customer. At contract inception, the variable



consideration is estimated based on the most likely amount of consideration expected from the transaction and constrained until it is highly probable that a significant revenue reversal in the amount of cumulative revenue recognized will not occur when the associated uncertainty with respect to the variable consideration is subsequently resolved. The estimated revenue is updated at each reporting date to reflect the current facts and circumstances.

If a contract with a customer contains more than one performance obligation, the transaction price is allocated to each performance obligation based on relative-stand-alone selling prices.

For each separate performance obligation, it is evaluated whether control is transferred either at a point in time or over time. For performance obligations that are satisfied over time, revenue is recognized based on a measure of progress, which depicts the performance in transferring control to the customer. Under the terms of its licensing arrangements, BioNTech provides the licensee with a research and development license, which represents a right to access BioNTech's intellectual property as it exists throughout the license period (as BioNTech's intellectual property is still subject to further research). Therefore, the promise to grant a license is accounted for as a performance obligation satisfied over time, as the licensee simultaneously receives and consumes the benefits of BioNTech's performance.

Earnings based on the collaboration partners' gross profit, which is shared under the respective collaboration agreements are recognized based on the sales-based or usage-based royalty exemption; *i.e.* when, or as, the underlying sales occur, which is when the performance obligation has been satisfied. As described further in Note 3, BioNTech uses certain information from its collaboration partners, some of which is based on preliminary data shared between the partners and might vary once final data is available.

Revenue arrangements that involve two or more partners who contribute to the provision of a specific good or service to a customer are assessed in terms of principal-agent considerations in order to determine the appropriate treatment for the transactions between BioNTech and the collaborator and the transactions between BioNTech and other third parties. The classification of transactions under such arrangements is determined based on the nature and contractual terms of the arrangement along with the nature of the operations of the participants. Any consideration related to activities in which BioNTech is considered the principal, which includes being in control of the good or service before such good or service is transferred to the customer, are accounted for as gross revenue. Any consideration related to activities in which BioNTech is considered the agent, are accounted for as net revenue.

Revenue from the sale of pharmaceutical and medical products (*e.g.* COVID-19 vaccine sales and other sales of peptides and retroviral vectors for clinical supply) is recognized when BioNTech transfers control of the product to the customer. Control of the product normally transfers when the customer gains physical possession and BioNTech has not retained any significant risks of ownership or future obligations with respect to the product. A receivable is recognized, as the consideration is unconditional and only the passage of time is required before payment is due. The transaction price is quoted in the relevant price lists in force at the date of customer placing the respective order for such products. Payments from customers are due within 20 days (Europe) or 30 days (non-Europe) after invoice.

#### **Contract Balances**

##### **Contract Assets**

A contract asset is the right to consideration in exchange for goods or services transferred to the customer. If BioNTech performs by transferring goods or services to a customer before the customer pays consideration or before payment is due, a contract asset is recognized for the earned consideration that is conditional.

##### **Trade Receivables**

A receivable represents BioNTech's right to an amount of consideration that is unconditional (*i.e.*, only the passage of time is required before payment of the consideration is due).

##### **Contract Liabilities**

A contract liability is the obligation to transfer goods or services to a customer for which BioNTech has received consideration (or an amount of consideration is due) from the customer. If a customer pays consideration before BioNTech transfers goods or services to the customer, a contract liability is recognized when the payment is made or when the payment is due (whichever is earlier). Contract liabilities are recognized as revenue when BioNTech performs under the contract.

### 2.3.5 Government Grants

Government grants are recognized where there is reasonable assurance that the grant will be received and all attached conditions will be complied with. When the grant relates to an expense item, it is recognized as other income on a systematic basis over the periods that the related costs, for which the grant is intended to compensate, are expensed. When the grant relates to an asset, it is recognized as deferred income within the consolidated statements of financial position. Other income is subsequently recognized in profit or loss over the useful life of the underlying asset subject to funding.

### 2.3.6 Taxes

#### Current Income Tax

Current income tax assets and liabilities are measured at the amount expected to be recovered from or paid to the taxation authorities. The tax rates and tax laws used to compute the amount are those that are enacted or substantively enacted at the reporting date in the countries where the Group operates and generates taxable income.

In addition, current income taxes presented for the period include adjustments for uncertain tax payments or tax refunds for periods not yet finally assessed, excluding interest expenses and penalties on the underpayment of taxes. Due to the increasing complexity of tax laws and the corresponding uncertainty regarding the legal interpretation by the fiscal authorities, tax calculations are generally subject to an elevated amount of uncertainty. In the event that amounts included in the tax return are considered unlikely to be accepted by the tax authorities (uncertain tax positions), a provision for income taxes is recognized.

Management periodically evaluates positions taken in the tax returns with respect to situations in which applicable tax regulations are subject to interpretation and establishes provisions where appropriate.

#### Deferred Tax

Deferred tax is provided using the liability method on temporary differences between the tax bases of assets and liabilities and their carrying amounts for financial reporting purposes at the reporting date.

Deferred tax liabilities are recognized for all taxable temporary differences, except:

- when the deferred tax liability arises from the initial recognition of goodwill or an asset or liability in a transaction that is not a business combination and, at the time of the transaction, affects neither the accounting profit nor taxable profit or loss; or
- in respect of taxable temporary differences associated with investments in subsidiaries, associates and interests in joint arrangements, when the timing of the reversal of the temporary differences can be controlled and it is probable that the temporary differences will not reverse in the foreseeable future.

Deferred tax assets are recognized for all deductible temporary differences, the carry forward of unused tax credits and any unused tax losses. Deferred tax assets are recognized to the extent that it is probable that taxable profit will be available against which the deductible temporary differences, the carry forward of unused tax credits and unused tax losses can be utilized, except:

- when the deferred tax asset relating to the deductible temporary difference arises from the initial recognition of an asset or liability in a transaction that is not a business combination and, at the time of the transaction, affects neither the accounting profit nor taxable profit or loss; or
- in respect of deductible temporary differences associated with investments in subsidiaries, associates and interests in joint arrangements, deferred tax assets are recognized only to the extent that it is probable that the temporary differences will reverse in the foreseeable future and taxable profit will be available against which the temporary differences can be utilized.

Deferred tax assets and liabilities are measured at the tax rates that are expected to apply in the year in which the asset is realized, or the liability is settled, based on tax rates (and tax laws) that have been enacted or substantively enacted at the reporting date.

Unrecognized deferred tax assets are re-assessed at each reporting date and are recognized to the extent that it has become probable that future taxable profits will allow the deferred tax asset to be recovered.

**Recognition of Taxes**

Current and deferred tax items are recognized similar to the underlying transaction either in profit or loss, other comprehensive income or directly in equity.

The Group offsets current tax assets and current tax liabilities if, and only if, it has a legally enforceable right to set off the recognized amounts and intends either to settle on a net basis, or to realize the asset and settle the liability simultaneously. Deferred tax assets and deferred tax liabilities are only offset when the Group has a legally enforceable right to set off current tax assets and current tax liabilities and the deferred tax assets and deferred tax liabilities relate to income taxes levied by the same taxation authority on either (i) the same taxable entity or (ii) different taxable entities, which intend either to settle current tax liabilities and assets on a net basis, or to realize the assets and settle the liabilities simultaneously, in each future period in which significant amounts of deferred tax liabilities or assets are expected to be settled or recovered.

**Sales Tax**

Expenses and assets are recognized net of sales tax, except when the sales tax incurred on a purchase of assets or services is not recoverable from the taxation authority.

The net amount of sales tax recoverable from, or payable to, the taxation authority is included as part of receivables or payables in the consolidated statements of financial position.

**2.3.7 Foreign Currencies**

The Group's consolidated financial statements are presented in Euros, which is also BioNTech SE's functional currency. For each entity, the Group determines the functional currency, and items included in the consolidated financial statements of such entity are measured using that functional currency. The Group uses the direct method of consolidation and on disposal of a foreign operation, the gain or loss that is reclassified to the consolidated statements of operations reflects the amount that arises from using this method.

**Transactions and Balances**

Transactions in foreign currencies are initially recorded by the Group's entities at their respective functional currency spot rates at the date the transaction first qualifies for recognition.

Monetary assets and liabilities denominated in foreign currencies are translated at the functional currency spot rates of exchange at the reporting date.

Non-monetary items that are measured in terms of historical cost in a foreign currency are translated using the exchange rates at the dates of the initial transactions.

In determining the spot exchange rate to use on initial recognition of the related asset, expense or income (or part of it) on the derecognition of a non-monetary asset or non-monetary liability relating to advance consideration, the date of the transaction is the date on which the Group initially recognizes the non-monetary asset or non-monetary liability arising from the advance consideration. If there are multiple payments or receipts in advance, the Group determines the transaction date for each payment or receipt of advance consideration.

**Foreign Currency Translation**

On consolidation, the assets and liabilities of foreign operations are translated into Euros at the rate of exchange prevailing at the reporting date and their consolidated statements of operations are translated at exchange rates prevailing at the dates of the transactions.

The exchange differences arising on translation for consolidation are recognized in other comprehensive income. On disposal of a foreign operation, the component of other comprehensive income relating to that particular foreign operation is reclassified to profit or loss.

Any goodwill arising on the acquisition of a foreign operation and any fair value adjustments to the carrying amounts of assets and liabilities arising upon the acquisition are treated as assets and liabilities of the foreign operation and translated at the spot rate of exchange at the reporting date.

### 2.3.8 Property, Plant and Equipment

Construction in progress is stated at cost, net of accumulated impairment losses, if any. Property, plant and equipment are stated at cost, net of accumulated depreciation and accumulated impairment losses, if any. Such cost includes the cost of replacing part of the property, plant and equipment if the recognition criteria are met. All other repair and maintenance costs are expensed as incurred.

Depreciation is calculated on a straight-line basis over the estimated useful lives of the assets, as follows:

Property, plant and equipment	Useful life (Years)
Buildings	7-33
Equipment, tools and installations	3-15

An item of property, plant and equipment initially recognized is derecognized upon disposal (*i.e.*, at the date the recipient obtains control) or when no future economic benefits are expected from its use or disposal. Any gain or loss arising on derecognition of the asset (calculated as the difference between the net disposal proceeds and the carrying amount of the asset) is included in the consolidated statements of operations when the asset is derecognized.

The residual values, useful lives and methods of depreciation of property, plant and equipment are reviewed at each financial year-end and adjusted prospectively, if appropriate.

### 2.3.9 Leases

At the inception of a contract, the Group assesses whether the contract is, or contains, a lease. A contract is, or contains, a lease if the contract conveys the right to control the use of an identified asset for a period of time in exchange for consideration. To assess whether a contract conveys the right to control the use of an identified asset, the Group assesses whether:

- the contract involves the use of an identified asset—this may be specified explicitly or implicitly and should be physically distinct or represent substantially all of the capacity of a physically distinct asset. If the supplier has a substantive substitution right, then the asset is not identified;
- the Group has the right to obtain substantially all of the economic benefits from use of the asset throughout the period of use; and
- the Group has the right to direct the use of the asset. The Group has this right when it has the decision-making rights that are most relevant to changing how and for what purpose the asset is used. In rare cases where the decision about how and for what purpose the asset is used is predetermined, the Group has the right to direct the use of the asset if either:
  - the Group has the right to operate the asset; or
  - the Group designed the asset in a way that predetermines how and for what purpose it will be used.

At inception or on reassessment of a contract that contains a lease component, the Group allocates the consideration in the contract to each lease component on the basis of their relative stand-alone prices. However, for the leases of land and buildings in which it is a lessee, the Group has elected not to separate non-lease components, and instead accounts for the lease and non-lease components as a single lease component.

The Group recognizes a right-of-use asset and a lease liability at the lease commencement date. The right-of-use asset is initially measured at cost, which comprises the initial amount of the lease liability adjusted for any lease payments made at or before the commencement date, plus any initial direct costs incurred and an estimate of the costs to dismantle and remove the underlying asset or to restore the underlying asset or the site on which it is located, less any lease incentives received by the Group.

The right-of-use asset is subsequently depreciated using the straight-line method from the commencement date to the earlier of the end of the useful life of the right-of-use asset and the end of the lease term. The estimated useful lives of right-of-use assets are determined on the same basis as those of property and equipment. In addition, the right-of-use asset is periodically reduced by impairment losses, if any, and adjusted for certain remeasurements of the lease liability.

The lease liability is initially measured at the present value of the lease payments that are not paid at the commencement date, discounted using the incremental borrowing interest rate implicit in the lease or, if that rate cannot be readily determined, the Group's incremental borrowing rate. Generally, the Group uses its incremental borrowing rate as the discount rate.

Lease payments included in the measurement of the lease liability comprise the following:

- fixed payments, including in-substance fixed payments;
- variable lease payments that depend on an index or a rate, initially measured using the index or rate as of the commencement date;
- amounts expected to be payable under a residual value guarantee; and
- the exercise price under a purchase option that the Group is reasonably certain to exercise, lease payments in an optional renewal period if the Group is reasonably certain to exercise an extension option, and penalties for early termination of a lease unless the Group is reasonably certain not to terminate early.

The lease liability is subsequently measured at amortized cost using the effective interest method. It is remeasured when there is a change in future lease payments arising from a change in an index or rate, if there is a change in the Group's estimate of the amount expected to be payable under a residual value guarantee, or if the Group changes its assessment of whether it will exercise a purchase, extension or termination option. When the lease liability is remeasured, a corresponding adjustment is made to the carrying amount of the right-of-use asset or is recorded in the consolidated statements of operations if the carrying amount of the right-of-use asset has been reduced to zero.

The Group presents right-of-use assets separately and lease liabilities in 'financial liabilities' in the consolidated statements of financial position.

Depreciation is calculated on a straight-line basis over the estimated useful lives of the assets or shorter lease term, as follows:

Right-of-use assets	Useful life (Years)
Buildings	2-25
Equipment, tools and installations	2-5
Production facilities	2-3
Automobiles	3-4

#### Short-Term Leases and Leases of Low-Value Assets

The Group has elected not to recognize right-of-use assets and lease liabilities for short-term leases of machinery that have a lease term of 12 months or less or leases of low-value assets. The Group recognizes the lease payments associated with these leases as an expense in the consolidated statements of operations on a straight-line basis over the lease term.

#### 2.3.10 Intangible Assets

Intangible assets acquired separately are measured on initial recognition at cost. The cost of intangible assets acquired in a business combination is their fair value at the date of acquisition. Following initial recognition, intangible assets are carried at cost less any accumulated amortization and accumulated impairment losses.

The useful lives of intangible assets are assessed as either finite or indefinite.

Intangible assets with finite lives are amortized generally on a straight-line basis over the useful economic life and assessed for impairment whenever there is an indication that the intangible asset may be impaired. The amortization period and the amortization method for an intangible asset with a finite useful life are at least reviewed at the end of each reporting period. The amortization expense on intangible assets with finite lives is recognized in the consolidated statements of operations in the expense category that is consistent with the function of the intangible assets.

A summary of the useful lives applied to the Group's intangible assets is as follows:

<b>Intangible assets</b>	<b>Useful life (Years)</b>
Intellectual property rights	10-20
Licenses	3-20
Software	3-8

Intangible assets with indefinite useful lives are not amortized, but are tested for impairment at least annually, or when there is an indication for impairment, either individually or at the level of a cash-generating unit (see Note 2.3.13 for further details). The assessment of indefinite life is reviewed annually to determine whether the indefinite life continues to be supportable. If not, the change in useful life from indefinite to finite is made on a prospective basis.

The Group has classified advanced payments on intangible assets as intangible assets, which are not yet ready for use. Advanced payments on intangible assets are tested for impairment on an annual basis.

An intangible asset is derecognized upon disposal (*i.e.*, at the date the recipient obtains control) or when no future economic benefits are expected from its use or disposal. Any gain or loss arising upon derecognition of the asset (calculated as the difference between the net disposal proceeds and the carrying amount of the asset) is included in the consolidated statements of operations.

#### **Research and Development Costs**

Research costs are expensed as incurred. Development expenditures on an individual project are recognized as an intangible asset if, and only if, all of the following six criteria can be demonstrated by the Group:

- the technical feasibility of completing the intangible asset so that the asset will be available for use or sale;
- its intention to complete the project;
- the ability and intention to use or sell the asset;
- how the asset will generate future economic benefits;
- the availability of resources to complete the asset; and
- the ability to reliably measure the expenditure during development.

Due to the inherent risk of failure in pharmaceutical development and the uncertainty of approval, management has determined that these criteria are not met in the biotech sector until regulatory approval has been obtained. The related expenditure is reflected in the consolidated statements of operations in the period in which the expenditure is incurred.

Following initial recognition of the development expenditure as an asset, the asset is carried at cost less any accumulated amortization and accumulated impairment losses. Amortization of the asset begins when development is complete and the asset is available for use. It is amortized over the period of expected future benefit. Amortization is recorded in cost of sales. During the period of development, the asset is tested for impairment annually.

#### **2.3.11 Financial Instruments – Initial Recognition and Subsequent Measurement**

A financial instrument is any contract that gives rise to a financial asset of one entity and a financial liability or equity instrument of another entity.

##### **i) Financial Assets**

###### **Initial recognition and Measurement**

Financial assets are initially measured at fair value. The Group's financial assets mainly include trade receivables as well as other receivables that reflect BioNTech's entitlement to cash. With respect to trade receivable, the Group has applied the practical expedient which means that they are measured at the transaction price determined under IFRS 15. Refer to the accounting policies in Note 2.3.4. Other financial assets are measured at amortized costs since they are held by the Group to collect contractual cash flows, which are solely payments of principal and interest. Gains and losses are recognized in profit or loss when the financial asset is derecognized, modified or impaired.

**Derecognition**

A financial asset (or, where applicable, a part of a financial asset or part of a group of similar financial assets) is primarily derecognized (i.e., removed from the Group's consolidated statements of financial position) when the rights to receive cash flows from the asset have expired or have been transferred in terms of fulfilling the derecognition criteria.

**Impairment of Financial Assets**

An allowance for expected credit losses (ECLs) is considered for all debt instruments of the Group. ECLs are based on the difference between the contractual cash flows due in accordance with the contract and all of the cash flows that the Group expects to receive, discounted at an approximation of the original effective interest rate. The expected cash flows will include cash flows from the sale of collateral held or other credit enhancements that are integral to the contractual terms.

For trade receivables and contract assets, the Group applies a simplified approach in calculating ECLs. Therefore, the Group does not track changes in credit risk, but instead recognizes a loss allowance based on lifetime ECLs at each reporting date. The Group has established a provision matrix that is based on its historical credit loss experience, adjusted for forward-looking factors specific to the debtors and the economic environment. In this analysis BioNTech also considered that governments and health ministries which are BioNTech's customers established in connection with progressing the commercial activities of the Group with respect to BioNTech's COVID-19 vaccine.

**ii) Financial Liabilities****Initial Recognition and Measurement**

Financial liabilities are classified, at initial recognition, as financial liabilities at fair value through profit or loss, loans and borrowings or as payables.

All financial liabilities are recognized initially at fair value and, in the case of loans and borrowings and payables, net of directly attributable transaction costs.

The Group's financial liabilities include trade payables and other financial liabilities.

**Subsequent Measurement**

The measurement of financial liabilities depends on their classification, as described below.

***Financial Liabilities at Fair Value through Profit or Loss***

Financial liabilities at fair value through profit of the Group include the embedded derivative, which was bifurcated from the convertible note, as host contract, and is recognized as a separate financial instrument until it is extinguished upon conversion. Financial liabilities at fair value further include contingent considerations resulting from the Group's business combinations.

Gains or losses arising from fair value measurement adjustments of the embedded derivative and the contingent consideration are recognized in profit and loss within the consolidated statements of operations.

***Loans, Borrowings, Trade Payables and Other Financial Liabilities***

After initial recognition, interest-bearing loans and borrowings, trade payables and other financial liabilities are subsequently measured at amortized cost using the EIR method. Gains and losses are recognized in the consolidated statements of operations when the liabilities are derecognized as well as through the EIR amortization process.

Amortized cost is calculated by taking into account any discount or premium on acquisition and fees or costs that are an integral part of the EIR. The EIR amortization is included as finance costs in the consolidated statements of operations.

This category generally applies to interest-bearing loans and borrowings.

### **Derecognition**

A financial liability is derecognized when the obligation under the liability is discharged or cancelled or expires. When an existing financial liability is replaced by another from the same lender on substantially different terms, or the terms of an existing liability are substantially modified, such an exchange or modification is treated as the derecognition of the original liability and the recognition of a new liability. The difference in the respective carrying amounts is recognized in the consolidated statements of operations.

### **2.3.12 Inventories**

Inventories are valued at the lower of cost and net realizable value.

Costs incurred in bringing each product to its present location and condition are accounted for as follows:

- raw materials and supplies: purchase cost on a first-in/first-out basis; or
- unfinished goods and finished goods: cost of direct materials and labor, including both internal manufacturing and third-party contract manufacturing organizations, or CMOs, and a proportion of manufacturing overheads based on the normal operating capacity, but excluding borrowing costs.

Net realizable value is the estimated selling price in the ordinary course of business, less estimated costs of completion and the estimated costs necessary to make the sale.

### **2.3.13 Impairment of Non-Financial Assets**

The Group assesses, at each reporting date, whether there is an indication that an asset may be impaired. Goodwill is tested for impairment annually as of October 1. Impairment is determined for goodwill by assessing the recoverable amount of each cash generating unit (or group of CGUs) to which the goodwill relates. If any indication exists, or when annual impairment testing is performed, the Group estimates the asset's or CGU's recoverable amount. The recoverable amount is the higher of an asset's or CGU's fair value less costs of disposal and its value in use. The recoverable amount is determined for an individual asset, unless the asset does not generate cash inflows that are largely independent of those from other assets or groups of assets. When the carrying amount of an asset or cash generating unit exceeds its recoverable amount, the asset is considered impaired and is written down to its recoverable amount.

In assessing value in use, the estimated future cash flows are discounted to their present value using a pre-tax discount rate that reflects current market assessments of the time value of money and the risks specific to the asset. In determining fair value less costs of disposal, recent market transactions are taken into account. If no such transactions can be identified, an appropriate valuation model is used. These calculations are corroborated by valuation multiples, quoted share prices for publicly traded companies or other available fair value indicators.

The Group bases its impairment calculation on detailed budgets and forecast calculations, which are prepared separately for each of the Group's cash generating units to which the individual assets are allocated. These budgets and forecast calculations generally cover a period of five years. A long-term growth rate is calculated and applied to project future cash flows after the fifth year.

Impairment losses of continuing operations are recognized in the consolidated statements of operations in expense categories consistent with the function of the impaired asset.

For assets excluding goodwill, an assessment is made at each reporting date to determine whether there is an indication that previously recognized impairment losses no longer exist or have decreased. If such indication exists, the Group estimates the asset's or cash generating unit's recoverable amount. A previously recognized impairment loss is reversed only if there has been a change in the assumptions used to determine the asset's recoverable amount since the last impairment loss was recognized. The reversal is limited so that the carrying amount of the asset does not exceed its recoverable amount, nor exceed the carrying amount that would have been determined, net of depreciation, had no impairment loss been recognized for the asset in prior years. Such reversal is recognized in the consolidated statements of operations unless the asset is carried at a revalued amount, in which case, the reversal is treated as a revaluation increase.

### **2.3.14 Cash and Cash Equivalents**

Cash and cash equivalents comprise cash in banks and on hand and short-term deposits with an original maturity of three months or less, which are subject to an insignificant risk of changes in value.



### 2.3.15 Pension

The liability in respect of defined benefit pension plans is the defined benefit obligation calculated annually by independent actuaries using the projected unit credit method. The current service cost for such post-employment benefit plans is included in the personnel expenses of the various functions of the respective employees, while the net interest on the net defined benefit liability or asset is recognized in finance expenses or finance income.

### 2.3.16 Provisions

Provisions are recognized when the Group has a present obligation (legal or constructive) as a result of a past event, it is probable that an outflow of resources embodying economic benefits will be required to settle the obligation and a reliable estimate can be made of the amount of the obligation. When the Group expects some or all of a provision to be reimbursed, for example, under an insurance contract, the reimbursement is recognized as a separate asset, but only when the reimbursement is virtually certain. The expense relating to a provision is presented in the consolidated statements of operations net of any reimbursement.

### 2.3.17 Share-Based Payments

Employees (and others providing similar services) receive remuneration in the form of share-based payments, which are settled in equity instruments (equity-settled transactions).

The cost of equity-settled transactions is determined by the fair value at the date when the grant is made using an appropriate valuation model, further details of which are given in Note 17.

These costs are recognized in cost of sales, research and development expenses, sales and marketing expenses or general and administrative expenses, together with a corresponding increase in equity (other reserves), over the period in which the service is provided (the vesting period). The cumulative expense recognized for equity-settled transactions at each reporting date until the vesting date reflects the extent to which the vesting period has expired and the Group's best estimate of the number of equity instruments that will ultimately vest.

## 2.4 Standards applied for the First Time

In 2020 several new and amended standards and interpretations became effective but did not have an impact on the consolidated financial statements of the Group.

Standards/Interpretations	Date of application
Amendments to IFRS 3 Business Combinations	January 1, 2020
Amendments to IFRS 9, IAS 39 and IFRS 7 Interest Rate Benchmark Reform	January 1, 2020
Amendments to IAS 1 and IAS 8 Definition of Material	January 1, 2020
Amendments to References to the Conceptual Framework in IFRS Standards	January 1, 2020
Amendment to IFRS 16 Leases COVID-19-Related Rent Concessions	June 1, 2020

## 2.5 Standard issued but not yet effective

The new and amended standards and interpretations that are issued, but not yet effective, up to the date of issuance of the Group's financial statements and that might have an impact on the Group's financial statements are disclosed below. The Group has not early adopted any standards and intends to adopt these new and amended standards and interpretations, if applicable, when they become effective.

Standards/Interpretations	Date of application
Amendments to IFRS 4 Insurance Contracts – deferral of IFRS 9	January 1, 2021
Amendments to IFRS 9, IAS 39, IFRS 7, IFRS 4 and IFRS 16 Interest Rate Benchmark Reform – Phase 2	January 1, 2021
Amendments to IFRS 3 Business Combinations: Reference to the Conceptual Framework	January 1, 2022
Amendments to IAS 16 Property, Plant and Equipment: Proceeds before Intended Use	January 1, 2022
Amendments to IAS 37 Provisions, Contingent Liabilities and Contingent Assets - Onerous Contracts – Cost of Fulfilling a Contract Amendments to IAS 37	January 1, 2022
Annual Improvements to IFRS Standards 2018-2020	January 1, 2022
Amendments to IAS 1 Presentation of Financial Statements: Classification of Liabilities as Current or Non-current - Deferral of Effective Date	January 1, 2023
IFRS 17 Insurance Contracts (issued on 18 May 2017); including Amendments to IFRS 17	January 1, 2023

The Group does not expect a significant impact of the application of any of these amendments.

### 3 Significant Accounting Judgments, Estimates and Assumptions

The preparation of the Group's consolidated financial statements requires management to make judgments, estimates and assumptions that affect the reported amounts of revenues, expenses, assets and liabilities, the accompanying disclosures, and the disclosure of contingent liabilities. Uncertainty about these assumptions and estimates could result in outcomes that require a material adjustment to the carrying amount of assets or liabilities affected in future periods.

#### Judgments

In the process of applying the Group's accounting policies, management has made the following judgments, which have the most significant effect on the amounts recognized in the consolidated financial statements:

#### Revenue from Contracts with Customers

BioNTech applied the following judgments that significantly affect the determination of the amount and timing of revenue from contracts with customers:

##### Identification and Determination of Performance Obligations

BioNTech generates revenues from collaboration and license agreements, which contain multiple elements, including licenses to use, research, develop, manufacture and commercialize candidates and products, research and development services as well as obligations to develop and manufacture preclinical and clinical material and products. BioNTech determined that those collaboration and license agreements qualify as contracts with its customers. At inception of each agreement, BioNTech applies judgment when determining which promises represent distinct performance obligations. If promises are not distinct, they are combined until the bundle of promised goods and services is distinct. For some agreements, this results in BioNTech accounting for goods and services promised in a collaboration and license agreement as a single performance obligation with a single measure of progress. For these combined performance obligations, BioNTech assesses which of these promises is the predominant promise to determine the nature of the performance obligation. When licenses are granted, BioNTech determined that the grant of the license is the predominant promise within the combined performance obligations. It is assessed that BioNTech grants their customers a right to access or a right to use BioNTech's intellectual property due to the collaboration and license agreements.

##### Measurement of the Transaction Price

BioNTech's collaboration and license agreements often include variable considerations, which are contingent on the occurrence or non-occurrence of a future event (*i.e.*, reaching a certain milestone). When determining deferred revenues of a collaboration and license agreement, BioNTech is required to estimate the amount of consideration to which it will be entitled in exchange for transferring the promised goods or services to the customer.

As there are usually only two possible outcomes (*i.e.*, milestone is reached or not), BioNTech has assessed that the method of the most likely amount is the best method to predict the amount of consideration to which BioNTech will be entitled. At contract inception, the most likely amount for milestone payments is estimated to be zero. BioNTech has assessed that the likelihood of achieving the respective milestone decreases depending on how far the expected date of achieving the milestone lies in the future. At each reporting date, BioNTech uses judgment to determine when to include variable consideration in the transaction price such that it is highly probable that a significant revenue reversal in the

amount of cumulative revenue recognized will not occur when the associated uncertainty with respect to the variable consideration is subsequently resolved. BioNTech has concluded that future milestone payments are fully constrained at the end of the current fiscal year.

Future milestone payments would become unconstrained at the satisfaction of the milestone event, specifically a development event, a regulatory approval or achievement of a sales milestone.

*Allocation of the Transaction Price to Performance Obligations and Revenue Recognition as Performance Obligations are satisfied*

BioNTech allocates the transaction price to performance obligations based on their relative standalone selling prices, which are generally based on best estimates and interpretations of facts and circumstances of each contractual agreement and may require significant judgment to determine appropriate allocation.

Upfront payments and reimbursement for expenses are initially deferred on BioNTech's consolidated statements of financial position. BioNTech assessed that no significant financing component exists within its collaboration agreements since the overall business purpose of advanced payments is to support the payment structure other than to provide a significant benefit of financing.

For performance obligations in which the costs vary based on progress, an input-based measure considering cost incurred depicts most reliably the progress of the related research activities. In other cases, revenue recognition on a straight-line basis may most reliably depict BioNTech's performance toward complete satisfaction. In case the contractual activities progress, the achievement of development milestones will be used to measure the progress toward complete satisfaction. BioNTech evaluates the measure of progress each reporting period and, if necessary, adjust the measure of performance and related revenue recognition. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenues and net loss in the period of adjustment.

Upon successfully commercializing a pharmaceutical product, the collaboration and license agreements also provide for additional profit-sharing or tiered royalties earned when customers recognize net sales of licensed products as well as sales milestone payments. Revenue is recognized based on the sales-based or usage-based royalty exemption when, or as, the underlying sales occur, which is when the performance obligation has been satisfied.

*Principal-Agent Considerations*

Collaboration agreements that involve two or more partners who contribute to the provision of a specific good or service to a customer are assessed in terms of principal-agent considerations. Under BioNTech's current collaboration agreements, the allocation of marketing and distribution rights defines territories in which the collaboration partner act as a principal respectively. BioNTech recognizes revenue net based on the collaboration partners' gross profit in territories where the partner is responsible for supply and on a gross basis when directly supplying customers in its territories when control has been transferred. Amounts paid to collaboration partners for their share of BioNTech's profits where BioNTech is the principal in the transaction are recorded as cost of sales.

*Pfizer Agreement Characteristics*

With respect to the collaboration with Pfizer, commercial revenue is recognized based on the collaboration partners' gross profit from COVID-19 vaccine sales, which is shared under the respective collaboration agreement. In determining commercial revenue pursuant to this collaboration agreement, BioNTech is reliant on the collaboration partner for detail regarding its gross profit for the period at hand. BioNTech has been informed by its collaboration partner that certain of the information it intends to provide BioNTech with regard to the gross profit will be, by necessity, preliminary and subject to change. This is mainly due to the fact that the partner's financial reporting cycle differs from BioNTech's. Pfizer's subsidiaries outside the United States have a fiscal year-end of November 30; that is, the details on sales in these territories are required in advance of closing the respective reporting periods. As a result, BioNTech's determination of its share of such gross profit for purposes of recognizing revenues will be subject to risks that amounts reported might vary from actual amounts reported once the collaboration partner's final financial results are available.

For the period covered in these consolidated financial statements, Pfizer has calculated gross profit for COVID-19 vaccine sales in the U.S. territory as well as shared preliminary gross profit for COVID-19 vaccine sales in territories outside the United States, both of which will be reconciled and finalized. The respective gross profit shares are calculated based on sales and include consideration of transfer prices. The latter includes manufacturing and shipping costs which

represent standard prices and include mark-ups on manufacturing costs as specified by the terms of the agreement. Manufacturing and shipping cost variances were considered as far as those have been identified. Nevertheless, those input parameters may be adjusted once actual costs are determined. The sales for the U.S. territory, as reported by Pfizer, as well as sales preliminary reported for territories outside the United States have been used to estimate license obligations in terms of royalties and sales milestones. Sales milestones and royalties are recognized as they are earned by the partners. Sales milestones are shared equally, while royalty payments are shared on the basis of revenue in the territories for which the partners are responsible. The estimated royalty fees applied to net sales reflect the license obligations to the extent currently identified from third party contractual arrangements. Changes in estimates are accounted for prospectively, when determined.

These estimated figures are likely to change prospectively in future periods as BioNTech receives final data from Pfizer. Those changes in BioNTech's share of the collaboration partner's gross profit will be recognized prospectively as changes to BioNTech's commercial revenues. To the extent that Pfizer does not provide such preliminary information in the future, BioNTech's provisional sales figures for territories outside of the United States will be subject to a greater level of estimation and judgment.

<i>(in thousands)</i>	Year ended December 31, 2020			Total
	German territory	U.S. territory	Territories outside the U.S.	
Direct product sales to BioNTech customers	€ 20,553			€ 20,553
Share of collaboration partner's gross profit		€ 46,997	€ 141,480	€ 188,477
Input parameters used within gross profit share calculation				
<i>Sales</i>		<i>reported</i>	<i>preliminary reported</i>	
<i>Transfer price (manufacturing, shipping costs and respective variances)</i>		<i>standard prices identified</i>	<i>standard prices identified</i>	
<i>License payments</i>		<i>royalty rate</i>	<i>royalty rate</i>	

Pfizer's determination of manufacturing and shipping costs also affects the transfer prices that have been charged to COVID-19 vaccine supplies that it manufactures and supplies to BioNTech and may be subject to adjustment whenever manufacturing and shipping cost variances are identified. Likewise, BioNTech's own cost of sales and the respective gross profit share owed to BioNTech's partner may be adjusted prospectively, when changes are determined.

For the carrying amounts of the revenue recognition-related contract balances, see Note 6.

#### Research and Development Expenses

Research and development expenses consist of costs incurred in performing research and development activities, including personnel-related expenses, contract services and costs for purchased materials, laboratory supplies and non-capital equipment used in the research and development process. Research and development expenses include BioNTech's share of expenses under the terms of collaboration agreements and 100% of the expenses for wholly-owned product candidates. Research and development expenses shared under collaboration agreements, which are initially incurred by the collaboration partners and subsequently charged to BioNTech, are recorded as purchased services classified within research and development. Cost reimbursements from partners for research and development expenses initially incurred by BioNTech and due to BioNTech under the agreements, are recorded as a reduction to purchased services classified within research and development expenses.

BioNTech has entered into agreements under which third parties grant licenses to BioNTech. Consideration paid under those agreements include upfront payments, development milestone payments and development expense reimbursements as well as sales-based milestone and royalty payments. Milestone payments are recorded when the specific milestone has been achieved. If those licenses grant access to technologies, both parties jointly perform research or development activities and both are exposed to significant risks and rewards of the activities. Costs incurred with the agreements are not treated differently from costs related to own product candidates. If the agreements grant BioNTech

rights to use certain patents and technologies, that meet the definition of an identifiable assets, they are treated as acquired intangible assets. This assessment is made based on the facts and circumstances of each contractual agreement.

The value of goods and services received from contract research organizations, or CROs, and contract manufacturing organizations, or CMOs, in the reporting period are estimated based on the level of services performed and progress made in the respective period. Amounts are recorded as accrued expenses if BioNTech has not received an invoice from the service provider. Advance payments for goods or services that will be used or rendered for future research and development activities are recognized as other current assets or other current financial assets respectively. The amounts are currently expensed as the related goods are delivered or the services performed. Management's estimates are based on the best information available at the time. However, additional information may become available in the future and management may adjust the estimate in such future periods. In this event, BioNTech may be required to record adjustments to research and development expenses in future periods when the actual level of activity becomes more certain. BioNTech considers resulting increases or decreases in cost as changes in estimates and reflects such changes in research and development expenses in the period identified.

Research costs are expensed as incurred. Development expenditures on an individual project are recognized as an intangible asset if, and only if, all of the six criteria can be demonstrated by the Group as shown under Note 2.3.10 above. Due to the inherent risk of failure in pharmaceutical development and the uncertainty of approval, management has determined that these criteria are not met in the biotech sector until regulatory approval has been obtained. The related expenditure is reflected in the consolidated statements of operations in the period in which the expenditure is incurred. Sales-based milestone or royalty payments incurred under license agreements relating to self-developed intangibles after the approval date of the respective pharmaceutical product are considered as contingent considerations. These contingent considerations are recognized as expenses as incurred.

Prior to initial regulatory approval, costs relating to production of products are expensed as research and development expenses in the period incurred. If pre-launch products are sold, the respective product gross margin may be higher compared to the expected recurring margin as the underlying costs will not be included in cost of sales.

#### **Estimates and Assumptions**

The key assumptions concerning the future and other key sources of estimation uncertainty at the reporting date that have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next financial year are described below. The Group based its assumptions and estimates on parameters available when the consolidated financial statements were prepared. Existing circumstances and assumptions about future developments, however, may change due to market changes or circumstances arising that are beyond the control of the Group. Such changes are reflected in the assumptions when they occur.

##### *Business Combinations*

The allocation of the purchase price for business acquisitions to the identifiable assets acquired and liabilities assumed based on their respective fair values, requires use of accounting estimates and judgment. Acquired intangible assets are valued using valuation models such as the Multi Period Excess Earnings Method under which fair values are derived from future net cash flows, which are discounted to the acquisition date using an appropriate discount factor. BioNTech has estimated fair values of assets acquired, liabilities assumed and contingent considerations based on reasonable assumptions. BioNTech continues to collect information and reevaluate these provisional estimates and assumptions in accordance with IFRS 3. Any adjustments to these provisional estimates and assumptions is recorded against goodwill provided they arise within the measurement period. Upon the conclusion of the measurement period or final determination of the fair value of assets acquired or liabilities assumed, whichever comes first, any subsequent adjustments are recorded to the consolidated statements of operations.

For further disclosures relating to business combinations, see Note 5.

##### *Impairment of Non-Financial Assets*

Impairment exists when the carrying value of an asset or cash generating unit exceeds its recoverable amount, which is the higher of its fair value less costs of disposal and its value in use. The fair value less costs of disposal calculation is based on DCF model less incremental costs of disposing of the asset. The value in use calculation is based on a DCF model as well. The cash flows are derived from the budget for the next five years and do not include restructuring activities that the Group is not yet committed to or significant future investments that will enhance the performance of the assets of the

CGU being tested. The recoverable amount is sensitive to the discount rate used for the DCF model as well as the expected future cash-inflows and the growth rate used for extrapolation purposes. These estimates are most relevant to goodwill and other intangibles with indefinite useful lives recognized by the Group.

The key assumptions used to determine the recoverable amount for the different CGUs, including a sensitivity analysis, are disclosed and further explained in Note 11.

#### *Share-Based Payments*

Determining the fair value of share-based payment transactions requires the most appropriate valuation for the specific program, which depends on the underlying terms and conditions.

The Group has used valuation models like a binomial or Monte-Carlo simulation model for the measurement of the cash- and equity-settled transactions' fair value at the grant date considering certain assumption relating to, e.g., the volatility of stock price, the determination of an appropriate risk-free interest rate, expected dividends and the probability of reaching a minimum hurdle to exercise the relevant options. For awards which were granted prior to the initial public offering, at a time where no quoted market prices existed, the valuation model assumptions included the option's underlying share price. For awards which were granted post the initial public offering, the grant date's share prices on the Nasdaq Global Select Market were included in the valuation.

For further disclosures relating to share-based payments, see Note 17.

#### *Embedded Derivatives*

Defining the fair value of the embedded derivative which was bifurcated from the convertible note, as host contract, requires significant judgment.

The Group has used the Cox-Rubinstein binomial tree model when determining the fair value of the conversion right. The primary inputs used in the model include stock price volatility, credit spreads, risk-free interest rate and foreign exchange forward rates. Stock price volatility is based on implied volatility for BioNTech, credit risk is model implied and adjusted for movement in credit spreads for B-rated corporates at each valuation date, the risk-free interest rate is based on currency specific time congruent IBOR and swap rates whereas the foreign exchange forward rates are based on observable market data.

For further disclosures relating to financial instruments, see Note 12.

#### *Leases*

Right-of-use assets are measured at the amount equal to the lease liability, adjusted by the amount of any prepaid or accrued lease payments relating to that lease.

Significant accounting judgments are required for the determination of the appropriate incremental borrowing rate, which is to be used in the calculation of the asset and liability that are recognized in the financial statements regarding the lease contracts.

For the carrying amounts of right-of-use assets and the related lease liability, see Note 19.

#### *Taxes*

The Group is subject to income taxes in more than one tax jurisdictions. Due to the increasing complexity of tax laws and the corresponding uncertainty regarding the legal interpretation by the fiscal authorities, tax calculations are generally subject to an elevated amount of uncertainty. To the extent necessary, possible tax risks are taken into account in form of provisions.

The Group does not recognize or impairs deferred tax assets when it is unlikely that a corresponding amount of future taxable profit will be available against which the deductible temporary differences, tax loss carry forwards and tax credits can be utilized. Significant management judgment is required when determining whether sufficient future taxable profit will be available against which the deductible temporary differences, tax loss carry forwards and tax credits can be utilized. This includes management's assessment on the character and amounts of taxable future profits, the periods in which those profits are expected to occur, and the availability of tax planning opportunities. As a matter of policy, convincing evidence

supporting the recognition of deferred tax assets is required if an entity has suffered a loss in either the current or the preceding periods.

As of December 31, 2020, based on BioNTech's product-based business plan, including commercial supply commitments agreed with various governments and health ministries under which BioNTech either directly supplies the COVID-19 vaccine or, if they relate to territories which have been allocated to Pfizer, BioNTech will receive the profit share to which its eligible, it is now considered highly probable that taxable profits for the German tax group will be available against which the tax losses can be utilized. On this basis, BioNTech has determined that a deferred tax asset with respect to the German tax group's tax losses carried forward can be recognized.

On the other hand, management has determined that deferred tax assets on tax losses carried forward that relate to subsidiaries which have a loss making history cannot be recognized. This includes the assessment that those subsidiaries neither have any taxable temporary difference nor any tax planning opportunities available that could support the recognition of deferred tax assets.

For further disclosures relating to deferred taxes, see Note 8.

#### 4 Group Information

##### Information about Subsidiaries

The consolidated financial statements of the Group include the following subsidiaries:

Name	Country of incorporation	Registered office	% equity interest	
			December 31, 2020	December 31, 2019
BioNTech RNA Pharmaceuticals GmbH	Germany	Mainz	100%	100%
BioNTech Delivery Technologies GmbH	Germany	Halle	100%	100%
BioNTech Diagnostics GmbH	Germany	Mainz	100%	100%
BioNTech Europe GmbH	Germany	Mainz	100%	100%
(previously BioNTech Small Molecules GmbH)				
BioNTech Manufacturing GmbH	Germany	Mainz	100%	100%
(previously BioNTech IVAC GmbH)				
BioNTech Manufacturing Marburg GmbH	Germany	Marburg	100%	n/a
BioNTech Austria Beteiligungen GmbH	Austria	Vienna	100%	100%
BioNTech Innovative Manufacturing Services GmbH	Germany	Idar-Oberstein	100%	100%
reSano GmbH (previously reBOOST Management GmbH)	Germany	Mainz	100%	100%
JPT Peptide Technologies GmbH	Germany	Berlin	100%	100%
JPT Peptide Technologies Inc.	United States	Cambridge (previously Acton)	100%	100%
BioNTech USA Holding, LLC	United States	Cambridge (previously New York)	100%	100%
BioNTech Research and Development, Inc.	United States	Cambridge (previously New York)	100%	100%
BioNTech US Inc.	United States	Cambridge	100%	n/a
BioNTech Pharmaceuticals Asia Pacific Pte. Ltd	Singapore	Singapore	100%	n/a
BioNTech UK Limited	United Kingdom	Reading	100%	n/a
BioNTech Cell & Gene Therapies GmbH	Germany	Mainz	100%	100%
BioNTech Real Estate Holding GmbH	Germany	Holzkirchen	100%	100%
BioNTech Real Estate Verwaltungs GmbH	Germany	Holzkirchen	100%	100%
BioNTech Real Estate GmbH & Co. KG	Germany	Holzkirchen	100%	100%
BioNTech Real Estate An der Goldgrube GmbH & Co. KG	Germany	Holzkirchen	100%	n/a
BioNTech Real Estate Haus Vier GmbH & Co. KG	Germany	Holzkirchen	100%	n/a
BioNTech Real Estate Adam Opel Straße GmbH & Co. KG	Germany	Holzkirchen	100%	n/a

During the year ended December 31, 2020, two entities were acquired: Neon Therapeutics, Inc. (subsequently renamed BioNTech US Inc.) and Novartis Manufacturing GmbH (subsequently renamed BioNTech Manufacturing

Marburg GmbH). Additionally, BioNTech UK Limited., BioNTech Pharmaceuticals Asia Pacific Pte. Ltd, BioNTech Real Estate Haus Vier GmbH & Co. KG, BioNTech Real Estate An der Goldgrube GmbH & Co. KG and BioNTech Real Estate Adam Opel Straße GmbH & Co. KG were established.

During the year ended December 31, 2019, two entities were founded in the United States: BioNTech USA Holding, LLC, a wholly-owned subsidiary of BioNTech SE, and BioNTech Research and Development, Inc. a wholly-owned subsidiary of BioNTech USA Holding, LLC. Additionally, reSano GmbH (previously reBOOST Management GmbH), was acquired through a share purchase which represents a related party transaction.

#### Parent Company

ATHOS KG, Holzkirchen, Germany is the sole shareholder of AT Impf GmbH, Munich, Germany and beneficial owner of the following percentage of ordinary shares in BioNTech at the dates as indicated. ATHOS KG via AT Impf GmbH has de facto control over BioNTech based on its substantial shareholding, which enabled it to exercise the majority of voting rights to pass resolutions at BioNTech's Annual General Meeting, or AGM.

Name	Country of incorporation	Registered office	Ownership of ordinary shares in BioNTech (in %)	
			December 31, 2020	December 31, 2019
AT Impf GmbH	Germany	Munich	47.37%	50.33%

#### Entity with significant Influence over the Group

Medine GmbH, Mainz owned the following percentage of ordinary shares in BioNTech at the following dates as indicated:

Name	Country of incorporation	Registered office	Ownership of ordinary shares in BioNTech (in %)	
			December 31, 2020	December 31, 2019
Medine GmbH	Germany	Mainz	17.25%	18.38%

## 5 Business Combinations

### Lipocalyx GmbH

In December 2019, BioNTech Delivery Technologies GmbH (previously BioNTech Protein Therapeutics GmbH), or BioNTech Delivery Technologies, a wholly-owned subsidiary of BioNTech SE, entered into an agreement to acquire all assets, employees and proprietary know-how of Lipocalyx GmbH, or Lipocalyx, and its related parties in exchange for a total cash consideration at an amount of €6.5 million and additional contingent consideration estimated at the closing date of January 6, 2020 in an amount of €0.6 million. The employees of Lipocalyx were transferred automatically to BioNTech Delivery Technologies with effect as of the closing date.

The Group acquired the assets of Lipocalyx and its related parties to combine the acquired technologies and the related know-how with already existing product candidates of the Group to improve their functionality and performance.



The final fair values of the identifiable net assets of Lipocalyx as at the date of acquisition were:

<i>(in thousands)</i>	Fair value recognized on acquisition Lipocalyx GmbH
<b>Assets</b>	
Goodwill	€896
Other intangible assets	5,978
Property, plant and equipment	75
Inventories	139
<b>Total identifiable net assets at fair value</b>	<b>€7,088</b>
<b>Consideration</b>	
Cash paid	€6,516
Contingent consideration liability	572
<b>Total consideration</b>	<b>€7,088</b>

The consolidated statements of operations include the result of Lipocalyx since the acquisition date. From the date of acquisition through December 31, 2020, Lipocalyx contributed €1.7 million as operating loss to the respective result of the Group. From the date of acquisition through December 31, 2020, Lipocalyx generated €0.2 million of revenues. Given the timing of closing, the contribution to operating loss and revenues, if the transaction had occurred at the beginning of the reporting period, would not differ materially. Goodwill recognized is primarily attributed to the expected synergies and other benefits from combining the assets and activities of Lipocalyx with those of the Group. The goodwill resulting from the Lipocalyx acquisition during the year ended December 31, 2020 was allocated to the CGU Immunotherapies.

Transaction costs of €17 thousand relating to the acquisition have been expensed and are included in the general and administrative expenses in the consolidated statements of operations and are included in cash flows used in operating activities in the consolidated statements of cash flows.

The purchase agreement with Lipocalyx includes the following contingent cash considerations to the previous owners:

- €1.0 million upon successful completion of a Phase 1 clinical trial designed to show and establish a sufficient safety margin justifying further development of the first pharmaceutical product relating to acquired technologies formulated in a manner covered by a valid granted claim in a major country of a patent within the assigned IP rights; and
- €1.0 million upon successful completion of the first Phase 2 clinical trial of the first pharmaceutical product relating to acquired technologies formulated in a manner covered by a valid granted claim in a major country of a patent within the assigned IP rights.

At the acquisition date, the fair value of the contingent consideration was €0.6 million. The contingent consideration is presented in 'non-current financial liabilities' in the consolidated statements of financial position (see Note 12).

#### **BioNTech US Inc. (previously Neon Therapeutics, Inc., or Neon)**

On May 6, 2020, BioNTech acquired Neon, a biotechnology company developing novel neoantigen-based T-cell therapies, to leverage Neon's expertise in the development of neoantigen therapies, with both vaccine and T cell capabilities.

Based on the acquisition date share price, the aggregate value of the merger consideration was €89.9 million (\$97.1 million) financed by issuing 1,935,488 American Depositary Shares representing BioNTech's ordinary shares as a stock transaction and including a de minimis cash consideration which was paid to settle Neon's outstanding stock options.

The fair values and values in accordance with IFRS 3 of the identifiable net assets of BioNTech US Inc. as at the date of acquisition were as follows:

<i>(in thousands)</i>	<b>Fair value recognized on acquisition BioNTech US Inc.</b>
<b>Assets</b>	
Intangible assets	€29,867
Property, plant and equipment	5,617
Right-of-use assets	6,896
Other assets non-current and current	2,704
Cash and cash equivalents	7,749
<b>Total assets</b>	<b>€52,833</b>
<b>Liabilities</b>	
Trade payables	1,723
Other liabilities non-current and current	17,793
<b>Total liabilities</b>	<b>€19,516</b>
<b>Total identifiable net assets at fair value</b>	<b>€33,317</b>
Goodwill from the acquisition	56,573
<b>Consideration transferred</b>	<b>€89,890</b>
<b>Consideration</b>	
Shares issued, at fair value	89,548
Cash paid	342
<b>Total consideration</b>	<b>€89,890</b>

The intangible assets comprise two neoantigen targeted therapies, BNT221 (NEO-PTC-01) and BNT222 (NEO-STC-01), which were identified and recorded as in-process R&D.

Deferred tax liabilities relating to temporary differences of the assets acquired in the business combination were recognized at an amount of € 8.0 million. To the extent of those deferred tax liabilities assumed, deferred tax assets relating to temporary differences and tax loss carryforwards which existed as of the acquisition date were recognized. Since the conditions to offset were fulfilled, the deferred tax assets and liabilities were offset.

The consolidated statements of operations include the results of BioNTech US since the acquisition date. From the date of acquisition through December 31, 2020, BioNTech US contributed €28.5 million operating loss to respective result of the Group. If the transaction had occurred at the beginning of the reporting period, €59.8 million would have contributed to the operating loss. This amount includes expenses resulting from the merger and should not necessarily be considered representative of the future consolidated results of operations or financial condition on a consolidated basis. From the date of acquisition, BioNTech US did not generate any revenue and no revenue would have been generated if the transaction had occurred at the beginning of the reporting period.

Goodwill recognized is primarily attributable to the expected synergies and other benefits from combining two organizations with a common culture of pioneering translational science and a shared vision for the future of cancer immunotherapy as described above. The goodwill resulting from the BioNTech US acquisition during the year ended December 31, 2020 was allocated to the CGU Immunotherapies.

Transaction costs of €1.1 million relating to the acquisition have been expensed and are included in the general and administrative expenses in the consolidated statements of operations. In the consolidated statements of cash flows they are included in cash flows used in operating activities. The attributable costs of the issuance of the shares of €1.3 million were recorded in equity as a deduction from the capital reserve and are included in cash flows from financing activities in the consolidated statements of cash flows.

**BioNTech Manufacturing Marburg GmbH (previously Novartis Manufacturing GmbH)**

On October 31, 2020, BioNTech acquired Novartis Manufacturing GmbH, a manufacturing facility in Marburg. Through the acquisition, BioNTech plans to produce its COVID-19 vaccine for global supply.

The fair values and values in accordance with IFRS 3 of the identifiable net assets of BioNTech Manufacturing Marburg GmbH, or BioNTech Marburg, as at the date of acquisition were as follows:

<i>(in thousands)</i>	<b>Fair value recognized on acquisition</b> BioNTech Manufacturing Marburg GmbH
<b>Assets</b>	
Property, plant and equipment	79,828
Right-of-use assets	28,514
Inventories	2,466
Other assets non-current and current	4,343
Cash and cash equivalents	16,319
<b>Total assets</b>	<b>€131,470</b>
<b>Liabilities</b>	
Provisions non-current and current	5,127
Trade payables	8,105
Other liabilities non-current and current	33,383
<b>Total liabilities</b>	<b>€46,615</b>
<b>Total identifiable net assets at fair value</b>	<b>€84,855</b>
Bargain purchase	(7,002)
<b>Consideration transferred</b>	<b>€77,853</b>
<b>Consideration</b>	
Cash paid	77,853
<b>Total consideration</b>	<b>€77,853</b>

The consolidated statements of operations include the results of BioNTech Marburg since the acquisition date. From the date of acquisition, the transition into a GMP certified manufacturing facility for BioNTech's COVID-19 vaccine was initiated rapidly. During this time, no revenues have been recognized and set-up, retooling and prepping expenses led to a €6.7 million operating loss, which contributed to the respective result of the Group. Projecting the revenue and result of the joint company as if the acquisition had occurred at the beginning of the reporting period is impracticable, since BioNTech intends to use the facility for manufacturing its COVID-19 vaccine. Information about revenues and net income generated by BioNTech Marburg before the acquisition were considered not to be useful as they are not representative of the future consolidated results of operations or financial condition on a consolidated basis.

The contracting parties shared the understanding that the manufacturing facility is well-equipped to make an important contribution in BioNTech's effort to develop and manufacture a COVID-19 vaccine. The possibility of acquiring a GMP certified manufacturing facility with well-established biotechnology drug substance and drug product manufacturing equipment as well as an experienced team was a very good opportunity for BioNTech to accelerate its efforts to scale-up the commercial manufacturing capacity for its COVID-19 vaccine production. The fact that the offer to sell and the need to acquire the facility overlapped at a convenient time, the underlying opportunities ultimately resulted in a bargain purchase of €7.0 million which was recognized in other operating income.

Transaction costs of €1.4 million relating to the acquisition have been expensed and are included in the general and administrative expenses in the consolidated statements of operations and are included in cash flows used in operating activities in the consolidated statements of cash flows.

## Reconciliation of Goodwill

The carrying amount of goodwill equals the acquisition costs adjusted by currency translation adjustments. The reconciliation of this carrying amount at the beginning and end of the reporting period is presented below:

<i>(in thousands)</i>	<b>Goodwill</b>
<b>As of January 1, 2020</b>	<b>€2,978</b>
Acquisition of subsidiaries and businesses	57,469
Currency differences	(6,750)
<b>As of December 31, 2020</b>	<b>€53,697</b>

## 6 Revenue from Contracts with Customers

### 6.1 Disaggregated revenue information

Set out below is the disaggregation of the Group's revenues from contracts with customers:

<i>(in thousands)</i>	<b>Years ended December 31,</b>		
	<b>2020</b>	<b>2019</b>	<b>2018</b>
<b>Research &amp; development revenues from collaborations</b>	<b>€178,849</b>	<b>€84,428</b>	<b>€101,837</b>
<i>Pfizer Inc.</i>	121,597	14,348	7,173
<i>Genentech Inc.</i>	49,195	64,026	49,536
<i>Shanghai Fosun Pharmaceutical (Group) Co., Ltd</i>	5,074	-	-
<i>Other</i>	2,983	6,054	45,128
<b>Commercial revenues</b>	<b>303,476</b>	<b>24,161</b>	<b>25,738</b>
COVID-19 vaccine revenues	270,490	-	-
<i>Sales to collaboration partner*</i>	61,460	-	-
<i>Direct product sales to BioNTech customers</i>	20,553	-	-
<i>Share of collaboration partner's gross profit</i>	188,477	-	-
Other sales	32,986	24,161	25,738
<b>Total</b>	<b>€482,325</b>	<b>€108,589</b>	<b>€127,575</b>

\*Represents sales to collaboration partner of products manufactured by BioNTech.

During the year ended December 31, 2020, revenues from contracts with customers mainly increased since revenues were recognized for the first time under two new collaboration agreements, which BioNTech entered into during the year ended December 31, 2020 in order to develop a COVID-19 vaccine, and ultimately led to the recognition of COVID-19 vaccine commercial revenues.

During the year ended December 31, 2020, revenues recognized from two customers, Pfizer (€371.5 million) and Genentech (€49.2 million), each account for more than 10% of total revenues. During the year ended December 31, 2019 revenues recognized from one customer, Genentech (€64.0 million), accounted for more than 10% of total revenues. During the year ended December 31, 2018 revenues recognized from two customers, Genentech (€49.5 million) and Sanofi (€41.7 million), accounted for more than 10% of total revenue. The geographic region which recognized revenues was mainly Germany (also the Country of BioNTech's domicile) and is based upon the location will bills customers.

### Research & Development Revenues from Collaborations

As part of its BNT162 vaccine program against COVID-19, BioNTech collaborates with Pfizer and Fosun Pharma.

Revenue from Pfizer was mainly derived from the collaboration and license agreement to develop a COVID-19 vaccine and, in addition, includes an amount of €3.5 million revenue derived from the existing Influenza collaboration. During the year ended December 31, 2020, a non-refundable upfront cash payment of €66.3 million was received. A regulatory milestone payment of €51.8 million became due, but has not yet been received. Both were fully recognized as revenue during the year ended December 31, 2020.

Fosun Pharma is the collaboration partner with whom BioNTech works together on the development of a COVID-19 vaccine in China. Through the collaboration agreement BioNTech is conducting clinical trials in China, using BioNTech's proprietary mRNA technology and leveraging Fosun Pharma's extensive clinical development, regulatory, and commercial capabilities in the country. Fosun Pharma has paid a non-refundable upfront cash payment of €0.9 million and development milestones of €4.2 million that were recognized as revenue during year ended December 31, 2020.

Other collaboration programs have been progressed during the year ended December 31, 2020 and revenues of €52.1 million have been derived from deferred upfront payments measured based on the costs incurred under the respective research programs. For certain collaboration programs, the commencement of trials has been delayed, partially due to slowed patient enrollment or other delays as a result of the COVID-19 pandemic. Accordingly, during the year ended December 31, 2020, revenues from collaboration programs with Genentech and from the Influenza collaboration with Pfizer have generally decreased compared to the prior year periods.

The revenues recorded during the year ended December 31, 2019 mainly included revenues resulting from collaboration and license agreements processed in the research and development phase. The amounts were mainly derived from deferred upfront fees received under the Genentech, Pfizer (Influenza) and Sanofi collaboration. The amounts were recognized as revenue as BioNTech performed under the agreement and measured based on the costs incurred under the respective research programs. Compared to the revenues recognized from collaboration and license agreements during the year ended December 31, 2018, revenues decreased since the revenue recognized in the year ended December 31, 2018 included an amount of €33.2 million collaboration revenue from the Sanofi collaboration for a reimbursement of 50% of CellScript sublicense costs pursuant to a separate sub-sublicense agreement dated December 22, 2018. This transaction only occurred in the year ended December 31, 2018.

#### **Commercial Revenues**

BioNTech's COVID-19 vaccine has evolved from the BNT162 program and has been authorized or approved for emergency or temporary use or has been granted conditional marketing authorization in over 65 countries worldwide, which resulted in recognition of revenues from the sale of pharmaceutical products for the first time. BioNTech is the marketing authorization holder in the European Union, and holder of emergency use authorizations or equivalent in the United States, United Kingdom, Canada and other countries in advance of a planned application for full marketing authorizations in these countries. BioNTech has marketing and distribution rights in Germany and Turkey. Pfizer has marketing and distribution rights worldwide with the exception of China, Germany, and Turkey. Fosun Pharma has marketing and distribution rights in China.

The COVID-19 vaccine manufacturing process leverages Pfizer's and BioNTech's manufacturing facilities, consequently responsibilities are shared between BioNTech and Pfizer. Whenever responsibilities in the manufacturing and supply process of the COVID-19 vaccine shift and the COVID-19 vaccine is transferred, it is sold from one partner to the other. During the year ended December 31, 2020, BioNTech has recognized €61.5 million of revenues from selling drug product batches manufactured by BioNTech to Pfizer's manufacturing site for fill and finish.

Upon receiving a conditional marketing authorization, emergency or temporary use authorization, BioNTech and Pfizer started selling the product. The allocation of marketing and distribution rights defines territories in which the collaboration partners act as a principal respectively. For supplying BioNTech's territory, Germany, BioNTech acquired COVID-19 vaccine from Pfizer and recognized €20.6 million of revenues from direct COVID-19 vaccine sales during the year ended December 31, 2020. The share of gross profit that Pfizer as collaboration partner has earned based on these sales is recognized as cost of sales.

Based on Pfizer's COVID-19 vaccine sales in the collaboration partner's territory, BioNTech is eligible to receive a share of the respective gross profit which represents a net figure and is recognized as collaboration revenue during the commercial phase. During the year ended December 31, 2020, a gross profit share of €188.5 million has been recognized. In order to determine our share of collaboration partner's gross profits, BioNTech used certain information from the collaboration partner, including revenue from the sale of products, some of which is based on preliminary data shared between the partners and might vary once final data is available.

During the year ended December 31, 2020, €33.0 million of revenues compared to €24.2 million of revenues during the year ended December 31, 2019, and €25.7 million during the year ended December 31, 2018 were recognized from other sales transactions based on sales of diagnostic products, peptides, retroviral vectors for clinical supply, and development and manufacturing services that were sold to third-party customers.

The revenues from contracts with customers disclosed above were recognized as follows:

<i>(in thousands)</i>	Years ended		
	2020	December 31, 2019	2018
Timing of revenue recognition			
<i>Goods and services transferred at a point in time</i>	€108,840	€16,955	€22,828
<i>Goods and services transferred over time</i>	373,485	91,634	104,747
<b>Total</b>	<b>€482,325</b>	<b>€108,589</b>	<b>€127,575</b>

During the year ended December 31, 2019, BioNTech recognized revenue of €1.1 million under a bill-and-hold transaction for which the customer already had obtained control. The bill-and-hold arrangement is substantive since the request to retain the product in BioNTech's facilities until January 2020 was initiated by the customer.

## 6.2 Contract Balances

<i>(in thousands)</i>	December 31, 2020	December 31, 2019
Trade receivables	€165,468	€11,913
Contract liabilities	371,475	190,692

Trade receivables are non-interest bearing and are generally settled within 20 to 30 days.

Contract assets are recognized for revenue earned from sales and services based on individual customer contracts of BioNTech Innovative Manufacturing Services GmbH. However, the customers' advance payments exceeded BioNTech's transferred goods and services for which a conditional right to consideration exists. Therefore, only contract liabilities net of contract assets are presented as of December 31, 2020 and December 31, 2019, respectively.

Contract liabilities mainly include upfront fees received from BioNTech's major collaboration and license agreements as well as advance payments received for future COVID-19 vaccine sales and other sales.

The contract liabilities from collaboration and commercial supply agreements as of December 31, 2020 comprise €131.8 million remaining upfront fees from collaboration agreements, €235.8 million of advance payments for future COVID-19 vaccine sales, which had been received during the year ended December 31, 2020 or for which an unconditional right of consideration exists as well as €3.9 million advance payments received on other sales (as of December 31, 2019: €187.6 million of remaining upfront fees from collaborations as well as €3.1 million advance payments received on other sales).

During the year ended December 31, 2020, the increase from payments received exceeded revenues recognized from contract liabilities recorded at the beginning of the year (during the year ended December 31, 2019: decrease in contract liabilities since recognizing revenues from amounts which had been included in contract liabilities at the beginning of the year exceeded advance payments on other sales received).

Set out below is the amount of revenue recognized for the periods indicated:

<i>(in thousands)</i>	Years ended		
	2020	December 31, 2019	2018
Amounts included in contract liabilities at the beginning of the year	€58,895	€84,112	€59,583

### 6.3 Performance Obligations

The contract liabilities allocated to the remaining performance obligations from collaboration or commercial supply agreements (unsatisfied or partially unsatisfied) as at year-end are as follows:

<i>(in thousands)</i>	December 31, 2020	December 31, 2019
Within one year	€299,583	€93,583
More than one year	71,892	97,109
<b>Total</b>	<b>€371,475</b>	<b>€190,692</b>

### 7 Income and Expenses

#### 7.1 Costs of Sales

<i>(in thousands)</i>	2020	Years ended December 31, 2019	2018
Cost of sales related to COVID-19 vaccine revenues	€35,616	-	-
Cost related to other sales	23,717	17,361	13,690
<b>Total</b>	<b>€59,333</b>	<b>€17,361</b>	<b>€13,690</b>

During the year ended December 31, 2020, cost of sales mainly increased compared to the year ended December 31, 2019 since costs were recognized for the first time with respect to BioNTech's COVID-19 vaccine sales and included Pfizer's share of gross profits earned by BioNTech in transactions, where BioNTech is the principal. Costs of sales do not include costs relating to production of pre-launch products since those are expensed as research and development expenses in the period incurred.

#### 7.2 Research and Development Expenses

<i>(in thousands)</i>	2020	Years ended December 31, 2019	2018
Purchased services	€359,880	€65,552	€42,079
Wages, benefits and social security expense	126,298	83,213	45,668
Laboratory supplies	107,792	37,218	22,921
Depreciation and amortization	30,192	27,533	18,312
IT costs	5,118	3,800	1,572
Lease and lease related cost	3,725	2,527	2,404
Transport costs	2,135	1,081	668
Other	9,889	5,542	9,416
<b>Total</b>	<b>€645,029</b>	<b>€226,466</b>	<b>€143,040</b>

During the year ended December 31, 2020, research and development expenses increased compared to the year ended December 31, 2019 due to an increase in research and development expenses from BioNTech's BNT162 program. Research and development expenses include BioNTech's share of expenses under the terms of the Pfizer collaboration agreement. Development costs, which are shared, are divided equally between BioNTech and Pfizer. The amount of shared development expenses, which were initially incurred by Pfizer and subsequently charged to BioNTech, were recorded as purchased services classified within research and development and the reimbursement from Pfizer for research and development expenses initially incurred by BioNTech were recorded as a reduction to research and development expenses. The increase was further driven by an increase in expenses for purchased laboratory supplies as well as an increase in headcount leading to higher wages, benefits and social security expenses. In addition, from May 6, 2020, the date of acquisition, the new U.S.-based subsidiary, BioNTech US Inc., contributed €21.0 million to the research and development expenses of the Group.

During the year ended December 31, 2019, research and development costs increased compared to the year ended December 31, 2018 based on an increase in wages, benefits and social security expenses due to an increase in headcount

and the full-year reflection of the Employee Stock Ownership Plan ("ESOP") expenses during the year ended December 31, 2019 as well as higher development expenses spent on purchased services and laboratory supplies.

### 7.3 Sales and Marketing Expenses

<i>(in thousands)</i>	Years ended		
	December 31,	2019	2018
	2020		
Purchased services	€10,929	€247	€794
Wages, benefits and social security expense	1,636	1,938	1,728
Other	1,947	533	519
<b>Total</b>	<b>€14,512</b>	<b>€2,718</b>	<b>€3,041</b>

During the year ended December 31, 2020, sales and marketing expenses increased compared to the year ended December 31, 2019 due to an increase in purchased service, which we incurred in connection with progressing the commercial activities of the Group with respect to BioNTech's COVID-19 vaccine.

### 7.4 General and Administrative Expenses

<i>(in thousands)</i>	Years ended		
	December 31,	2019	2018
	2020		
Wages, benefits and social security expense	€33,007	€19,122	€8,582
Purchased services	26,022	6,419	5,177
IT and office equipment	7,404	4,573	3,774
Depreciation and amortization	5,104	4,855	2,284
Insurance premiums	4,840	1,061	145
Job advertisement expenses	2,897	548	861
Lease and lease related cost	2,390	1,715	1,012
Research services	2,033	232	26
Laboratory supplies	1,191	785	456
Contract staffing	1,108	686	781
Other	8,053	5,551	3,236
<b>Total</b>	<b>€94,049</b>	<b>€45,547</b>	<b>€26,334</b>

During the year ended December 31, 2020, general and administrative expenses increased compared to the year ended December 31, 2019 due to higher expenses for purchased management consulting and legal services, an increase in headcount leading to higher wages, benefits and social security expenses and higher insurance premiums. In addition, from May 6, 2020, the date of acquisition, the new U.S.-based subsidiary, BioNTech US Inc., contributed €7.4 million to the general and administrative expenses of the Group, respectively.

During the year ended December 31, 2019, general and administrative expenses increased compared to the year ended December 31, 2018 based on an increase in headcount and the full-year reflection of the ESOP program expenses during the year ended December 31, 2019 as well as a charge of €2.6 million in connection with certain withholding tax payments for intellectual property licenses related to prior years that was recorded during the year ended December 31, 2019 but not during the year ended December 31, 2018.

### 7.5 Other Operating Income

<i>(in thousands)</i>	Years ended		
	December 31,	2019	2018
	2020		
Government grants	€239,017	€1,547	€4,228
Bargain purchase	7,002	-	50
Other	4,520	1,177	1,118
<b>Total</b>	<b>€250,539</b>	<b>€2,724</b>	<b>€5,396</b>



During the year ended December 31, 2020, the other income increased compared to the year ended December 31, 2019. The increase mainly results from government grants for which BioNTech became eligible as part of an initiative by the German Federal Ministry of Education (*Bundesministerium für Bildung und Forschung*, or the BMBF) to support its COVID-19 vaccine program, BNT162. The BMBF funding was granted to accelerate BioNTech's vaccine development, and to upscale its manufacturing capabilities in Germany. The funding will also compensate further costs that incur since the COVID-19 vaccine continues to be tested in clinical trials, for example to test it against new variants or to approve it for additional groups (pregnant women, individuals less 16 years), and because study participants will continue to be followed for two years to continue evaluating safety and efficacy. The proportion of the grant that related to expenses incurred by BioNTech is recognized as other operating income with an amount of €238.9 million; the proportion which was received and will compensate BioNTech for future expenses, has been deferred and is presented as government grant in the consolidated statements of financial position with an amount of €88.0 million.

The following table illustrates the changes regarding the government grants:

<i>(in thousands)</i>	<b>2020</b>	<b>Years ended December 31,</b>	
		<b>2019</b>	<b>2018</b>
As of January 1	-	-	-
Received during the year	330,968	1,547	4,228
Released to the consolidated statements of operations	(239,017)	(1,547)	(4,228)
<b>As of December 31</b>	<b>€91,951</b>	-	-
Total current	91,951	-	-
Total non-current	-	-	-

#### 7.6 Finance Income

<i>(in thousands)</i>	<b>2020</b>	<b>Years ended December 31,</b>	
		<b>2019</b>	<b>2018</b>
Interest income	€1,564	€1,781	€1,996
Foreign exchange gains, net	-	2,341	6,050
<b>Total</b>	<b>€1,564</b>	<b>€4,122</b>	<b>€8,046</b>

During the year ended December 31, 2019, finance income included €2.3 million foreign exchange gains. Foreign exchange differences on a cumulative basis, are either shown as finance income or expenses.

#### 7.7 Finance Expense

<i>(in thousands)</i>	<b>2020</b>	<b>Years ended December 31,</b>	
		<b>2019</b>	<b>2018</b>
Amortization of financial instruments	€3,048	€326	€48
Fair value adjustments of financial instruments measured at fair value	17,289	-	-
Foreign exchange loss, net	42,609	-	-
<b>Total</b>	<b>€62,946</b>	<b>€326</b>	<b>€48</b>

During the year ended December 31, 2020, finance expenses included €42.6 million foreign exchange losses as well as €17.3 million in expenses arising from fair value measurement adjustments of the derivative embedded within the convertible note. The increase in foreign exchange losses is mainly due to higher balances in U.S. dollar bank accounts and the weakening of the U.S. dollar when compared to the Euro.

7.8 **Employee Benefits Expense**

<i>(in thousands)</i>	Years ended December 31,		
	2020	2019	2018
Wages and salaries	€160,655	€98,568	€54,149
Social security costs	17,988	12,394	8,231
Pension costs	761	517	324
<b>Total</b>	<b>€179,404</b>	<b>€111,479</b>	<b>€62,704</b>

The item wages and salaries includes, among other things, expenses for share-based payments.

8 **Income Tax**

Income tax for the years ended December 31, 2020, December 31, 2019 and December 31, 2018 comprised current income taxes, other taxes and deferred taxes. BioNTech SE is subject to corporate taxes, the solidarity surcharge and trade taxes. The Company's corporate tax rate in the reporting year remained unchanged (15.0%) as did the solidarity surcharge (5.5%) whereas the average trade tax rate (15.0%) changed. BioNTech USA Holding, LLC is subject to Federal Corporate Income Tax (21.0%) as well as State Income Tax in various state jurisdictions (average rate of 8.1%).

The following table illustrates the current and deferred taxes for the periods indicated:

<i>(in thousands)</i>	Years ended December 31,		
	2020	2019	2018
Current income taxes	€17	€(296)	€600
Deferred taxes	(161,034)	-	-
Other taxes	17	28	-
<b>Income taxes</b>	<b>€(161,000)</b>	<b>€(268)</b>	<b>€600</b>

The following table reconciles the expected income taxes to the actual current income taxes and deferred taxes as presented in the table above. The combined income tax rate of 30.79% in the year ended December 31, 2020 (during the years ended December 31, 2019 and 2018: 30.78% and 30.99%, respectively) was applied to loss before taxes to calculate the expected income taxes. This rate consists of above outlined tax rates of BioNTech SE applicable to the Group. The slight decrease of the tax rate results from the Lipocalyx GmbH business combination.

<i>(in thousands)</i>	Years ended		
	2020	2019	2018
Loss before tax	€(145,802)	€(179,440)	€(47,662)
Expected tax benefit (based on BioNTech's statutory tax rate of 30.79%, 2019: 30.78%, 2018: 30.99%)	44,891	55,240	14,776
<i>Effects</i>			
Government grants exempted from taxes	14	48	28
Non-deductible expenses	(770)	(58)	(18)
Add-back for trade tax purposes	(595)	(110)	(96)
Non-tax effective bargain purchase	2,156	-	-
Non-recognition of tax effect on share-based payment expenses	(9,806)	(9,308)	-
Tax-effective equity transaction costs	10,229	5,121	-
Utilization of tax losses	-	-	1,165
Non-recognition of deferred taxes on tax losses and temporary differences	(12,961)	(51,197)	(13,634)
Recognition of deferred taxes on tax losses not recognized in prior periods	102,231	-	-
Recognition of deferred taxes on temporary differences not recognized in prior periods	26,241	192	-
Effect from lower foreign income tax rate	(1,304)	(102)	-
Adjustment prior year tax	(326)	316	-
Tax credit	1,059	-	-
Other effects	(59)	126	(2,821)
<b>Income taxes</b>	<b>€161,000</b>	<b>€268</b>	<b>€(600)</b>

## Deferred Taxes

Deferred taxes for the periods indicated relate to the following:

### Year ended December 31, 2020

	January 1, 2020	Recognized in P&L*	Recognized in OCI	Acquisition of subsidiaries and businesses	December 31, 2020
<i>(in thousands)</i>					
Fixed assets	€(655)	€(2,370)	-	€8,637	€5,612
Inventories	596	46	-	329	971
Leases	512	(5,091)	-	(14)	(4,593)
Contract liabilities	23,543	(174)	-	-	23,369
Interest-bearing loans and borrowings	-	(2,741)	-	195	(2,546)
Net employee defined benefit liabilities	-	169	(63)	698	804
Provisions	187	886	-	419	1,492
Other (incl. deferred expenses)	2,087	8,336	-	202	10,625
Tax loss carryforward / tax credit	109,764	41,660	-	24,280	175,704
<b>Deferred Tax Assets Net (before valuation)</b>	<b>€136,034</b>	<b>€40,721</b>	<b>€(63)</b>	<b>€34,746</b>	<b>€211,438</b>
Valuation Adjustment	(136,034)	120,313	-	(34,765)	(50,486)
<b>Deferred Tax Assets Net (after valuation)</b>	<b>-</b>	<b>€161,034</b>	<b>€(63)</b>	<b>€(19)</b>	<b>€160,952</b>

\*Includes all changes in deferred taxes related to U.S. tax group other than those acquired in business combination

### Year ended December 31, 2019

	January 1, 2019	Recognized in P&L	Recognized in OCI	Acquisition of subsidiaries and businesses	December 31, 2019
<i>(in thousands)</i>					
Fixed assets	€(90)	€(565)	-	-	€(655)
Inventories	-	596	-	-	€596
Leases	306	206	-	-	€512
Contract liabilities	28,441	(4,898)	-	-	€23,543
Provisions	134	53	-	-	€187
Other (incl. deferred expenses)	161	1,926	-	-	€2,087
Tax loss carryforward / tax credit	55,848	53,916	-	-	€109,764
<b>Deferred Tax Assets Net (before valuation)</b>	<b>€84,799</b>	<b>€51,235</b>	<b>-</b>	<b>-</b>	<b>€136,034</b>
Valuation Adjustment	(84,799)	(51,235)	-	-	(136,034)
<b>Deferred Tax Assets Net (after valuation)</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>

Accumulated tax losses of the German tax group, German entities not within the tax group and U.S. tax group for the periods indicated amount to the following:

<i>(in thousands)</i>	Years ended December 31,		
	2020	2019	2018
Corporate Tax	€596,359	€356,044	€179,264
Trade Tax	513,561	352,341	176,425

<i>(in thousands)</i>	Years ended December 31,		
	2020	2019	2018
Federal Tax Credits	€756	-	-
State Tax Credits	250	-	-

The accumulated tax losses related to the German tax group include €457.9 million of corporate income tax losses and €450.9 million of trade tax losses. Under German law, tax losses do not expire. Deferred tax assets on tax losses had not been capitalized in previous years, as there was not sufficient probability in terms of IAS 12 that there would have been future taxable profits available against which the unused tax losses could have been utilized. Following the authorization and approval of the COVID-19 vaccine for emergency or temporary use or having been granted conditional marketing authorization in over 65 countries worldwide, BioNTech re-evaluated previously unrecognized tax losses. Based on BioNTech's product-based business plan, including commercial supply commitments agreed with various governments and health ministries under which BioNTech either directly supplies the COVID-19 vaccine or, if they relate to territories which have been allocated to Pfizer, BioNTech will receive the profit share to which it is eligible, it is now considered highly probable that taxable profits for the German tax group will be available against which the tax losses can be utilized. On this basis, BioNTech recognized deferred tax assets and liabilities with a net amount of €161.0 million for the losses and temporary differences determined for the German tax group as of December 31, 2020.

The accumulated tax losses related to German entities not within the tax group include €1.7 million of corporate income tax losses and €1.8 million of trade tax losses. With respect to those tax losses, no deferred tax assets have been capitalized, as there is not sufficient probability in terms of IAS 12 that there will be future taxable profits available against which the unused tax losses can be utilized.

The accumulated tax losses related to U.S. tax group include €136.8 million of corporate income tax losses and €60.9 million of trade tax losses. The tax losses related to the U.S. tax group include €20.9 million of federal losses that are expected to expire in 2033 and €115.9 million of federal losses which have no expiration date and can be carried forward indefinitely. In addition, the U.S. tax group has state tax losses of €60.9 million, which may be available to offset future taxable profit and that expire at various dates beginning in 2033. BioNTech's forecast for the U.S. tax group does not provide sufficient probability for the use of existing tax loss carryforwards in the near future. Therefore, the requirements set out by IAS 12 are not fulfilled for the U.S. tax group. As of December 31, 2020, deferred tax assets are only recognized up to the amount of deferred tax liabilities.

In addition to accumulated tax losses, BioNTech had accumulated federal tax credits of €0.8 million and state tax credits of €0.3 million in the United States as of December 31, 2020. The tax credits in the United States will expire at various dates beginning in 2035 if they are not used.

## **9 Earnings per Share**

Basic earnings per share (EPS) is calculated by dividing the profit / (loss) for the year attributable to ordinary equity holders of the parent by the weighted average number of ordinary shares outstanding during the year.

Diluted EPS is calculated by dividing the profit / (loss) attributable to ordinary equity holders of the parent by the weighted average number of ordinary shares outstanding during the year plus the weighted average number of ordinary shares that would be issued on conversion of all the dilutive potential ordinary shares into ordinary shares.

On September 18, 2019, BioNTech effected a 1:18 share split by issuing 206,595,492 shares by way of a capital increase from its own funds; thus, no outside proceeds were received. This capital increase came into effect upon registration with the commercial register (*Handelsregister*). The accompanying financial statements and notes to the financial statements including the EPS information below give retroactive effect to the share split for all periods presented.

The following table reflects the income and share data used in the basic and diluted EPS calculations:

<i>(in thousands)</i>	Years ended December 31,		
	2020	2019	2018
<b>Gain (loss) attributable to ordinary equity holders of the parent for basic earnings</b>	<b>€15,198</b>	<b>€(179,056)</b>	<b>€(48,019)</b>
<b>Weighted average number of ordinary shares for basic EPS</b>	<b>235,442</b>	<b>211,499</b>	<b>190,710</b>
Effects of dilution from share options	13,085	-	-
<b>Weighted average number of ordinary shares adjusted for the effect of dilution</b>	<b>248,527</b>	<b>211,499</b>	<b>190,710</b>

**Earnings per share**

*in EUR*

Basic and diluted, profit / (loss) for the period attributable to ordinary equity holders of the parent*	€0.06	€(0.85)	€(0.25)
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\* Numbers of shares for calculating the earnings per share for the years ended December 31, 2019 and December 31, 2018 have been adjusted to reflect capital increase due to 1:18 share split, which occurred on September 18, 2019.

There have been no other transactions involving ordinary shares or potential ordinary shares between the reporting date and the date of authorization of these financial statements. Share options were not included in the calculation of diluted EPS for periods in which they were antidilutive; i.e. for the periods in which a loss was incurred.

**10 Property, Plant and Equipment**

<i>(in thousands)</i>	Land and buildings	Equipment, tools and installations	Construction in progress and advance payments	Total
<b>Acquisition and production costs</b>				
As of January 1, 2019	€22,147	€73,613	€7,091	€102,853
Additions	7,269	8,700	22,623	38,592
Disposals	-	(105)	(10)	(115)
Reclassifications	53	-	(53)	-
Currency differences	-	(1)	1	-
Acquisition of subsidiaries and businesses	-	999	-	999
<b>As of December 31, 2019</b>	<b>€29,469</b>	<b>€83,206</b>	<b>€29,652</b>	<b>€142,329</b>
As of January 1, 2020	€29,469	€83,206	€29,652	€142,329
Additions	14,927	10,093	41,013	66,033
Disposals	(41)	(6,892)	(958)	(7,891)
Reclassifications	8,561	1,832	(10,391)	-
Currency differences	(52)	(638)	-	(690)
Acquisition of subsidiaries and businesses	8,400	54,817	22,302	85,519
<b>As of December 31, 2020</b>	<b>€61,264</b>	<b>€142,418</b>	<b>€81,618</b>	<b>€285,300</b>

<i>(in thousands)</i>	Land and buildings	Equipment, tools and installations	Construction in progress and advance payments	Total
<b>Cumulative depreciation and impairment charges</b>				
As of January 1, 2019	€6,472	€30,180	-	€36,652
Depreciation	1,854	10,861	-	12,715
Disposals	-	(79)	-	(79)
Reclassifications	-	-	-	-
Currency differences	-	(3)	-	(3)
<b>As of December 31, 2019</b>	<b>€8,326</b>	<b>€40,959</b>	-	<b>€49,285</b>
As of January 1, 2020	€8,326	€40,959	-	€49,285
Depreciation	2,074	13,753	-	15,827
Disposals	(41)	(6,683)	-	(6,724)
Reclassifications	-	-	-	-
Currency differences	(3)	(53)	-	(56)
<b>As of December 31, 2020</b>	<b>€10,356</b>	<b>€47,976</b>	-	<b>€58,332</b>

<i>(in thousands)</i>	Land and buildings	Equipment, tools and installations	Construction in progress and advance payments	Total
<b>Carrying amount</b>				
As of January 1, 2019	€15,675	€43,433	€7,091	€66,200
As of December 31, 2019	€21,143	€42,247	€29,652	€93,044
<b>As of December 31, 2020</b>	<b>€50,908</b>	<b>€94,442</b>	<b>€81,618</b>	<b>€226,968</b>

## 11 Intangible Assets

<i>(in thousands)</i>	Goodwill	Concessions, licenses, in-process R&D and similar rights	Advance payments	Total
<b>Acquisition costs</b>				
As of January 1, 2019	€534	€101,853	€1,497	€103,883
Additions	-	11,744	1,529	13,273
Disposals	-	(133)	(477)	(610)
Reclassifications	-	146	(146)	-
Currency differences	-	(23)	-	(23)
Acquisition of subsidiaries and businesses	2,444	2,726	-	5,170
<b>As of December 31, 2019</b>	<b>€2,978</b>	<b>€116,313</b>	<b>€2,403</b>	<b>€121,693</b>
As of January 1, 2020	€2,978	€116,313	€2,403	€121,693
Additions	-	4,187	4,426	8,613
Disposals	-	(5,435)	(643)	(6,078)
Reclassifications	-	233	(233)	-
Currency differences	(6,750)	(3,897)	-	(10,647)
Acquisition of subsidiaries and businesses	57,469	35,845	-	93,314
<b>As of December 31, 2020</b>	<b>€53,697</b>	<b>€147,246</b>	<b>€5,953</b>	<b>€206,895</b>

<i>(in thousands)</i>	Goodwill	Concessions, licenses, in-process R&D and similar rights	Advance payments	Total
<b>Cumulative depreciation and impairment charges</b>				
As of January 1, 2019	-	€15,842	-	€15,842
Depreciation	-	16,502	-	16,502
Disposals	-	(81)	-	(81)
Reclassifications	-	-	-	-
Currency differences	-	(3)	-	(3)
<b>As of December 31, 2019</b>	-	<b>€32,260</b>	-	<b>€32,260</b>
As of January 1, 2020	-	€32,260	-	€32,260
Depreciation	-	16,627	-	16,627
Disposals	-	(5,410)	-	(5,410)
Reclassifications	-	-	-	-
Currency differences	-	(72)	-	(72)
<b>As of December 31, 2020</b>	-	<b>€43,405</b>	-	<b>€43,405</b>

<i>(in thousands)</i>	Goodwill	Concessions, licenses, in-process R&D and similar rights	Advance payments	Total
<b>Carrying amount</b>				
As of January 1, 2019	€534	€86,011	€1,497	€88,042
As of December 31, 2019	€2,978	€84,053	€2,403	€89,434
<b>As of December 31, 2020</b>	<b>€53,697</b>	<b>€103,841</b>	<b>€5,953</b>	<b>€163,490</b>

#### Goodwill and intangible assets with indefinite useful lives

For impairment testing, goodwill acquired through business combinations has been allocated to the cash-generating units (CGU) as shown in the following table:

<i>(in thousands)</i>	CGU Immunotherapies		External Product Sales of JPT		Total	
	As of December 31, 2020	As of December 31, 2019	As of December 31, 2020	As of December 31, 2019	As of December 31, 2020	As of December 31, 2019
<b>Goodwill</b>	€53,163	€2,444	€534	€534	€53,697	€2,978

The Group performs its annual goodwill impairment test for the respective year as of October 1. As a result of the change to one reportable segment (Note 2.1), BioNTech evaluated the implications on its determination of CGUs for allocation of goodwill. As a result, two CGUs were identified:

- The Immunotherapies CGU focuses on the development of therapies to address a range of rare and infectious diseases and includes BioNTech's broad pipeline includes mRNA-based immune activators, antigen-targeting T-cells and antibodies, and defined immunomodulators of various immune cell mechanisms.
- The External Products Sales of JPT Peptide Technologies GmbH CGU includes the distribution of innovative peptide-based products to external customers.

#### CGU Immunotherapies

The recoverable amount of the CGU Immunotherapies has been determined based on a value in use calculation using cash flow projections from financial budgets approved by the Management Board covering a fifteen-year period. The projected cash flows have been updated to reflect the near-term effect from BioNTech's COVID-19 vaccine. The discount rate applied to cash flow projections is 8.9% and cash flows beyond the forecast period are extrapolated using a 1.0% growth rate that is the same as the long-term average growth rate for the biotech industry. It was concluded that the fair value less costs of disposal did not exceed the value in use. As a result of the analysis, management did not identify an impairment for this CGU.



#### CGU External Product Sales of JPT Peptide Technologies GmbH

The recoverable amount of the CGU External Product Sales of JPT Peptide Technologies GmbH has been determined based on a value in use calculation using cash flow projections from financial budgets approved by senior management covering a ten-year period. The discount rate applied to cash flow projections is 7.9% and cash flows beyond the forecast period are extrapolated using a 1.0% growth rate which is in line with industry standard. It was concluded that the fair value less costs of disposal did not exceed the value in use. As a result of the analysis, management did not identify an impairment for this CGU.

#### Key assumptions used in value in use calculations and sensitivity to changes in assumptions

The calculation of value in use for both CGUs, Immunotherapies and External Product Sales of JPT Peptide Technologies GmbH, is most sensitive to the following assumptions:

- Discount rates
- Growth rates used to extrapolate cash flows beyond the forecast period

**Discount rates** – Discount rates represent the current market assessment of the risks specific to the CGU, taking into consideration the time value of money and individual risks of the underlying assets that have not been incorporated in the cash flow estimates. The discount rate calculation is based on the specific circumstances of the Group and the respective CGU. It is derived from its weighted average cost of capital (WACC). The WACC takes into account both debt and equity. The cost of equity is derived from the expected return on investment by the Group's investors. The cost of debt is based on the interest-bearing borrowings the Group is obliged to service. CGU-specific risk is incorporated by applying individual beta factors. The beta factors are evaluated annually based on publicly available market data. Adjustments to the discount rate are made to factor in the specific amount and timing of the future tax flows in order to reflect a pre-tax discount rate.

An increase in the discount rate to 9.4% (i.e., +1.5%point) in the CGU External Product Sales of JPT Peptide Technologies GmbH would result in a goodwill impairment as of October 1, 2020. With respect to the CGU Immunotherapies, no reasonable rise in the discount rate would result in an impairment.

**Growth rate estimates** – Rates are based on published industry research. Management recognizes that the speed of technological change and the possibility of new entrants (further market approvals) can have a significant impact on growth rate assumptions. The effect of new entrants is not expected to have an adverse impact on the forecasts, but could yield a reasonably possible alternative to the estimated long-term growth rate of 1.0%.

With respect to both CGUs, no reasonable reduction in the growth rate estimate would result in an impairment.

In general, BioNTech concluded that no reasonable possible change of key assumptions on which the calculation of the recoverable amount is based would cause the carrying amount of the CGU to exceed its recoverable amount.

#### Intangible Assets not yet Available for Use

Intangible assets not yet available for use did not exist in the years ended December 31, 2020 and December 31, 2019.

#### Non-Current assets by Region

As of December 31, 2020 and December 31, 2019, non-current assets comprised €89.2 million respectively €3.8 million intangible assets, property, plant and equipment, right-of-use assets and other assets of our subsidiaries incorporated in the United States respectively. The remaining non-current assets relate to subsidiaries incorporated in Germany.

## 12 Financial Assets and Financial Liabilities

### 12.1 Capital Risk Management

BioNTech's capital management objectives are designed primarily to finance the Group's growth strategy.

The Group's controlling committee reviews the total amount of cash of the Group on a weekly basis. As part of this review, the committee considers the total cash and cash equivalents, the cash outflow, currency translation differences and

refinancing activities. The Group monitors cash using a burn rate. The cash burn rate is defined as the average monthly net cash flow from operating and investing activities during a financial year.

<i>(in thousands)</i>	December 31, 2020	December 31, 2019
Cash and cash equivalents at banks and on hand	€1,210,209	€519,149
<b>Total</b>	<b>€1,210,209</b>	<b>€519,149</b>

In meeting its financing objectives, the Group negotiates and enters into research cooperation agreements. In general, the aim is to maximize the financial resources available for further research and development projects.

BioNTech is not subject to externally imposed capital requirements. BioNTech's capital management objectives were achieved in the reporting year.

No changes were made in the objectives, policies or processes for managing cash during the years ended December 31, 2020 and December 31, 2019.

## 12.2 Categories of Financial Instruments

### Financial assets at amortized cost

Set out below, is an overview of financial assets, other than cash and cash equivalents, held by the Group as of the dates indicated:

<i>(in thousands)</i>	December 31, 2020	December 31, 2019
Trade receivables	€165,468	€11,913
Other financial assets	137,234	1,680
<b>Total</b>	<b>€302,702</b>	<b>€13,593</b>
Total current	302,702	13,593
Total non-current	-	-

As of December 31, 2020, other financial assets mainly include advance-payments received by BioNTech's collaboration partner on future deliveries and payable to BioNTech.

### Financial liabilities: Financial liabilities at amortized cost (including Interest-bearing loans and borrowings and other financial liabilities)

Set out below, is an overview of financial liabilities, other financial liabilities and trade payables held by the Group as of the dates indicated:

### Interest-bearing loans and borrowings

<i>(in thousands)</i>	Maturity	December 31, 2020	December 31, 2019
Lease liabilities		€84,158	€57,611
Convertible note - host contract	08/28/2024	87,457	-
3.50% € 50,000,000 secured bank loan	12/21/2026	47,176	-
2.15% € 10,000,000 secured bank loan	12/30/2027	9,032	9,000
2.08% € 9,450,000 secured bank loan	09/30/2028	8,877	7,600
1.90% € 3,528,892.48 secured bank loan	05/30/2039	3,489	-
<b>Total</b>		<b>€240,189</b>	<b>€74,211</b>
Total current		9,142	5,307
Total non-current		231,047	68,904

**Other financial liabilities**

<i>(in thousands)</i>	<b>December 31, 2020</b>	<b>December 31, 2019</b>
<b>Derivatives not designated as hedging instrument</b>		
Convertible note - embedded derivative	€30,903	-
<b>Financial liabilities at fair value through profit or loss</b>		
Contingent consideration	572	-
<b>Total financial liabilities at fair value</b>	<b>€31,475</b>	<b>-</b>
<b>Other financial liabilities at amortized cost, other than interest-bearing loans and borrowings</b>		
Trade payables	102,288	20,498
Other financial liabilities	74,076	10,352
<b>Total other financial liabilities at amortized cost, other than interest-bearing loans and borrowings</b>	<b>€176,364</b>	<b>€30,850</b>
<b>Total other financial liabilities</b>	<b>€207,839</b>	<b>€30,850</b>
Total current	176,363	30,850
Total non-current	31,476	-

**Total financial liabilities**

<i>(in thousands)</i>	<b>December 31, 2020</b>	<b>December 31, 2019</b>
Interest-bearing loans and borrowings	€240,189	€74,211
Other financial liabilities	€207,839	€30,850
<b>Total</b>	<b>€448,028</b>	<b>€105,061</b>
Total current	185,505	36,157
Total non-current	262,523	68,904

**Interest-Bearing Loans and Borrowings***2.15% and 2.08% Secured Bank Loan*

BioNTech maintains two secured loans with Deutsche Bank AG, or Deutsche Bank, to finance the buildouts of the JPT Peptide Technologies GmbH facility and BioNTech Innovative Manufacturing Services GmbH facility. The €10.0 million secured credit facility, entered into with Deutsche Bank by the subsidiary BioNTech Innovative Manufacturing Services GmbH, bears interest at a rate of 2.15% and matures on December 30, 2027. The loan is repayable in equal quarterly installments of €0.3 million commencing on June 30, 2020. As of December 31, 2020, the full amount under this facility is drawn down and the first three scheduled repayments have occurred. The €9.45 million secured credit facility, entered into with Deutsche Bank by the subsidiary JPT Peptide Technologies GmbH, bears interest at a rate of 2.08% and matures on September 30, 2028. The loan is repayable by quarterly installments of €0.3 million commencing on September 30, 2020. As of December 31, 2020, the full amount under this facility is drawn down and the first two scheduled repayments have occurred. Each of these facilities is secured by liens over property.

*EIB Manufacturing Financing – 3.50% Secured Bank Loan*

In June 2020, BioNTech entered into an agreement with the EIB for a €100.0 million credit facility to partially support the development of BNT162 and fund expansion of the manufacturing capacity to provide worldwide supply of BNT162 in response to the COVID-19 pandemic. The credit consists of (i) a term loan in the amount of €50 million that may be drawn in a single tranche upon the achievement of certain milestone events (Credit A), and (ii) a term loan in the amount of €50.0 million that may be drawn in a single tranche (Credit B). Credit B may only be drawn down after Credit A has been drawn down and upon the achievement of certain milestone events. The financing arrangement is to be secured by way of liens over certain of our property. On December 21, 2020, €50.0 million from Credit A was drawn down. Interest is payable on the outstanding balance of Credit A at the cash interest fixed rate of 1% per annum quarterly in arrears, plus deferred interest at fixed rate of 2.5% per annum. The nominal amount must be repaid on December 21, 2026.

A fund associated with Temasek Capital Management Pte. Ltd., or Temasek, and another accredited investor, contributed a private investment which closed as of August 28, 2020 following the satisfaction of customary closing conditions. The private placement includes an investment in ordinary shares (see Note 16) and a €100.0 million investment in a 4-year mandatory convertible note with a coupon of 4.5% per annum and a conversion premium of 20% above its reference price. As of closing, the convertible note has been classified as a financial liability according to IAS 32 because the conversion features of the note lead to a conversion into a variable number of shares and is measured at amortized costs since the fair value option was not applied. On initial recognition, the financial liability was measured at the present value of the contractually determined future cash flows discounted at the effective interest rate of 9.0%. The financial liability is subsequently measured at amortized cost by using the effective interest rate method until extinguished upon conversion. The conversion features provided for in the contract were identified as a combined embedded derivative since they share the same risk exposure and are interdependent. The embedded derivative was bifurcated from the convertible note, as host contract, and is recognized as a separate financial instrument. Based on the classification as derivative, the instrument is measured at fair value through profit and loss until it is extinguished upon conversion. The fair value of the embedded derivative is determined by modeling the stock price movement using the Cox-Rubinstein binomial tree model to derive the value of the conversion right. The primary inputs used in the model include stock price volatility, credit spreads, risk-free interest rate and foreign exchange forward rates. Stock price volatility is based on implied volatility for BioNTech, credit risk is model implied and adjusted for movement in credit spreads for B-rated corporates at each valuation date, the risk-free interest rate is based on currency specific time congruent IBOR and swap rates whereas the foreign exchange forward rates are based on observable market data.

#### **Other Financial Liabilities at Amortized Cost**

Other financial liabilities at amortized cost mainly include provision for outstanding services and obligations derived from license agreements as well as CRO and CMO contracts.

#### **12.3 Fair Values**

Fair values of cash and cash equivalents, trade receivables, trade payables and other current financial assets and liabilities approximate their carrying amounts as of December 31, 2020, largely due to the short-term maturities of these instruments.

The liabilities measured at amortized cost include four fixed-interest rate loans as well as a recently issued convertible note. As of December 31, 2020, the carrying value approximates their fair values as there have been no significant changes in relevant interest rates since the inception of the respective loans and note.

The fair values of financial instruments measured at fair value are reassessed on a quarterly basis. The valuation technique used for measuring the fair value of the embedded derivative is based on significant observable inputs (Level 2).

During the year ended December 31, 2020, the fair value adjustment derived from remeasuring the embedded derivative was recognized as finance expenses in profit or loss and amounted to €17.3 million. The initial fair value of the contingent consideration determined at acquisition remains valid since no changes of the underlying performance criteria have occurred.

#### **12.4 Financial Instruments Risk Management Objectives and Policies**

The Group's financial liabilities comprise of bank loans, lease liabilities, trade and other payables as well as the recently issued convertible note. The main purpose of these financial liabilities is to enable the Group's operations. The Group's principal financial assets include mainly cash and trade receivables that derive directly from its operations.

The Group is exposed to market risk, credit risk and liquidity risk. The Group's Management Board oversees the management of these risks.

The controlling committee provides assurance to the Group's Management Board that the Group's financial risk activities are governed by appropriate policies and procedures and that financial risks are identified, measured and managed in accordance with the Group's policies and risk objectives. The Management Board reviews and agrees policies for managing each of these risks, which are summarized below.

## 12.5 Market Risk

Market risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate due to changes in market prices. Market risk comprises of three types of risk: interest risk, foreign currency risk and other price risk. Financial instruments affected by market risk include cash and cash equivalents. Interest risk as well as other price risk are not considered as risks for the Group.

The sensitivity analysis in the following sections relate to the position as of December 31, 2020 and December 31, 2019.

There were no material changes in the Group's market risk exposures or changes in the way risk was managed and valued during the periods.

### Foreign Currency Risk

Foreign currency risk is the risk that the fair value or future cash flows of an exposure will fluctuate because of changes in foreign exchange rates. The Group's exposure to the risk of changes in foreign currency rates relates primarily to the Group's operating activities (when revenue or expense is denominated in a foreign currency).

In order to reduce exchange rate risk, BioNTech makes every effort to generate expenses and income in the same functional currency. The Group does not hedge exchange rate risks.

The carrying amount of the monetary assets (the Group's cash and cash equivalents) of BioNTech denominated in foreign currencies at the dates indicated are as follows:

<i>(in thousands)</i>	December 31, 2020	December 31, 2019
U.S. dollar Bank accounts	€673,545	€213,913
Other financial assets in U.S. dollar	85,573	-
Financial liabilities in U.S. dollar	72,821	-
<b>Total</b>	<b>€686,297</b>	<b>€213,913</b>

The following tables demonstrate the sensitivity to a reasonably possible change in U.S. dollar exchange rates, with all other variables held constant. The impact on the Group's profit before tax is due to changes in the fair value of monetary assets. The Group's exposure to foreign currency changes for all other currencies is not material.

Currency	Country	1 € =		Closing rate		Average rate	
				2020	2019	2020	2019
U.S. dollar	United States			1.2271	1.1234	1.1422	1.1195

<i>(in thousands)</i>	Change in U.S. dollar rate	Effect on loss before tax	Effect on pre-tax equity
2020	+5 %	€(32,491)	€(32,681)
2020	-5%	€35,911	€36,121
2019	+5 %	€(10,186)	€(10,186)
2019	-5%	€11,259	€11,259

## 12.6 Credit Risk Management

Credit risk is the risk that a counterparty will not meet its obligations under a financial instrument or customer contract, leading to a financial loss. The Group is exposed to credit risk from its operating activities, including deposits with banks and financial institutions, foreign exchange transactions and trade accounts receivable.

### Trade Receivables and Contract Assets

The Group's exposure to credit risk of trade receivables and contract assets is primarily on transactions with corporate customers in the biopharma/biotech industry that operate in Germany or in the United States as well as governments which are BioNTech's customers established in connection with progressing the commercial activities of the Group with respect to BioNTech's COVID-19 vaccine. An analysis of the aging of receivables and the creditworthiness of

customers is used to evaluate this risk at each reporting date. The Group follows risk control procedures to assess the credit quality of the customers taking into account their financial position, past experience and other factors. The compliance with credit limits by corporate customers is regularly monitored by BioNTech.

As of December 31, 2020, the outstanding trade receivables were mainly due from BioNTech's collaboration partner Pfizer as well as the German government. To a smaller extent, BioNTech's other customers are medical universities, other public institutions and peers in the biopharma industry, which all have a very high credit rating. Due to this customer portfolio, the credit risk on trade receivables and contract assets is very low. BioNTech has not incurred bad debt expense and does not expect that this will change with respect to the trade receivables recognized as of December 31, 2020.

Generally, trade receivables are written off if past due for more than one year and are not subject to enforcement activity. The maximum exposure to credit risk at the reporting date is the carrying value of each class of financial assets disclosed in Note 12.2. The expected credit risk on trade accounts receivables and other financial assets was estimated to be not material as of December 31, 2020 as well as December 31, 2019. The Group does not hold collateral as security.

#### **Cash and Cash Equivalents**

Credit risk from balances with banks and financial institutions is managed by the Group's controlling department in accordance with the Group's policy.

Credit risk stemming from cash and cash equivalents is very low due to its demand feature and the high credit rating of the respective banks.

The Group's maximum exposure to credit risk for the components of the consolidated statements of financial position as of December 31, 2020 and December 31, 2019 are the carrying amounts as illustrated in Note 12.1.

#### **12.7 Liquidity Risk**

Generally, BioNTech has relied on the financing from shareholders and collaborators in order to ensure sufficient liquidity. Lack of external financial support could pose a risk of going concern. The liquidity management of BioNTech ensures the availability of cash and cash equivalents for operational activities and further investments through appropriate budget planning. In addition, a sufficient level of cash and cash equivalents, which is managed centrally, is always maintained to finance the operational activities.

The Group monitors liquidity risks using a liquidity planning tool.

Ultimately, the responsibility for liquidity risk management lies with the Management Board, which has established an appropriate approach to managing short-, medium- and long-term financing and liquidity requirements. BioNTech manages liquidity risks by holding appropriate reserves, as well as by monitoring forecasted and actual cash flows and reconciling the maturity profiles of financial assets and liabilities.

#### **Risk Concentration**

Concentrations arise when a number of counterparties are engaged in similar business activities, or activities in the same geographical region, or have economic features that would cause their ability to meet contractual obligations to be affected similarly by changes in economic, political or other conditions. Concentrations indicate the relative sensitivity of the Group's performance to developments affecting a particular industry.

In order to avoid concentrations of risk, the Group's policies and procedures include specific guidelines to focus on the maintenance of an effective diversification in the sources of funding and distribution of cash deposits. Identified concentrations of credit risks are controlled and managed accordingly.

The maturity profile of the Group's financial liabilities based on contractual undiscounted payments is summarized as follows:

**Year ended December 31, 2020**

<i>(in thousands)</i>	Less than 1 year	1 to 5 years	More than 5 years	Total
Interest bearing loans and borrowings	€3,173	€12,643	€66,730	€82,546
Trade and other payables	102,288	-	-	€102,288
Lease liabilities	8,525	27,283	71,780	€107,588
Contingent consideration	-	-	572	€572
Other financial liabilities	74,076	-	-	€74,076
<b>Total</b>	<b>€188,062</b>	<b>€39,926</b>	<b>€139,082</b>	<b>€367,070</b>

The mandatory convertible note, which was issued during the year ended December 31, 2020 and which is expected to be settled in equity is excluded from the table above.

**12.8 Changes in Liabilities arising from Financing Activities**

**Year ended December 31, 2020**

<i>(in thousands)</i>	January 1, 2020	Cash flows	Acquisition of subsidiaries and businesses	New leases and disposals	Reclassification	Other	December 31, 2020
Current obligations under lease contracts	€3,485	€(12,743)	€2,719	€8,684	€3,982	-	€6,127
Non-current obligations under lease contracts	54,126	-	32,331	(4,444)	(3,982)	-	78,031
Interest-bearing loans and borrowings	16,600	140,847	-	-	-	(1,416)	156,031
Convertible note - embedded derivative	-	13,614	-	-	-	17,289	30,903
<b>Total</b>	<b>€74,211</b>	<b>€141,718</b>	<b>€35,050</b>	<b>€4,240</b>	<b>-</b>	<b>€15,873</b>	<b>€271,092</b>

**Year ended December 31, 2019**

<i>(in thousands)</i>	January 1, 2019	Cash flows	Acquisition of subsidiaries and businesses	New leases and disposals	Reclassification	Other	December 31, 2019
Current obligations under lease contracts	€2,134	€(3,061)	-	€1,484	€2,928	-	€3,485
Non-current obligations under lease contracts	48,618	-	-	8,436	(2,928)	-	54,126
Interest-bearing loans and borrowings	5,600	11,000	-	-	-	-	16,600
<b>Total</b>	<b>€56,352</b>	<b>€7,939</b>	<b>-</b>	<b>€9,920</b>	<b>-</b>	<b>-</b>	<b>€74,211</b>

**13 Inventories**

<i>(in thousands)</i>	December 31, 2020	December 31, 2019
Raw materials and supplies	€44,283	€8,201
Unfinished goods	19,380	2,888
Finished goods	457	633
<b>Total</b>	<b>€64,120</b>	<b>€11,722</b>

BioNTech has not pledged any inventories as securities for liabilities.

**14 Other Assets**

<i>(in thousands)</i>	<b>December 31, 2020</b>	<b>December 31, 2019</b>
Prepayments on inventories	29,845	351
Prepayments related to CRO and CMO contracts	14,140	-
Sales tax receivable	4,155	7,536
Prepayments related to service contracts	3,825	-
Other	10,046	1,182
<b>Total</b>	<b>€62,011</b>	<b>€9,069</b>
Total current	60,966	9,069
Total non-current	1,045	-

**15 Deferred Expenses**

<i>(in thousands)</i>	<b>December 31, 2020</b>	<b>December 31, 2019</b>
Deferred expenses from insurance contracts	€13,845	€1,758
Deferred expenses from CRO and CMO contracts	5,725	-
Other	8,431	4,104
<b>Total</b>	<b>€28,001</b>	<b>€5,862</b>
Total current	28,001	5,862
Total non-current	-	-

**16 Issued Capital and Reserves**

On September 18, 2019, BioNTech effected a 1:18 share split by issuing 206,595,492 shares by way of a capital increase from its own funds; thus, no outside proceeds were received. This capital increase came into effect upon registration with the commercial register (*Handelsregister*). The accompanying consolidated financial statements and notes to the consolidated financial statements give retroactive effect to the share split for all periods presented.

**Capital transactions during the year ended December 31, 2020**

During the year ended December 31, 2020, the issued share capital of BioNTech increased by €14.0 million. Each share has a nominal value of €1.00. As a result of the financing transactions, treasury shares decreased by €0.7 million and capital reserve increased by €861.0 million. Costs of €33.2 million related to these equity transactions were recorded in equity as deduction from the capital reserve. The financing transactions that occurred during year ended December 31, 2020 were as follows:

*Shanghai Fosun Pharmaceuticals (Group) Co., Ltd*

As part of the BNT162 program, BioNTech entered a strategic alliance with Fosun Pharma to develop COVID-19 vaccine candidates in China. Fosun Pharma agreed to make an equity investment of €45.6 million (\$50.0 million) for 1,580,777 ordinary shares in BioNTech via Fosun Industrial Co., Limited, Hong Kong. The increase in share capital with a nominal amount of €1.6 million was subject to execution of share subscription documentation and approval from regulatory authorities in China and became effective with the registration with the commercial register (*Handelsregister*) on April 23, 2020. As a result of the transaction the capital reserve increased by €44.0 million.

*Pfizer Inc., New York, New York, United States*

As part of the collaboration between BioNTech and Pfizer, for the co-development of BNT162, Pfizer agreed to make an equity investment of €103.9 million (\$113.0 million). The issuance of 2,377,446 ordinary shares with the nominal amount of € 2.4 million was registered with the commercial register (*Handelsregister*) on May 5, 2020. As a result of the transaction the capital reserve increased by €101.5 million.

*Neon Therapeutics, Inc., Cambridge, Massachusetts, United States*

BioNTech acquired Neon by issuing 1,935,488 ADS representing BioNTech's ordinary shares with the nominal amount of € 1.9 million to former stockholders of Neon in the Merger. The capital increase was registered with the



commercial register (*Handelsregister*) on May 8, 2020. As a result of the transaction the capital reserve increased by €87.6 million.

#### *Global Offering*

On July 27, 2020 BioNTech increased its share capital by €5.5 million (\$6.4 million) in conjunction with the underwritten offering of 5,500,000 ADS each representing one of BioNTech's ordinary shares at a public offering price of \$93.00 per ADS ("Underwritten Offering"). On August 27, 2020, following the Underwritten Offering, BioNTech increased its share capital by additional €16 thousand (\$19 thousand) in conjunction with the rights offering of 16,124 ADS each representing one of BioNTech's ordinary shares at a public offering price of \$93.00 per ADS ("Rights Offering"). The Underwritten Offering and the Rights Offering are part of a single, global offering which BioNTech refers to as the Global Offering. The gross proceeds of the Global Offering were €436.3 million (\$513.0 million) including €5.5 million increase in share capital and €430.8 million increase in capital reserve.

#### *June 2020 Private Placement – Equity Investment*

A fund associated with Temasek Capital Management Pte. Ltd., or Temasek, and another accredited investor, contributed a private investment. The private placement includes an investment in a 4-year mandatory convertible note (see Note 12) and an investment of €123.9 million in ordinary shares. The issuance of 2,595,996 ordinary shares with the nominal amount of € 2.6 million was registered with the commercial register (*Handelsregister*) on September 8, 2020. As result of the transaction the capital reserve increased by €121.3 million.

#### *At-The-Market Offering Program*

In November 2020, BioNTech entered into a sales agreement ("Sales Agreement") with Jefferies LLC and SVB Leerink LLC, as sales agents, to establish an at-the-market offering program, pursuant to which BioNTech may sell, from time to time, ADS representing ordinary shares for aggregate gross proceeds of up to \$500.0 million. During the year ended December 31, 2020, BioNTech sold 735,490 ADSs, each representing one of its ordinary shares that had previously been held in treasury, under the Sales Agreement for aggregate gross proceeds of €76.5 million (\$92.9 million). Re-issuing 735,490 ordinary shares was registered as decrease of €0.7 million in treasury shares. As a result of the transaction the capital reserve increased by €75.8 million.

#### **Capital transactions during the year ended December 31, 2019**

During the year ended December 31, 2019, the issued share capital of BioNTech increased by €39.0 million. Each share has a nominal value of €1.00. As a result of the financing transactions the capital reserve increased by €359.2 million. Costs of €16.6 million related to these equity transactions were recorded in equity as deduction from the capital reserve.

In January 2019, BioNTech issued 5,088,204 shares and increased its share capital by €5.1 million. The cash investment of €80.0 million was received in 2018.

As of March 14, 2019, BioNTech acquired the remaining 5.5% of non-controlling interests in BioNTech Cell & Gene Therapies GmbH previously held by Eli Lilly Nederland B.V. in exchange for issuing 2,374,794 new ordinary shares with an imputed nominal value of €1.00 each. This acquisition was recognized within equity and resulted in the derecognition of the non-controlling interest of €0.7 million as well as an increase in share capital of €2.4 million. The net effect of the transaction of €1.6 million was recognized as a decrease in capital reserve.

Of the share capital issued in 2019, €12.5 million related to a new financing round (referred to as the Series B round). As part of the Series B round, 12,465,288 ordinary shares (excluding 5,524,506 ordinary shares which were issued to a Hong Kong-based investor and subsequently transferred to BioNTech for no consideration; these shares are held as treasury shares) were issued to certain new and existing shareholders. As a result of the Series B round, the capital reserve increased by €186.1 million.

On August 30, 2019, BioNTech entered into agreements with the Bill & Melinda Gates Foundation under which BioNTech is required to perform certain research and development activities. The issuance of 3,038,674 ordinary shares with the nominal amount of €3.0 million was registered with the commercial register (*Handelsregister*) on September 26, 2019. As result of the transaction the capital reserve increased by €46.8 million.

On October 10, 2019, BioNTech increased its share capital by €10.0 million in conjunction with the Initial Public Offering. American Depositary Shares which represent ordinary shares were offered on the Nasdaq Global Select Market at

a price of \$15.00. On November 6, 2019, BioNTech increased its share capital by €0.5 million upon the execution of the underwriter's option. American Depositary Shares which represent ordinary shares were issued at a price of \$15.00 (under both issuances). The gross proceeds were €143.3 million (\$157.8 million) including €10.5 million increase in share capital and €132.7 million increase in capital reserve.

## 17 Share-Based Payments

During the years ended December 31, 2020, December 31, 2019 and December 31, 2018, the Group had the following share-based arrangements.

### 17.1 BioNTech Employee Equity Plan (LTI and LTI-plus Program) (Equity-Settled)

In December 2020, BioNTech adopted the BioNTech Employee 2020 Equity Plan and the BioNTech 2020 Restricted Stock Unit Plan for North America Employees. Under the plans Restricted Cash Units, or RSUs, will be offered to employees based in Europe and the United States respectively. The plan to which employees based in Europe will be eligible, was communicated in December 2020. Since those employees obtained a valid expectation of the award as of the announcement date and started rendering services as of such date, BioNTech concluded that the service commencement date for the BioNTech Employee 2020 Equity Plan was December 17, 2020. This is the date as of which BioNTech started to recognize the expenses related to the services received. Since the BioNTech 2020 Restricted Stock Unit Plan for North America Employees had not been communicated in detail to employees based in the United States during the year ended December 31, 2020, no expenses have been recognized in the Consolidated Statements of Operations for the year ended December 31, 2020.

#### *BioNTech Employee 2020 Equity Plan for employees based in Europe*

##### Description of Share-Based Payments

The BioNTech Employee 2020 Equity Plan share-based payment transaction for employees based in Europe includes two programs, LTI and LTI-plus. The LTI program will be offered to all employees. The LTI-plus program intends to compensate employees who did not participate in the ESOP. Under both programs, RSUs will be offered to employees based in Europe. Both programs are classified as equity-settled because BioNTech has the ability to determine the method of settlement. The LTI will vest annually in equal installments after four years commencing on December 15, 2020. The LTI-plus will vest annually in equal installments after two years commencing on December 15, 2020. Moreover, the LTI-plus contains a non-vesting condition concerning 50% of the granted RSUs. These units will be awarded to the participant after the FDA fully approves BNT162b2.

##### Measurement of Fair Values

BioNTech estimates the grant date fair value of the awards for services received in advance of grant date based upon the share-price at the reporting date. The estimate is revised at subsequent reporting periods until the date of grant has been established (refer to Note 22). An estimate for the number of equity instruments for which service conditions are expected to be satisfied is calculated considering a retention assumption and will be revised in case material differences arise. Ultimately, a true-up to the number satisfied until Settlement Date will be recorded.

##### Reconciliation of Outstanding Share-Options

	Restricted Stock Units (expected to be allocated)	Share price (in €)
As of January 1, 2020	-	-
Expected to be allocated under LTI Program	252,766	66.43
Expected to be allocated under LTI-plus Program	396,938	66.43
<b>As of December 31, 2020</b>	<b>649,704</b>	<b>66.43</b>

**Expense recognized in the Consolidated Statements of Operations**

<i>(in thousands)</i>	<b>Year ended December 31,</b>	<b>2020</b>
Cost of sales		€179
Research and development expenses		681
Sales and marketing expenses		8
General and administrative expenses		147
<b>Total</b>		<b>€1,015</b>

**17.2 Management Board Grant (Cash-Settled)**

Since the beginning of 2020, the first year following the completion of BioNTech's initial public offering ("IPO"), the current service agreements with BioNTech's Management Board have provided for a short-term incentive compensation of up to a maximum of fifty percent of the annual base salary for the years 2020, 2021 and 2022. The amount of such short-term incentive compensation will depend on the achievement of certain company goals in the particular fiscal year, which goals will be set uniformly for all members of the Management Board. Fifty percent of the incentive compensation will be paid promptly upon achievement of the applicable company goals (first installment), with the remaining amount payable one year later, subject to adjustment relative to the performance of the price of the American Depositary Shares representing BioNTech's ordinary shares during that year (second installment).

For each of the three yearly awards, the second installment of the short-term incentive compensation that is dependent on the price of the American Depositary Shares representing BioNTech's ordinary shares, represents a cash-settled share-based payment arrangement. The fair values of the liabilities are recognized over the award's vesting period beginning as of the service commencement date (January 1, 2020) until each separate determination date and are remeasured until settlement date.

During the year ended December 31, 2020, the Group recognized share-based payment expenses of €0.3 million as research and development expenses and of €0.4 million as general and administrative expenses in the consolidated statements of operations and €0.7 million of other financial liabilities in the statements of financial position as of December 31, 2020.

**17.3 Management Board Grant (Equity-Settled)**

**Description of Share-Based Payments**

From the beginning of 2020, the first year following the completion of BioNTech's IPO, until the end of the term of the Management Board member's employment agreement, the service agreements with BioNTech's Management Board provide for a long-term incentive compensation in terms of a yearly grant of options to purchase BioNTech shares. The right to receive options in 2020, 2021 and 2022 represents an equity-settled share-based payment arrangement.

The options allocated each year will be subject to the terms, conditions, definitions and provisions of the ESOP and the applicable option agreement thereunder. The number of options to be allocated each year to Prof. Ugur Sahin, Sean Marett, Dr. Sierk Poetting, Dr. Özlem Türeci and Ryan Richardson is to be calculated based on a value of €750,000, €300,000, €300,000, €300,000 and €260,000, respectively, in each case divided by the amount by which a certain target share price exceeds the exercise price. The value used to calculate the number of options for Ryan Richardson increases to €280,000 for the year 2022.

The allocation of the number of issued options in 2020 occurred as of February 13, 2020 (allocation date). As of December 31, 2020, the assessment about options expected to be granted in 2021 and 2022 was based on estimated allocation dates in the middle of the years 2021 and 2022, respectively.

The share options allocated and expected to be allocated to BioNTech's Management Board as of the dates indicated are presented in the tables below.

	Share options (expected to be allocated)	Weighted-average exercise price (€)
As of January 1, 2020	-	-
Granted as of allocation date February 13, 2020	248,096	28.32
Expected to be allocated as of estimated allocation date 2021	101,422	67.26*
Expected to be allocated as of estimated allocation date 2022	102,463	67.27*
<b>As of December 31, 2020</b>	<b>451,981</b>	<b>45.89</b>

\*Valuation parameter derived from the Monte-Carlo simulation model

For the awards with estimated allocation dates the numbers of options expected to be allocated have been derived from the Monte-Carlo simulation model. Those will be adjusted until the actual allocation has occurred and the number of options granted has ultimately been determined. The options will vest annually in equal installments over four years commencing on the first anniversary of the allocation date and will be exercisable four years after the allocation date.

The options will be subject to the terms, conditions, definitions and provisions of the ESOP and the applicable option agreement thereunder. The vested options can only be exercised if and to the extent that each of the following performance criteria has been achieved: (i) at the time of exercise, the current price is equal to or greater than the threshold amount (that is, the exercise price, provided that such amount increases by seven percentage points on each anniversary of the allocation date); (ii) at the time of exercise, the current price is at least equal to the target price (that is, (a) for the twelve-month period starting on the fourth anniversary of the allocation date, \$8.5 billion divided by the total number of the ordinary shares outstanding immediately following the initial public offering (other than ordinary shares owned by BioNTech), and (b) for each twelve-month period starting on the fifth or subsequent anniversary of the allocation date, 107% of the target share price applicable for the prior twelve-month period); and (iii) the closing price for the fifth trading day prior to the start of the relevant exercise window is higher than the exercise price by at least the same percentage by which the Nasdaq Biotechnology Index or a comparable successor index as of such time is higher than such index was as of the last trading day before the allocation date. The options expire ten years after the allocation date. If they have not been exercised by that date, they will lapse without compensation.

#### Measurement of Fair Values

A Monte-Carlo simulation model has been used to measure the fair values at the (estimated) allocation dates of the Management Board Grant. This model incorporates the impact of the performance criteria regarding share price and index development described above. The parameters used for measuring the fair values as of the respective (estimated) allocation dates were as follows:

	Allocation date February 13, 2020	Estimated allocation date 2021	Estimated allocation date 2022
Weighted average fair value*	€10.83	€26.85	€26.61
Weighted average share price	€28.20	€ 66.43*	€ 66.43*
Exercise price	€28.32	€ 67.26*	€ 67.27*
Expected volatility (%)	36.6%	41.0%	40.7%
Expected life (years)*	4.75	5.01	6.05
Risk-free interest rate (%)	1.61 %	0.88%	0.88%

\*Valuation parameter derived from the Monte-Carlo simulation model

The exercise of the option rights in accordance with the terms of the ESOP gives the Management Board members the right to obtain shares against payment of the exercise price. The per share exercise price of the options is the Euro equivalent of the arithmetic mean of the closing prices of the ten last trading days prior to the allocation date. For the award allocated as of February 13, 2020, the exercise price has been determined to be \$30.78 (€28.32). For the awards with estimated allocation dates the exercise prices of options expected to be allocated have been derived from the Monte-Carlo simulation model. Those will be adjusted until the actual allocation has occurred and the exercise price has ultimately been

determined. Expected volatility was based on an evaluation of the historical volatilities of comparable companies over the historical period commensurate with the expected option term. The expected term was based on general optionholder behavior for employee options.

#### Reconciliation of Outstanding Share-Options

The share options allocated and expected to be allocated under the Management Board Grant were as follows:

Allocation date February 13, 2020	Share options outstanding	Weighted-average exercise price (€)
Prof. Ugur Sahin, M.D.	97,420	28.32
Sean Marett	38,968	28.32
Dr. Sierk Poetting	38,968	28.32
Dr. Özlem Türeçci, M.D.	38,968	28.32
Ryan Richardson	33,772	28.32

Estimated allocation date 2021	Share options outstanding (expected to be allocated)	Weighted-average exercise price (€)
Prof. Ugur Sahin, M.D.	39,826	67.26*
Sean Marett	15,930	67.26*
Dr. Sierk Poetting	15,930	67.26*
Dr. Özlem Türeçci, M.D.	15,930	67.26*
Ryan Richardson	13,806	67.26*

\*Valuation parameter derived from the Monte-Carlo simulation model

Estimated allocation date 2022	Share options outstanding (expected to be allocated)	Weighted-average exercise price (€)
Prof. Ugur Sahin, M.D.	39,817	67.27*
Sean Marett	15,927	67.27*
Dr. Sierk Poetting	15,927	67.27*
Dr. Özlem Türeçci, M.D.	15,927	67.27*
Ryan Richardson	14,865	67.27*

\*Valuation parameter derived from the Monte-Carlo simulation model

As of December 31, 2020, the share options allocated and expected to be allocated had a remaining weighted-average expected life of 4.63 years.

#### Expense recognized in the Consolidated Statements of Operations

The expenses recognized for employee services received during the periods indicated are shown in the following table:

<i>(in thousands)</i>	Year ended	
	December 31,	
	2020	2020
Research and development expenses		€1,514
General and administrative expenses		1,246
<b>Total</b>		<b>€2,760</b>

#### 17.4 Chief Executive Officer Grant (Equity-Settled)

##### Description of Share-Based Payments

In September 2019, BioNTech granted Prof. Ugur Sahin, M.D. an option to purchase 4,374,963 ordinary shares, subject to Prof. Sahin's continuous employment with BioNTech. The options' exercise price per share is the Euro translation of the public offering price from BioNTech's initial public offering, €13.60 (\$15.00). The option vests annually in equal installments after four years commencing on the first anniversary of the initial public offering and will be exercisable four years after the initial public offering. The option is subject to the terms, conditions, definitions and provisions of the ESOP and the applicable option agreement thereunder. The vested option rights can only be exercised if and to the extent that each of the following performance criteria has been achieved: (i) at the time of exercise, the current price is equal to or greater than the threshold amount (that is, the exercise price, provided that such amount increases by seven percentage points on each anniversary of the allocation date); (ii) at the time of exercise, the current price is at least equal to the Target Price (that is, (a) for the twelve-month period starting on the fourth anniversary of the allocation date, \$8.5 billion divided by the total number of the shares outstanding immediately following the initial public offering (other than shares owned by BioNTech), and (b) for each twelve-month period starting on the fifth or subsequent anniversary of the allocation date, 107% of the target share price applicable for the prior twelve-month period); and (iii) the closing price for the fifth trading day prior to the start of the relevant exercise window is higher than the exercise price by at least the same percentage by which the Nasdaq Biotechnology Index or a comparable successor index as of such time is higher than such index was as of the last trading day before the allocation date. The option rights can be exercised up to ten years after the allocation date. If they have not been exercised by that date, they will lapse without compensation.

##### Measurement of Fair Values

A Monte-Carlo simulation model has been used to measure the fair value at grant date of the Chief Executive Officer Grant. This model incorporates the impact of the performance criteria regarding share price and index development described above in the calculation of the award's fair value at grant date. The inputs used in the measurement of the fair value at grant date of the Chief Executive Officer Grant were as follows:

	Grant date October 10, 2019
Weighted average fair value	€5.63
Weighted average share price	€13.60
Exercise price	€13.60
Expected volatility (%)	41.4%
Expected life (years)	5.37
Risk-free interest rate (%)	1.52 %

Expected volatility was based on an evaluation of the historical volatilities of comparable companies over the historical period commensurate with the expected term. The expected term was based on general optionholder behavior for employee options.

##### Reconciliation of Outstanding Share-Options

During the year ended December 31, 2020, no further options were granted or forfeited.

As of December 31, 2020, the share options outstanding had a remaining weighted-average expected life of 4.12 years.

##### Expense recognized in the Statement of Operations

During the year ended December 31, 2020, the Group has recognized €11.3 million of share-based payment expenses as research and development expenses in the consolidated statements of operations (during the year ended December 31, 2019: €3.2 million).

#### 17.5 Employee Stock Ownership Plan (Equity-Settled)

##### Description of Share-Based Payments

On November 15, 2018, the Group established a share option program that grants selected employees options to receive shares in the Company. The program is designed as an ESOP. The Group has offered the participants a certain

number of rights (Option Rights) by explicit acceptance of the participants. The exercise of the Option Rights in accordance with the terms of the ESOP, gives the participants the right to obtain shares against payment of the exercise price. The Option Rights vest over four years and can only be exercised if the company has executed a public offering in the United States (IPO) and when the Threshold Amount is met. Threshold Amount means the exercise price provided that such price increases by eight percentage points on the first and then each subsequent anniversary of the Allocation Date (September 26, 2018). The Option Rights can be exercised at the latest eight years after the Allocation Date. If they have not been exercised by that date, they will be forfeited without compensation.

#### Measurement of Fair Values

The fair value of the ESOP has been measured using a binomial model. Service conditions attached to the arrangement were not taken into account in measuring the fair value.

The share options can only be exercised by the grantee if the price of the share is equal or greater to the Threshold Amount as defined in the arrangement. Moreover, the option rights can only be exercised if the IPO has occurred. Both conditions have been incorporated into the fair value at grant date.

The inputs used in the measurement of the fair values at grant date of the ESOP was as follows:

	Grant date 15 November 2018	Grant dates between February 21 - April 3, 2019	Grant dates between April 29 - May 31, 2019	Grant date December 1, 2019
Weighted average fair value	€7.41	€6.93	€7.04	€9.49
Weighted average share price	€14.40	€15.72	€16.03	€19.84
Exercise price	€10.14	€15.03	€15.39	€15.82
Expected volatility (%)	46.0%	46.0%	46.0%	46.0%
Expected life (years)	5.84	6.00	6.00	5.50
Risk-free interest rate (%)	0.05%	0.05%	0.05%	0.05%

Expected volatility has been based on an evaluation of the historical and the implied volatilities of comparable companies over the historical period commensurate with the expected term. The expected term has been based on general option holder behavior for employee options.

#### Reconciliation of Outstanding Share-Options

Set out below is an overview of changes to share options outstanding and number of ordinary shares underlying these options that occurred during the periods indicated:

	Share options outstanding	Number of ordinary shares underlying options	Weighted-average exercise price (€)
As of January 1, 2019	658,109	11,845,962	10.14
Granted	14,511	261,198	15.17
Forfeited	(17,237)	(310,266)	10.85
<b>As of December 31, 2019</b>	<b>655,383</b>	<b>11,796,894</b>	<b>10.23</b>
As of January 1, 2020	655,383	11,796,894	10.23
Forfeited	(9,491)	(170,838)	10.81
<b>As of December 31, 2020</b>	<b>645,892</b>	<b>11,626,056</b>	<b>10.23</b>

As of December 31, 2020, the share options outstanding had a remaining weighted-average expected life of 3.73 years.

The share options outstanding as of December 31, 2020 issued to the Management Board Grant were as follows:

	Share options outstanding	Number of ordinary shares underlying options	Weighted-average exercise price (€)
Prof. Ugur Sahin, M.D.	101,686	1,830,348	10.14
Sean Marett	33,895	610,110	10.14
Dr. Sierk Poetting	33,895	610,110	10.14
Dr. Özlem Türeçci, M.D.	108,463*	1,952,334	10.14
Ryan Richardson**	8,306***	149,508	10.14

\* Options fully vested on March 16, 2019, however these options will not become exercisable until September 16, 2022.

\*\* Ryan Richardson was appointed to the Management Board as Chief Strategy Officer (CSO) and Managing Director on January 12, 2020. The share options granted on November 15, 2018 under the Employee Stock Ownership Plan were granted before his appointment to the Management Board.

\*\*\* Options fully vested on October 10, 2019, however these options will not become exercisable until September 16, 2022.

The expenses recognized for employee services received during the periods indicated are shown in the following table:

(in thousands)	Years ended December 31,		
	2020	2019	2018
Cost of sales	€869	€896	€114
Research and development expenses	11,120	20,016	6,786
Sales and marketing expenses	111	108	13
General and administrative expenses	4,975	6,008	728
<b>Total</b>	<b>€17,075</b>	<b>€27,028</b>	<b>€7,641</b>

## 18 Other Liabilities

(in thousands)	December 31,	
	2020	2019
Liabilities to employees	€24,248	€6,710
Other	4,379	780
<b>Total</b>	<b>€28,627</b>	<b>€7,490</b>
Total current	28,061	7,490
Total non-current	566	-

## 19 Leases

### 19.1 Amounts Recognized in the Consolidated Statements of Financial Position

#### Right-of-Use Assets

The following amounts are presented as right-of-use assets within the consolidated statements of financial position as of the dates indicated:

(in thousands)	December 31,	
	2020	2019
Buildings	€80,875	€54,956
Equipment, tools and installations	3	7
Automobiles	108	55
Production facilities	7,202	-
Advance payments	10,800	-
<b>Total</b>	<b>€98,988</b>	<b>€55,018</b>



Additions to the right-of-use assets during the year ended December 31, 2020 were €22.1 million (during the year ended December 31, 2019: €10.0 million) including advanced payments of €10.8 million related to embedded leases under contract manufacturing agreements that not yet commenced. Since the advanced lease payments have already been settled, the amounts are not included in the lease liability presented below.

#### Lease Liability

The following amounts are included in interest-bearing loans and borrowings as of the dates indicated:

<i>(in thousands)</i>	<b>December 31, 2020</b>	<b>December 31, 2019</b>
Current	€6,127	€3,485
Non-current	78,031	54,126
<b>Total</b>	<b>€84,158</b>	<b>€57,611</b>

The Group has various lease contracts that have not yet commenced as of December 31, 2020. The future lease payments for these non-cancellable lease contracts are €2.8 million for the year 2021 and €10.2 million for the years 2022 and beyond.

Several lease contracts include extension and termination options. These options are negotiated by management to provide flexibility in managing the leased-asset portfolio and align with the Group's business needs. Management exercises significant judgement in determining whether these extension and termination options are reasonably certain to be exercised.

#### 19.2 Amounts Recognized in the Consolidated Statements of Operations

##### Depreciation Charge of Right-of-Use Assets

<i>(in thousands)</i>	<b>2020</b>	<b>Years ended December 31,</b>		<b>2018</b>
		<b>2019</b>	<b>2018</b>	
Buildings	€4,628	€4,614	€2,751	€2,751
Equipment, tools and installations	4	25	60	60
Automobiles	45	40	35	35
Production facilities	1,613	-	-	-
<b>Total depreciation charge</b>	<b>€6,290</b>	<b>€4,679</b>	<b>€2,846</b>	<b>€2,846</b>
Interest on lease liabilities	€2,003	€1,718	€1,721	€1,721
Expense related to short-term leases (included in other expenses)	875	442	431	431
Expense relating to leases of low-value assets that are not short-term leases (included in other expenses)	300	90	90	90
<b>Total amounts recognized in profit or loss</b>	<b>€9,468</b>	<b>€6,929</b>	<b>€5,088</b>	<b>€5,088</b>

#### 19.3 Amounts recognized in the Consolidated Statements of Cash Flows

During the year ended December 31, 2020, the total cash outflow for leases amounted to €14.7 million (during the year ended December 31, 2019: €4.8 million; during the year ended December 31, 2018: €2.3 million).

#### 19.3 Extension Options

The Group has several lease contracts that include extension options. These options are negotiated by management to provide flexibility in managing the leased-asset portfolio and align with the Group's business needs. Management exercises judgement in determining whether these extension options are reasonably certain to be exercised. The undiscounted potential future lease payments, which relate to periods after the exercise date of renewal options and are not included in lease liabilities, amount to up to €38.3 million until 2049.

## 20 Pensions

In 2020, BioNTech adopted a defined benefit pension plan through the acquisition of BioNTech Manufacturing Marburg GmbH in Germany. The defined benefit pension plan is a final salary plan for German employees, which requires contributions to be made to a separately administered fund.

The pension plan is governed by the employment laws of Germany and consists of a funded base plan and a non-funded supplement plan. The base plan through *Pensionskasse Hoechst* is a multi-employer plan. *Pensionskasse Hoechst* is a legally independent insurance company that is subject to the Insurance Supervision Act (*BaFin*). Plan participants may elect to contribute a percentage of their income (between 1.5% and 2.5% of salary components up to the social security contribution ceiling). A €1.00 employee contribution results in an annual pension entitlement of €0.42. The aforementioned contributions include contributions to the *Pensionskasse Hoechst* in the amount of €34 thousand. Contributions in the amount of €0.2 million are expected for the following financial year. Since the obligation of the sponsoring company is not limited to the payment of the contributions for the financial year, this is a multi-employer defined benefit plan, which is generally to be accounted for proportionally as such. However, pension fund benefits are financed in accordance with the financing methodology of the pension fund (*Bedarfsdeckungsverfahren*). Consequently, the actuarial valuation is performed to determine the present value of future contributions based upon the present value of future benefit obligation less plan assets for all employers and the level of the pension fund portfolio, not at the level of an individual insurer's risk. The calculation of the contribution rates is based on the future coverage of the total obligation, so that all sponsoring companies pay the same contribution rates. Accordingly, the portion of the base plan financed through *Pensionskasse Hoechst* is not accounted for as a defined benefit plan, but as a defined contribution plan. There are no minimum funding requirements. It is not possible to withdraw the funds from the multi-employer plan or to transfer them to another pension fund. It is not possible to withdraw from the pension fund. Upon expiry of the plan, any underfunding is to be made up by the employer and therefore recognized as liability in the consolidated statement of financial positions; any remaining surplus would be used for charitable purposes. Both plans have been closed so that no further employees can obtain entitlements.

Since the German Company Pension Act (*Betriebsrentengesetz*) applies to the pension obligation, the pensions are subject to adjustments at least every three years by the increase in the consumer price index or by the net wage development of comparable groups of employees. Therefore, the pension obligation is subject to inflation risk. In addition, there is longevity risk as the pensions are paid for life. Part of the obligations is also based on the level of salaries, so that the obligations will also increase if salaries develop more strongly than expected. Plan assets benefits from pension funds are offset. In this case, there is a risk that the external pension provider will not be able to provide the benefits to the extent expected and that the payments to be made directly by the employer will therefore increase.

The following table summarizes the defined benefit obligation recognized in non-current provisions:

<i>(in thousands)</i>	December 31, 2020
Base plan	€2,140
Supplement plan	2,125
<b>Total</b>	<b>€4,265</b>

The following table summarizes the components of net benefit expense recognized in the statement of profit or loss for both plans:

<i>(in thousands)</i>	Years ended December 31, 2020
Service cost	€24
Net interest expense	6
<b>Total</b>	<b>€30</b>

The current service cost is included in the personnel expenses of the various functions of the respective employees, while the net interest is recognized in finance expenses or finance income.

The following table summarizes the components of remeasurements recognized in other comprehensive income for both plans:

	Years ended December 31,	2020
<i>(in thousands)</i>		
Actuarial changes arising from changes in financial assumptions		€227
Experience adjustments		(17)
<b>Total</b>		<b>€210</b>

Set out below is an overview of changes to the defined benefit obligation during the period indicated for both plans:

<i>(in thousands)</i>	Defined benefit obligations
As of January 1, 2020	-
Acquisition of subsidiaries and businesses	(4,029)
Service cost	(24)
Net interest expense	(6)
Benefits paid	4
Actuarial changes arising from changes in financial assumptions	(227)
Experience adjustments	17
<b>As of December 31, 2020</b>	<b>€(4,265)</b>

The principal assumptions used in determining the defined benefit obligation for the Group's plans are shown below:

	December 31, 2020
Discount rate	0.80%
Price inflation	2.00%
Rate of salary increase	2.50%
Pension increases for in-payment benefits	1.75%

#### Sensitivity analysis

The main actuarial assumptions that are used to calculate the provisions for post-employment benefits are the discount rate and the trend for future increases in post-employment benefit payments. A reasonably possible increase, or respective decrease, in the significant actuarial assumptions would have impacted the present value of the post-employment benefit obligations as of December 31, 2020 as shown below:

#### Quantitative sensitivity analysis

	December 31, 2020
Discount rate increase 0.25%	€(282)
Discount rate decrease 0.25%	309
Pension increases for in payment benefits 0.25%	475
Pension decreases for in payment benefits 0.25%	(447)

#### Duration

The average duration of the German obligations are 35.92 years for the base plan and 19.77 years for the supplement plan.

## Expected benefit payments

The following are the expected payments or contributions to the plans in future years:

### Expected payments or contributions in future years

<i>(in thousands)</i>	December 31, 2020
Less than 1 year	€29
1 to 5 years	317
More than 5 years	340
<b>Total</b>	<b>€686</b>

## 21 Related Party Disclosures

### 21.1 Parent and Ultimate Controlling Party

ATHOS KG, Holzkirchen, Germany is the sole shareholder of AT Impf GmbH, Munich, Germany and beneficial owner of ordinary shares in BioNTech. ATHOS KG via AT Impf GmbH has de facto control over BioNTech based on its substantial shareholding, which enabled it to exercise the majority of voting rights to pass resolutions at BioNTech's Annual General Meeting, or AGM.

### 21.2 Transactions with Key Management Personnel

#### Key Management Personnel Compensation

Key management personnel at BioNTech has been defined as the members of the Management Board and of the Supervisory Board. Key management personnel compensation is comprised of the following:

#### Compensation of key management personnel of the Group

<i>(in thousands)</i>	2020	Years ended December 31, 2019	2018
Short-term employee benefits incurred	€2,627	€1,847	€1,161
Short-term employee benefits accrued*	740	-	-
Share-based payments	20,700**	18,151	6,163
<b>Total compensation paid to key management personnel</b>	<b>€24,067</b>	<b>€19,998</b>	<b>€7,324</b>

\* Includes the fair value of the second installment of the short-term incentive compensation, which has been classified as cash-settled share-based payment arrangement was determined pursuant to the regulations of IFRS 2 "Share-based Payments". This table shows the pro-rata share of personnel expenses for the respective financial year that are recognized over the award's vesting period beginning as of the service commencement date (January 1, 2020) until each separate determination date and are remeasured until settlement date.

\*\* Includes expenses from a bonus arrangement agreed with Ryan Richardson in advance of his appointment to the Management Board. During the year ended December 31, 2020, the arrangement was modified from an all-equity share-based payment arrangement into a partly cash and partly equity settled share-based payment arrangement including 4,534 ordinary shares which have not yet been issued.

In September 2019, BioNTech agreed to grant Prof. Ugur Sahin, M.D., BioNTech's co-founder and Chief Executive Officer, an option to purchase 4,374,963 ordinary shares (see Note 17).

Management Board members participate in the Group's ESOP program (see Note 17).

#### Key Management Personnel Transactions

A number of key management personnel, or their related parties, hold positions in other companies that result in them having control or significant influence over these companies. A number of these companies have entered into transactions with the Group during the year.

The Group purchases various goods and services from Translationale Onkologie an der Universitätsmedizin der Johannes Gutenberg-Universität Mainz gemeinnützige GmbH, or TRON, an institute which was co-founded by Prof. Ugur

Sahin, M.D., the co-founder and Chief Executive Officer of BioNTech. Prof. Ugur Sahin, M.D. served as Managing Director at TRON until September 10, 2019 and currently serves as scientific advisor at TRON and as a Professor of Medicine at the University of Mainz. Additionally, Prof. Christoph Huber, M.D., a member of our Supervisory Board, served on TRON's supervisory board until his resignation in April 2019. Prof. Ugur Sahin, M.D., our co-founder and Chief Executive Officer, owns a significant amount of shares in TRON.

The aggregate value of transactions related to key management personnel were as follows for the periods indicated:

<i>(in thousands)</i>	2020	Years ended December 31,		2018
		2019		
Consulting services / patent assignment	€25	€56		€25
Purchases of various goods and services from TRON	10,105	9,968		11,160
<b>Total</b>	<b>€10,130</b>	<b>€10,024</b>		<b>€11,185</b>

The outstanding balances of transactions related to key management personnel were as follows as at the periods indicated:

<i>(in thousands)</i>	December 31,		December 31,
	2020	2019	
Consulting service provider	€7		-
TRON	1,229		1,843
<b>Total</b>	<b>€1,236</b>		<b>€1,843</b>

### 21.3 Other Related Party Transactions

The total amount of transactions with ATHOS KG or entities controlled by it was as follows for the periods indicated:

<i>(in thousands)</i>	2020	Years ended December 31,		2018
		2019		
Purchases of various goods and services from entities controlled by ATHOS KG	€2,296	€2,071		€2,431
Purchases of property and other assets from entities controlled by ATHOS KG	2,349	-		4,748
<b>Total</b>	<b>€4,645</b>	<b>€2,071</b>		<b>€7,179</b>

The outstanding balances of transactions with ATHOS KG or entities controlled by them were as follows as at the periods indicated:

<i>(in thousands)</i>	December 31,		December 31,
	2020	2019	
ATHOS KG	€500		€51
<b>Total</b>	<b>€500</b>		<b>€51</b>

None of the balances are secured and no bad debt expense has been recognized in respect of amounts owed by related parties.

### 22 Events After the Reporting Period

On February 12, 2021, BioNTech and Pfizer announced that the U.S. government has exercised its option to purchase an additional 100 million doses of the Pfizer-BioNTech COVID-19 vaccine. This brings the total number of doses to be supplied by the companies to the U.S. government to 300 million.

On February 17, 2021, BioNTech and Pfizer announced an agreement with the European Commission (EC) to supply an additional 200 million doses of COVID-19 vaccine to the 27 European Union member states. The EC has the option to request supply of an additional 100 million doses.

In February 2021, RSUs under the BioNTech Employee 2020 Equity Plan were offered to employees based in Europe which determined the grant date fair value. Given that the share price had increased since the plan was established, a significant true-up in fair value occurred.

In February 2021, RSUs under the BioNTech 2020 Restricted Stock Unit Plan for North America Employees were offered to employees based in the United States. As from this date, BioNTech started recognizing expenses for this plan in the Consolidated Statements of Operations.

On March 12, 2021, BioNTech Turkey Tıbbi Ürünler Ve Klinik Araştırma Ticaret Anonim Şirketi, translates as BioNTech Turkey Pharmaceutical Products and Clinical Trials Trading JSC, Istanbul, Turkey, was founded and is a wholly-owned subsidiary of BioNTech SE.

## ARTICLES OF ASSOCIATION OF BIONTECH SE

### I. General provisions

#### § 1 Company name, registered office and financial year

- (1) The name of the company is "BioNTech SE".
- (2) The company has its seat in Mainz, Germany.
- (3) The financial year is the calendar year.

#### § 2 Purpose of enterprise

- (1) The purpose of the company is to research and develop, as well as to manufacture and market immunological and RNA-based drugs and test methods for the diagnosis, prevention and treatment of cancer, infectious diseases and other serious diseases.
- (2) The company may undertake all transactions and actions that are expedient for serving the company's purpose. It is also entitled to establish and acquire other companies and to invest in other companies, as well as to manage such companies or to limit itself to the administration of the investment.

#### § 3 Announcements

All of the company's announcements shall be made exclusively in the German Federal Gazette (Bundesanzeiger).

### II. Share capital and shares

#### § 4 Amount and division of share capital; deviating profit participation

- (1) The company's share capital totals EUR 232,304,250.00 and is divided across 232,304,250 no-par value shares.
  - (2) Any entitlement of shareholders to the right of issuance of share certificates is excluded, to the extent permitted by law or unless certification is required under the rules applicable at a stock exchange where the shares or rights or certificates representing them are admitted for trading. Global certificates for shares may be issued. Form and content of these certificates shall be determined by the Management Board.
  - (3) The shares are registered shares.
  - (4) In the event of a capital increase, the profit sharing of new shares may be determined in deviation from Section 60(2) Sentence 3 German Stock Corporation Act (*AktG*).
-

- (5) The Management Board is authorized, subject to the consent of the Supervisory Board, to increase the company's share capital in the period up to 18 August 2024 on one occasion or on multiple occasions by up to a total of EUR 105,818,002.00 by issuing up to 105,818,002 new, no-par value registered shares against contributions in cash or in kind (Authorized Capital). In principle, the shareholders are to be granted a right of subscription. The shares may also be assumed by one or more banking institution(s) or one or more companies operating according to Section 53(1) sentence 1 Banking Act (*Kreditwesengesetz; KWG*) or Section 53b(1) sentence 1 or (7) KWG with the requirement that the shares are offered to the company's shareholders for purchase (so-called indirect right to subscription). The Management Board is authorized to exclude the subscription right of shareholders in one or more instance(s) of a capital increase as part of the Authorized Capital, subject to Supervisory Board approval,
- (a) to exclude fractional amounts from the subscription right,
  - (b) in the case of a capital increase against cash contributions, if the issue price of the new shares is not significantly lower than the market price of the company's shares already listed on the stock exchange at the time the issue price is finally determined. However, this authorization shall only apply subject to the provision that the shares issued excluding subscription rights in accordance with Section 186(3) Sentence 4 AktG may not exceed a total of 10% of the share capital either at the time this authorization takes effect or - if this amount is lower - at the time this authorization is exercised. This limit of 10% of the share capital includes shares which are issued or disposed of during the term of this authorization until the date of its exercise in direct or equivalent application of Section 186(3) Sentence 4 AktG. Shares which are used to service bonds with convertible or option rights or convertible obligations are to be offset against the 10% limit if these bonds were issued under exclusion of shareholder subscription rights in accordance with Section 186(3) Sentence 4 AktG during the entitlement period. Treasury shares are to be offset against the 10% limit, where they were disposed of by the company during the term of this authorization with the exclusion of subscription rights pursuant to or in analogous application of Section 186(3) Sentence 4 AktG;
  - (c) in the case of capital increases in exchange for contributions in kind, in particular in order to be able to offer the shares to third parties when purchasing companies, parts of companies or interests in companies as well as licenses or industrial property rights;
  - (d) in order to grant subscription rights to new shares to holders of conversion or option rights in respect of bonds issued by the company or its subordinated domestic or foreign Group



companies, to the extent to which they would be entitled after exercising their conversion or option rights or after fulfilling an agreed conversion obligation;

- (e) to implement an election dividend (*scrip dividend*/share dividend) by which shareholders are given the option to contribute their dividend entitlements to the company (either in whole or part) as a contribution in kind against issuance of new shares in the company;
- (f) if shares are issued to one or more investors on one or more occasions or in connection therewith to shareholders by way of co-investments (within the meaning of the **Annex to Section 4(5)**), on the basis of agreements concluded by 30 June 2020 at an issue price (including any further payment agreed under the law of obligations) of at least USD 18.10 (to this extent, the more detailed provisions of the Annex to Section 4(5) shall apply) and, in doing so, the provisions of the Annex to Section 4(5) are complied with. However, this authority to exclude the subscription right pursuant to this letter f) shall lapse if the shares of the Company or the rights or certificates representing them have been admitted to trading on a stock exchange or any other multilateral trading system,
- (g) in case shares are to be issued to a member of the Management Board of the Company or to another person who is employed by the company or one of its affiliates and a minimum holding period of at least one year and the obligation to transfer back the shares in the event that the beneficiary is not employed by the company or one of its affiliated companies for the entire duration of the holding period or any other agreed period is agreed upon. Additional restrictions with regard to the shares issued may be agreed upon,
- (h) in a capital increase effected after introduction of the Company's shares or certificates representing them to trading on a stock exchange or a multilateral trading system, if excluding subscription rights, according to the written declaration of an internationally renowned investment bank, is expedient to the shares' successful placement in view of the requirements of eligible investors and if the discount by which the issue price of the shares may be below the current stock exchange price at the time the Management Board adopts the resolution on using authorised capital, according to such declaration, does not exceed the extent necessary for a successful placement, and
- (i) in order to be able to satisfy an option to acquire additional shares or American Depositary Shares that has been agreed with the issuing banks in connection with a public offering of shares in the Company in the form of American Depositary Shares.

The total number of new shares issued from the Authorized Capital and under exclusion of subscription rights pursuant to sentence 4 lit. a) to c) and h) above may not exceed 20% of the share capital, either at the time this authorization becomes effective or – if lower – at the time it is utilized. To be counted against the aforementioned 20%-limit are: (i) those shares issued or to be issued to service conversion or option rights or conversion or option obligations or tender rights of the issuer under bonds, if the bonds have been issued during the term of this authorization up to the time of its exercise, excluding the subscription rights of shareholders, as well as (ii) treasury shares that have been disposed under exclusion of subscription rights during the term of this authorization (except in the case of lit. b) para (v), (vi) or (vii) of the resolution to item no. 8 of the General Meeting of 19 August 2019).

The new shares participate in the profits as of the beginning of the first fiscal year for which the annual financial statements have not yet been submitted to the General Meeting at the time of registration of the implementation of the capital increase. The Management Board shall be authorized, with the consent of the Supervisory Board, to determine further details of the capital increase and its implementation.

- (6) The share capital is conditionally increased by up to EUR 21,874,806.00 by issuing up to 21,874,806 new registered no-par value shares each representing a notional value of EUR 1.00 of the share capital (Conditional Capital ESOP 2017/2019). The sole purpose of the Conditional Capital ESOP 2017/2019 is the grant of rights to holders of stock options issued by the Company under the authorisation granted by the General Meeting of 18 August 2017 under agenda item 5.a), also in the version of such authorisation as amended by resolution of the General Meeting of 19 August 2019 on agenda item 6.a) (together the “Authorisation 2017/2019”). The shares shall be issued at the strike price determined in accordance with the provisions of the Authorisation 2017/2019 in the version applicable at the time of its exercise. The conditional capital increase shall only be implemented to the extent that the holders of the stock options issued by the Company under the Authorisation 2017/2019 exercise their subscription rights and the Company does not service the stock options by delivering treasury shares or by a cash payment. The new shares shall be entitled to dividends from the beginning of the previous financial year in case they are created by the exercise of subscription rights until the start of the Annual General Meeting of the Company, and otherwise from the beginning of the financial year in which they are created as a result of the exercise of the stock options.
- (7) The share capital is conditionally increased by up to EUR 87,499,260.00 by issuing up to 87,499,260 new registered no-par value shares, each representing a notional value of EUR 1.00 of the share capital (Conditional Capital WSV 2019). The conditional capital increase shall only be carried out to the extent that the holders or creditors of option rights or conversion rights or those under an

obligation to convert under warrant-linked or convertible bonds issued in return for cash contributions and issued or guaranteed by the Company or by a subordinate Company group entity up to, and including, 18 August 2024 based on Management Board authorisation as per the shareholder resolution conferring said authorisation passed at the General Meeting of 19 August 2019 avail of their option rights or conversion rights or where they are under an obligation to convert, to the extent they satisfy their obligation to convert, or to the extent that the Company exercises a right to choose to grant Company shares, in whole or in part instead of paying a monetary amount due, and to the extent cash compensation is not granted in each relevant case or treasury shares or shares of another stock-listed company are not utilised for servicing. The new shares are issued at the warrant exercise price or conversion price to be determined in each case in accordance with the aforementioned resolution granting authorisation. The new shares shall carry an entitlement to dividends from the beginning of the financial year in which they are created; as far as the law permits, the Management Board can confer dividend rights for new shares in derogation of the foregoing and of section 60(2) AktG and also for a financial year that has already ended. The Management Board shall be authorised, subject to Supervisory Board approval, to determine the remaining details for implementing the conditional capital increase.

- (8) To the extent that the above paragraphs provide for authorized or conditional capital, the Supervisory Board is authorized to amend the wording of the Articles of Association after expiry of the period for utilization of the authorized capital and in accordance with the extent of capital increases carried out on the basis thereof.

### **III. The executive bodies of the company**

#### **§ 5 Two-tier system**

- (1) The company has a two-tier management and supervisory system consisting of a management body (Management Board) and a supervisory body (Supervisory Board).
- (2) The company's executive bodies are the Management Board, the Supervisory Board and the General Meeting.

### **IV. Management Board**

#### **§ 6 Composition**

- (1) The Management Board shall consist of at least two persons. The members of the Management Board are appointed for a maximum term of five years. Reappointments are permitted.
- (2) The number of members of the Management Board is otherwise determined by the Supervisory Board.

- (3) The appointment of deputy members of the Management Board is permissible.

**§ 7**

**Management, representation**

- (1) The members of the Management Board shall conduct the business of the company in accordance with the law, the Articles of Association and the Rules of Procedure issued by the Supervisory Board.
- (2) The company shall be represented by two members of the Management Board or by one member of the Management Board jointly with one holder of a general commercial power of representation (*Prokurist*). If only one member of the Management Board is appointed, the company will be represented by this individual alone. The Supervisory Board may grant one, several or all members of the Management Board sole power of representation.
- (3) The Supervisory Board may, by resolution, authorize members of the Management Board in general or in individual cases to conclude legal transactions simultaneously for the company and as representatives of a company affiliated with the company within the meaning of Section 15 AktG as well as in individual cases simultaneously for the company and as representatives of a third party.
- (4) The Supervisory Board may appoint a spokesman or a chairperson of the Management Board
- (5) Furthermore, the Supervisory Board shall issue rules of procedure for the Management Board and shall determine in particular which types of business may only be transacted with its consent.

**§ 8**

**Passing of Resolutions**

- (1) The Management Board has a quorum if all members of the Management Board are invited and at least half of its members participate in the adoption of the resolution, unless otherwise required by mandatory law. Members of the Management Board may cast their vote in writing, by telephone, by telefax or by means of electronic media.
- (2) The resolutions of the Management Board are passed by a majority of the votes cast, unless otherwise stipulated by mandatory law with abstentions not to be taken into account. In the event of a tie the chairperson shall have a casting vote, if such person has been appointed. This does not apply to a spokesman of the Management Board who may have been appointed.

**V.**

**Supervisory Board**

**§ 9**

**Composition, term of office and remuneration**

- (1) The Supervisory Board shall comprise of four members.

- (2) Unless the General Meeting resolves on a shorter period when electing individual Supervisory Board members to be elected by it or for the full Supervisory Board, the Supervisory Board members shall be elected at the longest until the end of the General Meeting which resolves on the discharge for the fourth financial year after the election. The fiscal year in which the term of office begins is not included in this calculation. Re-election is possible.
- (3) The successor to a member who leaves the Supervisory Board before the end of his or her term of office shall only be elected for the remainder of the term of office of the member who has left the Supervisory Board.
- (4) When electing Supervisory Board members, the General Meeting may for the same period elect a substitute member for several or all Supervisory Board members or as many substitute members as Supervisory Board members and determine the order in which they shall replace the Supervisory Board members who leave the Supervisory Board during their term of office for the remaining term of office.
- (5) Each member of the Supervisory Board may resign from office by submitting a written declaration to the Management Board. A period of one month must be observed.
- (6) In addition to reimbursement of their expenses, the members of the Supervisory Board receive an annual remuneration of EUR 50,000, the chairperson three times this amount and the deputy chairperson one and a half times this amount. The chairperson of the Audit Committee receives an additional annual remuneration of EUR 20,000. The members of the Supervisory Board who are only members of the Supervisory Board for part of the fiscal year or who chair or deputy chair the Supervisory Board or the Audit Committee receive the respective remuneration pro rata temporis. The same shall apply if this provision or a specific version of this provision is only in force for part of the financial year. If the reimbursement of out-of-pocket expenses or the remuneration is subject to value-added tax, value-added tax shall be payable in addition.

#### **§ 10 Chairperson and deputy**

- (1) The Supervisory Board shall elect a chairperson and a deputy chairperson from among its members for the duration of its term of office. In these elections the oldest member of the Supervisory Board in terms of age is the chairperson. The deputy shall have the rights of the chairperson if the latter is prevented from attending or delegates his or her representation to him or her.
- (2) If the chairperson or his/her deputy departs prematurely from their office, then the Supervisory Board shall immediately hold a new election to cover the remaining term of office.

**Convening and passing resolutions**

- (1) As far as possible, the Supervisory Board shall be convened in each calendar quarter. It must be convened twice every calendar half-year.
- (2) The meetings of the Supervisory Board shall be convened by the chairperson verbally, by telephone, in writing, by fax or by email, stating the agenda.
- (3) The Supervisory Board constitutes a quorum if at least three members participate in the adoption of the resolution. A member shall also participate in the adoption of a resolution if he or she abstains from voting.
- (4) Resolutions require a majority of the votes cast by the members of the Supervisory Board not taking into account any abstentions. In the case of a tie, the votes of the chairperson of the Supervisory Board or, if he does not participate in the passing of the resolution, the vote of the deputy chairman of the Supervisory Board shall be the casting vote.
- (5) Resolutions of the Supervisory Board are in principle passed at meetings with personal attendance of the members of the Supervisory Board. Absent members of the Supervisory Board may submit their written vote through another member of the Supervisory Board. Unless the chairperson of the Supervisory Board states otherwise in the invitation due to special circumstances of the individual case, it is permissible for Supervisory Board members to participate and cast their vote in a face-to-face meeting by telephone. The Supervisory Board may also vote without convening a meeting by doing so in writing, by telephone, fax, video conference or email, or in a combined resolution. The chairperson shall decide on the form in which resolutions are to be passed. The Rules of Procedure for the Supervisory Board may stipulate that resolutions are to be postponed in individual cases to be specified in more detail.
- (6) Minutes shall be taken of the meetings of the Supervisory Board and signed by the chairperson of the meeting. If resolutions are passed outside meetings, the minutes must be signed by the chairperson of the Supervisory Board and forwarded to all members without delay.
- (7) The chairperson is authorized to on behalf of the Supervisory Board make the declarations required to implement the resolutions and to receive the declarations addressed to the Supervisory Board.
- (8) The Supervisory Board is empowered to resolve upon changes and amendments to the Articles of Association as long as such changes only affect the wording.

**Rules of Procedure**

The Supervisory Board may issue Rules of Procedure for itself within the framework of the statutory provisions and the provisions of these Articles of Association.

**§ 13 Committees**

The Supervisory Board may form committees and may refer items for resolution to these committees within the scope of what is permitted by law.

**VI. General Meeting**

**§ 14 Venue and convocation**

- (1) The General Meeting shall take place within the first six months of the expiry of the fiscal year at the registered office of the company or in a German city with at least 500,000 inhabitants.
- (2) The General Meeting shall be convened by the Management Board or by the Supervisory Board.
- (3) Extraordinary General Meetings shall be convened when the best interests of the company so require.

**§ 15 Chairing the General Meeting, right to participate, participation of Supervisory Board members**

- (1) The General Meeting shall be chaired by the chairperson of the Supervisory Board or, in his/her absence, by his/her deputy or, in his/her absence, by another person determined by the Supervisory Board. If no such determination has been made, the chairperson of the meeting shall be elected by the General Meeting.
- (2) Shareholders registered in the share register are entitled to participation and the exercising of their voting rights in the General Meeting if they are registered in good time with the Company for participation. The registration to attend the General Meeting must be in German or English and must be received by the Company at least six days prior to the meeting, unless a shorter period, expressed in days, is provided for in the invitation to the General Meeting, at the address and in the form (written form, text form or another (electronic) form further specified by the Company) as stipulated in the said invitation. The day of the General Meeting and the day of receipt shall not be counted.
- (3) The chairperson of the meeting shall determine the order of items on the agenda as well as the type and form of voting. The chairperson is authorized to limit the question and speaking rights of the shareholders, as appropriate and to the extent permitted by law. In particular, he/she is authorized, at the beginning or during the course of the General Meeting, to set a reasonable time limit for the entire General Meeting, for discussion of particular items on the agenda, or for any particular speech or question. Furthermore, the chairperson of the General

Meeting may prematurely close the list of requests to speak and close the debate, as far as this is necessary for the proper execution of the General Meeting.

- (4) The chairperson of the General Meeting may permit the video and audio transmission of the General Meeting in whole or in part, including a transmission via the Internet.

**§ 16 Procedure, minutes**

- (1) Each share carries one vote.
- (2) Voting rights may be exercised by representatives. The power of attorney must be granted in text form by other means. The details shall be determined by the company. They will be announced with the invitation to the General Meeting.
- (3) The Management Board is authorized to provide for shareholders to vote without attendance in the General Meeting in written form or by way of electronic communication (postal vote) as well as participate in the General Meeting and exercise all or some of their rights in whole or in part by means of electronic communication without physical participation and without being represented by a proxy (online participation). The Management Board determines the details of the postal vote as well as the scope and procedure of online participation in the invitation to the General Meeting. Minutes shall be kept of the proceedings and shall be signed by the chairperson of the Supervisory Board unless a notarial record is required by law.

**§ 17 Resolution**

- (1) Unless a larger majority is required by law or these Articles of Association, resolutions of the General Meeting shall be adopted by a simple majority of the votes cast. To the extent that statutory provisions also require a majority of the share capital present at the time the resolution is adopted, a simple majority of the share capital present shall suffice, unless a larger majority is required by law. In the event of an undecided vote, an agenda item shall be deemed rejected.
- (2) However, unless a larger majority is required by law, resolutions to amend the Articles of Association require a majority of at least two thirds of the votes cast and of the share capital present, except where at least half of the share capital is present.
- (3) Should no majority be obtained in the first ballot in elections, the candidates with the two highest numbers of votes reached shall be put on a shortlist. If the election results in a tie between these two candidates, the decision shall be made by lot.

**VII. Annual Financial Statements, appropriation of profits**



**§ 18 Annual Financial Statements, Management Report**

- (1) The Management Board shall prepare the Annual Financial Statements and any Management Report as well as the Consolidated Financial Statements and any Group Management Report for the past financial year within the statutory period.
- (2) The Management Board shall submit the Annual Financial Statements and any Management Report as well as the Consolidated Financial Statements and any Group Management Report to the Supervisory Board immediately after they have been prepared, together with its proposal to the General Meeting for the appropriation of net profit.
- (3) The Supervisory Board shall examine the Annual Financial Statements, the potential Management Report of the Management Board, the Consolidated Financial Statements and any Group Management Report and the proposal for the appropriation of net profits and report the results of its examination in writing to the General Meeting. It must forward its report to the Management Board within one month of receipt of the documents. Should the Supervisory Board approve the Annual Financial Statements after examination, they shall be adopted unless the Management Board and Supervisory Board decide to leave the adoption of the Annual Financial Statements to the General Meeting.

**§ 19 Retained earnings**

- (1) Should the Management Board and the Supervisory Board adopt the Annual Financial Statements, they may transfer amounts of up to half of the net profit for the year to retained earnings. In addition, they are authorized to transfer amounts to retained earnings of up to a further quarter of the net profit for the year as long as the retained earnings do not exceed half of the share capital or insofar as they would not exceed half of the share capital after the transfer.
- (2) When calculating the portion of the net profit to be transferred to retained earnings in accordance with paragraph (1), allocations to the statutory reserve and accumulated losses carried forward shall be taken into account in advance.
- (3) The General Meeting resolves on the appropriation of profits retained resulting from the adopted Annual Financial Statements. It may allocate further portions of the profits retained to retained earnings, carry these profits forward to a new account – also by way of distribution in kind - or distribute them among the shareholders.

**VIII. Legal disputes**

**§ 20 Jurisdiction of the US Federal Courts**

In the case of litigation on the grounds of or in connection with federal or state capital market laws of the United States of America to be settled in front of a federal or state court of the United States of America only the United States District Court for the Southern District of New York or, in the case of it being replaced by any other first-instance Federal Court of the United States of America having judiciary over the borough of Manhattan, such court, shall be the competent court of jurisdiction, in each case insofar as this may be determined by these Articles of Association. This shall leave unaffected any exclusive international jurisdiction under German or European law of the court seated at the venue of the Company's statutory seat.

**IX. Expenses**

**§ 21 Formation expenses**

- (1) The formation costs of the company shall be borne by FORATIS AG.
- (2) The company shall bear the expenses of the formation of the BioNTech SE by conversion of BioNTech AG into a European company (SE) in the amount of up to EUR 100,000.

**Stipulations which are to be fulfilled in the event of an exclusion of the subscription right pursuant to Section 4(5) Sentence 4 Subsection (f) (the 'new investor clause')**

- (i) The portion of shares issued on the basis of the respective Management Board resolution on the utilization of the authorized capital (including the shares issued to shareholders on the basis of co-investments pursuant to item (iv)) does not exceed one tenth of the share capital existing at the time of the resolution. In the event that shares have already been issued previously using the authorization to exclude subscription rights in accordance with the new investor clause, said tenth shall be replaced by the aforementioned tenth less the fractions which the shares issued in each case represented in relation to the share capital existing at the time of the respective resolution of the Management Board.
- (ii) The issue price in US dollars (including any further payment agreed under the law of obligations) shall be converted into euros for the purpose of determining an issue price in euros on the basis of an exchange rate that is determined by the Management Board in its dutiful discretion and that is current at the time of the resolution on the issuance or, in the case of further payments agreed under the law of obligations, at the time of the request for further payment.
- (iii) Shareholders who hold a total of 60 % of the company's shares and among whom are Medine GmbH, the AT Impf GmbH, at least one Fidelity fund and at least one Redmile fund, have approved the issuance of shares by declaration in text form. "Fidelity fund" or "Redmile fund" means any investment fund managed or advised by Fidelity Management & Research Company or any of its affiliates or, respectively, by Redmile Group LLC or any of its affiliates on the basis of a contract.
- (iv) In connection with any capital increase under exclusion of subscription rights pursuant to the new investor clause either (x) no shareholder nor any company affiliated with a shareholder will be given the opportunity to participate in the envisaged share issue, or (y) the company will announce the envisaged share issue to each shareholder by email notifying the number of shares that the respective new investor intends to subscribe for, the issue price per share (including any further payment agreed under the law of obligations) and the total issue price to be paid by the respective investor (including, if applicable, the further payment), will request each shareholder, with a deadline of at least one week, to make a binding declaration in text form as to the extent to which he/she

himself/herself wishes to subscribe for shares in the context of the relevant capital increase ("co-investment"), and offer those who have submitted the declaration in due time to conclude a corresponding subscription agreement by submitting a proper draft subscription form. Each shareholder may transfer or assign his or her right to co-invest to companies affiliated with him or, in the case of an investment fund, to another investment fund advised directly or indirectly by the same investment advisor or by an investment advisor affiliated to the same. The invitation and the offer shall be restricted (in the cases set out in letters b and c below in the event that a determination of the relevant content is made) to the extent that;

- a. the pro rata amount of the share capital represented by the total shares to be subscribed for by way of co-investments in the context of the capital increase in question may not exceed the fraction set out in item (i) with the proviso that existing subscription requests are initially taken into account in proportion to the pro rata shareholdings and are otherwise disregarded to the extent that this amount would otherwise be exceeded,
- b. the pro rata amount of the share capital represented by the total number of shares to be subscribed for by way of co-investments within the framework of the capital increase in question may not exceed the amount determined in the invitation and the offer (which amounts to at least half of the total envisaged amount of the capital increase); in such a case, the provisions of letter a shall apply *mutatis mutandis*, and
- c. the co-investment is subject to the condition that, upon penalty of exclusion from the co-investment, within a period of at least five banking days to be determined by the company, starting from the date of availability of the proper draft of the subscription form corresponding to the declaration (x) the company receives the duly signed subscription form in two originals, and (y) that the issue amount (in whole or the part claimed by the company) is fully paid.

## DESCRIPTION OF SECURITIES

The following description sets forth certain material terms and provisions of ordinary shares and American Depositary Shares representing ordinary shares of BioNTech SE (“BioNTech,” the “Company,” “we,” “us,” and “our”) that are registered under Section 12 of the U.S. Securities Exchange Act of 1934, as amended. This description also summarizes certain provisions of our articles of association and German law as of the date of the filing of the Annual Report on Form 20-F of which this exhibit forms a part. This summary does not purport to be complete and is qualified in its entirety by the provisions of our articles of association filed with the Securities and Exchange Commission as an exhibit to the Annual Report on Form 20-F of which this exhibit forms a part, as well as to the applicable provisions of German legislation on stock corporations. We encourage you to read our articles of association and the applicable provisions of German law for additional information.

**Ordinary Shares**

We were incorporated as a German stock corporation (*Aktiengesellschaft*) with the legal name Petersberg 91. V AG under the laws of the Federal Republic of Germany on June 2, 2008. We changed our name to BioNTech AG on December 11, 2008. Effective as of March 8, 2019, the date on which the change of legal form and company was registered with the commercial register (*Handelsregister*) of the local court (*Amtsgericht*) of Mainz, Germany, we converted to a *Societas Europaea* with the legal name BioNTech SE. We completed our initial public offering in October 2019. The principal legislation under which we operate and our shares are issued are the Council Regulation (EC) No 2157/2001 of October 8, 2001 on the Statute for a European company (SE), the German Law on the Implementation of Council Regulation (EC) No 2157/2001 of October 8, 2001 on the Statute for a European company (SE) (*Gesetz zur Ausführung der Verordnung (EG) NR. 2157/2001 des Rates vom 8. Oktober 2001 über das Statut der Europäischen Gesellschaft (SE) (SE-Ausführungsgesetz—SEAG)*) and the German Stock Corporation Act (*Aktengesetz*), in each case as amended.

We are registered with the commercial register (*Handelsregister*) of the local court (*Amtsgericht*) in Mainz, Germany, under number HRB 48720. Our statutory seat is in Mainz, Germany, and our registered office is An der Goldgrube 12, 55131 Mainz, Germany. Copies of our Articles of Association (*Satzung*) will be publicly available from the commercial register (*Handelsregister*) at the local court of Mainz, Germany, electronically at [www.unternehmensregister.de](http://www.unternehmensregister.de) and as an exhibit to this Annual Report.

**Share Capital**

We have share capital registered in the commercial register (*Handelsregister*) in the amount of €246,310,081, which is divided into 246,310,081 registered shares (*Namensaktien*). All shares are shares with no par value (*Stückaktien ohne Nennbetrag*) with a notional amount attributable to each ordinary share of €1. Each issued ordinary share is fully paid.

**Form, Certification and Transferability of Shares**

The form and contents of our share certificates, collective share certificates and global share certificates are determined by our Management Board. A shareholder’s right to certification of its shares is excluded, to the extent permitted by law and to the extent that certification is not required by the stock exchange on which the shares or rights or certificates representing them are admitted to trading. We are permitted to issue collective share certificates and global share certificates that represent multiple or all of our shares.

Our shares are freely transferable under German law.

**Anti-takeover Provisions of Our Charter Documents**

Our Articles of Association (*Satzung*) do not include any provisions that would have a direct effect of delaying, deferring or preventing a change of control. However, in the event of a hostile takeover, we could use our authorized capital to increase our share capital to issue new shares to an investor at a premium. An increase in the number of shares outstanding could have a negative effect on a party’s ability to carry out a hostile takeover. The provisions of German law relating to public bids and takeovers that require any such bids to be carried out in a manner designed to safeguard equal and fair treatment to all shareholders and give them a right to be bought out at an adequate compensation where a party acquires “control” (as such term is defined in such provisions) over the relevant company do not apply.

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## Future Changes to the Share Capital

### Authorized Capital

Under the relevant law, the general meeting of a European stock corporation (*Societas Europaea*) governed by German law can authorize the Management Board to, with the consent of the Supervisory Board, issue shares in a specified aggregate nominal amount of up to 50% of the issued share capital of such company at the time the resolution becomes effective. The shareholders' authorization becomes effective upon registration in the commercial register (*Handelsregister*) and may extend for a period of no more than five years thereafter. Under § 4(5) of our Articles of Association (*Satzung*), the Management Board is authorized to increase our share capital, on one or more occasions, by a total of up to €91,812,171 by issuing, on one or more occasions, up to 91,812,171 new, registered shares with no par value (*Genehmigtes Kapital*), in each case with consent of the Supervisory Board. This authorization expires on August 18, 2024.

Any new shares issued from the authorized capital will participate in the profits starting with the fiscal year for which the annual financial statements have not yet been submitted to the general meeting at the time of registration of the implementation of the capital increase. Further details of a capital increase from the authorized capital may be specified by the Management Board.

### Conditional Capital

Pursuant to § 4(6) of our Articles of Association (*Satzung*), our share capital is conditionally increased by €21,874,806 through issuance of new, registered shares with no par value (*Bedingtes Kapital ESOP 2017/2019*). The conditional capital may only be used to issue shares to the holders of option rights granted under our ESOP to members of our Management Board and to certain of our employees.

The conditional capital increase will only be implemented to the extent that stock options under our ESOP are exercised and said stock options are not serviced by our providing treasury shares or through cash payments. Any new shares issued under the conditional capital pursuant to the said § 4(6) of our Articles of Association (*Satzung*) shall be entitled to dividends from the beginning of the previous financial year in case they are created by the exercise of subscription rights until the start of the annual general meeting of the Company and otherwise from the beginning of the financial year in which they are created as a result of the exercise of the stock options.

Pursuant to § 4(7) of our Articles of Association (*Satzung*), our share capital is conditionally increased by €87,499,260 through issuance of new, registered shares with no par value (*Bedingtes Kapital WSV 2019*). The conditional capital may only be used to issue shares to the holders or creditors of option rights or conversion rights or those under an obligation to convert under warrant-linked or convertible bonds avail of their option rights or conversion rights or where they are under an obligation to convert, to the extent they satisfy their obligation to convert, or to the extent that we exercise a right to choose to grant our shares, in whole or in part instead of paying a monetary amount due, and to the extent cash compensation is not granted in each relevant case or treasury shares or shares of another stock-listed company are not utilized for servicing.

Any new shares issued under the said conditional capital pursuant to the said § 4(7) of our Articles of Association shall carry an entitlement to dividends from the beginning of the financial year in which they are created; however, as far as the law permits, the Management Board can confer dividend rights for new shares in derogation of the foregoing.

### Preemptive Rights

German law generally provides shareholders with preemptive rights when new shares convertible bonds, bonds with warrants, profit participation rights or participating bonds are issued. This requirement, however, may also be satisfied by way of a credit institution subscribing for the securities and then offering them to the shareholders for purchase (*mittelbares Bezugsrecht*).

Further, it is possible for a shareholder resolution approved by three-quarters of the share capital voting on the resolution to exclude preemptive rights both where the general meeting itself resolves that the new securities to be issued and in relation to the authorized capital, i.e., an authorization to the Management Board to, with the consent of the Supervisory Board, resolve on the issuance of new securities; provided, however, that in each case the exclusion or the authorization to so exclude preemptive rights, respectively, must be justified by specific facts, in accordance with established case law of the German Federal Court of Justice (*BGH*). The

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German Federal Court of Justice (*BGH*) considers the exclusion of subscription rights justified if it (i) serves a purpose in the company's interests, (ii) is suitable for attaining such purpose, and (iii) is necessary and appropriate. Additionally, the management board must submit a written report to the shareholders' meeting in which it presents the reasons for the exclusion of the subscription rights.

Accordingly, under our Articles of Association (*Satzung*), the Management Board may, with the consent of the Supervisory Board, exclude such preemptive rights in a capital increase from the authorized capital in the following circumstances:

- to exclude fractional amounts from the subscription right;
  - in the case of a capital increase against cash contributions, if the issue price of the new shares is not significantly lower than the market price of the company's shares already listed on the stock exchange at the time the issue price is finally determined. However, this authorization shall only apply subject to the provision that the shares issued excluding subscription rights in accordance with Section 186(3) Sentence 4 AktG may not exceed a total of 10% of the share capital either at the time this authorization takes effect or, if this amount is lower, at the time this authorization is exercised. This limit of 10% of the share capital includes shares which are issued or disposed of during the term of this authorization until the date of its exercise in direct or equivalent application of Section 186(3) Sentence 4 AktG. Shares which are used to service bonds with convertible or option rights or convertible obligations are to be offset against the 10% limit if these bonds were issued under exclusion of shareholder subscription rights in accordance with Section 186(3) Sentence 4 AktG during the entitlement period. Treasury shares are to be offset against the 10% limit, where they were disposed of by the company during the term of this authorization with the exclusion of subscription rights pursuant to or in analogous application of Section 186(3) Sentence 4 AktG;
  - in the case of capital increases in exchange for contributions in kind, in particular in order to be able to offer the shares to third parties when purchasing companies, parts of companies or interests in companies as well as licenses or industrial property rights;
  - in order to grant subscription rights to new shares to holders of conversion or option rights in respect of bonds issued by the company or its subordinated domestic or foreign Group companies, to the extent to which they would be entitled after exercising their conversion or option rights or after fulfilling an agreed conversion obligation;
  - to implement an election dividend by which shareholders are given the option to contribute their dividend entitlements (either in whole or part) as a contribution in kind against issuance of our new shares;
  - in capital increases, in each case if excluding subscription rights, according to the assessment by the Management Board, is expedient to the shares' successful placement in view of the requirements of eligible investors and if the discount by which the issue price of the shares may be below the current stock exchange price at the time the Management Board adopts the resolution on using authorized capital, according to the assessment by the Management Board, does not exceed the extent necessary for a successful placement and in any case does not exceed 10% of either the latest available closing price at the time when the issue price is fixed or the volume-weighted average price over a period of up to five trading days ending on the day on which the issue price is so fixed;
  - in case shares are to be issued to a member of our Management Board or to another person who is employed by us or one of our affiliates and a minimum holding period of at least one year and the obligation to transfer back the shares in the event that the beneficiary is not employed by us or one of our affiliated companies for the entire duration of the holding period or any other agreed period is agreed upon. Additional restrictions with regard to the shares issued may be agreed upon; and
  - in order to be able to satisfy an option to acquire additional ordinary shares or American Depositary Shares that has been agreed with the issuing banks in connection with a public offering of our shares in the form of American Depositary Shares.
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The total number of new shares issued from the authorized capital and under exclusion of subscription rights pursuant to bullets one through three and six above may not exceed 20% of the share capital, either at the time that the amendment to the Articles of Association (*Satzung*), resolved upon by the general meeting of June 26, 2020, has come into effect or, if lower, at the time of utilization of the authorization. To be counted against the aforementioned 20% limit are: (i) those shares issued or to be issued to service conversion or option rights or conversion or option obligations or tender rights of the issuer under bonds, if the bonds have been issued during the term of this authorization up to the time of its exercise, excluding the subscription rights of shareholders, as well as, to a certain extent (ii) treasury shares that have been disposed under exclusion of subscription rights during the term of this authorization (except in the case of certain exceptions of the resolution to item no. 8 of the general meeting of August 19, 2019).

#### **Shareholders' Meetings and Voting Rights**

Pursuant to our Articles of Association (*Satzung*), shareholders' meetings may be held at our seat or in any municipality in Germany with more than 500,000 inhabitants. Generally, shareholders' meetings are convened by our Management Board, or our Supervisory Board. Shareholders representing in the aggregate at least five percent of our ordinary shares may, subject to certain formal prerequisites, request that a shareholders' meeting be convened. Shareholders representing in the aggregate at least five percent of our ordinary shares or owning shares with an aggregate nominal value of at least €500,000 may request the addition of one or several items to the agenda of any shareholders' meeting. Shareholders' meetings may be summoned either via publication in the German Federal Gazette (*Bundesanzeiger*) or via mail or via email, in each case generally at least 36 days before the meeting.

Shareholders may participate in and vote in the shareholders' meeting if they are registered as a shareholder with the Company's share register. A shareholder who wishes to attend the shareholders' meeting—either in person or by proxy, which may also be appointed by us (*Stimmrechtsvertreter*)—must register for the meeting, which registration must occur no later than six days before the meeting (or at a later date, if so determined by our Management Board).

Each share carries one vote at a shareholders' meeting. Resolutions are, in accordance with our Articles of Association (*Satzung*), generally taken by simple majority of the votes cast. However, under applicable German and European law, a number of resolutions must be passed by either a three-quarter majority of the votes cast or a three-quarter majority of the share capital represented at the meeting. The fact that in these cases the quorum is determined in relation to the share capital or shares present (as opposed to, for example, all shares eligible to vote) means that holders of a minority of our shares could potentially control the outcome of resolutions.

#### **Claims against Directors and Shareholders' Derivative Actions**

Under German law, generally, the company, rather than its shareholders, is the proper claimant in an action with respect to a wrong committed against the company, or in cases where there is an irregularity in the company's internal management or supervision. Therefore, such claims may only be raised by the company represented by its management board, or, in the case of a wrong committed by a member of the Management Board, by the Supervisory Board. This concerns, in particular, claims against members of the Management Board or the Supervisory Board.

However, pursuant to German case law, the Supervisory Board is obliged to pursue the company's claims against the Management Board, unless the interest of the company keeps them from doing so. Further, the Management Board, or, if a claim is against a member of the Management Board, the Supervisory Board, is obliged to pursue the company's claims against the designated individuals if so resolved by a simple majority of votes cast during a shareholders' meeting. With a simple majority of votes, shareholders can also request that a representative pursue the claim on behalf of the company. The court may appoint such a representative upon the request of shareholders holding at least 10% of the company's share capital or a participation of at least €1,000,000 in the share capital.

If the company is unable to fulfill its third-party obligations, the company's creditors may pursue the company's damage claims against members of the Management Board for certain wrongdoings.

Under certain circumstances, shareholders can bring forward damage claims of the company against its management on their own behalf. In order to bring forward such a claim one shareholder alone or together with other shareholders needs to hold at least 1% of the company's share capital or a participation of €100,000 in the

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share capital. Additionally, the claimant(s) must comply with special claim approval procedures conducted before a competent court which will allow the pertinent request only if there are circumstances justifying the assumption that damage has been afflicted on the company by improper conduct or a gross breach of the law or the articles of association.

#### **Dividend Rights**

Under German law, distributions of dividends on shares for a given fiscal year are generally determined by a process in which the Management Board and Supervisory Board submit a proposal to the company's annual general shareholders' meeting held in the subsequent fiscal year and such annual general shareholders' meeting adopts a resolution.

German law provides that a resolution concerning dividends and distribution thereof may be adopted only if the company's unconsolidated financial statements prepared in accordance with German law show net retained profits. In determining the profit available for distribution, the result for the relevant year must be adjusted for profits and losses brought forward from the previous year and for withdrawals from or transfers to reserves. Certain reserves are required by law and must be deducted when calculating the profit available for distribution.

Shareholders generally participate in profit distributions in proportion to the number of shares they hold. Dividends on shares resolved by the general shareholders' meeting are paid annually, shortly after the general shareholders' meeting, in compliance with the rules of the respective clearing system. Dividend payment claims are subject to a three-year statute of limitation in the company's favor.

#### **Authorization to Purchase and Sell Our Own Shares**

We may not purchase our own shares unless authorized by the shareholders' meeting or in other very limited circumstances as set out in the German Stock Corporation Act. The Company's shareholders' meeting held on August 19, 2019 authorized the Management Board until August 18, 2024, provided it complies with the legal requirement of equal treatment, to acquire treasury shares up to a total of 10% of the Company's share capital at the time of the relevant resolution or at the time the authorization is exercised. These shares held by the Company (including shares attributable to it pursuant to the AktG) must never exceed 10% of the share capital. The shares may be purchased (i) through the stock exchange, (ii) by means of a public offer directed to all shareholders of the Company, (iii) by means of a public invitation to the shareholders to make a sales offer or (iv) from the Bill & Melinda Gates Foundation under very limited circumstances as specified in the authorization. Such shares may not be purchased for trading purposes. The Management Board is authorized to use the shares only as specified in the authorization.

#### **Squeeze-Out of Minority Shareholders**

Under German law, the shareholders' meeting of a stock corporation may resolve, upon request of a shareholder that holds at least 95% of the share capital, that the shares held by any remaining minority shareholders be transferred to the majority shareholder against payment of "adequate cash compensation" (*Ausschluss von Minderheitsaktionären*). This amount must take into account the full value of the company at the time of the resolution, which is generally determined using the future earnings value method (*Ertragswertmethode*).

A squeeze-out in the context of a merger (*umwandlungsrechtlicher Squeeze-Out*) only requires a majority shareholder to hold at least 90% of the share capital.

#### **Liquidation Rights**

Apart from liquidation, e.g., as a result of insolvency proceedings, we may be liquidated with a vote of the holders of at least three-quarters of the share capital represented at the shareholders' meeting at which such a vote is taken. If we are liquidated, any assets remaining after all of our liabilities have been paid off would be distributed among our shareholders in proportion to their holdings in accordance with German statutory law. The German Stock Corporation Act provides certain protections for creditors which must be observed in the event of liquidation.

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## Differences in Corporate Law

The applicable provisions of the SE Regulation in conjunction with the German Stock Corporation Act as applied to a European stock corporation that has its legal seat in Germany differ from laws applicable to U.S. corporations and their shareholders. Set forth below is a summary of certain differences between the provisions of the SE Regulation in conjunction with the German Stock Corporation Act applicable to us and the General Corporation Law of the State of Delaware relating to shareholders' rights and protections. This summary is not intended to be a complete discussion of the respective rights and it is qualified in its entirety by reference to Delaware law and European and German law.

	<i>European Union/Federal Republic of Germany</i>	<i>Delaware</i>
Board System	<p>A European stock corporation may choose to have a two-tier board structure composed of the Management Board (<i>Vorstand</i>) and the Supervisory Board (<i>Aufsichtsrat</i>). We have chosen this structure.</p> <p>The Management Board is responsible for running the company's affairs and representing the company in dealings with third parties.</p> <p>The Supervisory Board of a European stock corporation under German law has a control and supervisory function. The Supervisory Board does not actively manage the company but certain Management Board actions require the approval of the Supervisory Board.</p>	<p>Under Delaware law, a corporation has a unitary board structure, and it is the responsibility of the board of directors to appoint and oversee the management of the corporation on behalf of and in the best interests of the stockholders of the corporation.</p> <p>Management is responsible for running the corporation and overseeing its day-to-day operations.</p>
Appointment and Number of Directors	<p>Under applicable European and German law, a European stock corporation governed by German law with a share capital of at least €3 million generally must have at least two members on its Management Board and the number of members shall be determined by or in the manner provided in the company's articles of association.</p> <p>The Supervisory Board must consist of at least three but—depending on the share capital—no more than 21 Supervisory Board members, whereby the number of Supervisory Board members must be divisible by three if this is necessary for the fulfilment of co-determination requirements. The articles of association of the company must specify if the Supervisory Board has more than three members.</p>	<p>Under Delaware law, a corporation must have at least one director and the number of directors shall be fixed by or in the manner provided in the bylaws.</p>

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Supervisory Board members are either appointed by the shareholders' meeting or delegated by one or more individual shareholders if so provided for in the company's articles of association. If the Supervisory Board consists of fewer members than is required to meet the quorum for resolutions (either statutory or pursuant to the company's articles of association), a competent court may appoint additional members as needed to meet the quorum. The provisions of German law in relation to employees' co-determination do not apply to the Company.

## Removal of Directors

Members of the Management Board of a European stock corporation are appointed by the Supervisory Board for a maximum period of six years with an opportunity to be reelected. The articles of association may provide for a shorter term, which in our case is up to five years. The members of the Management Board may be reelected, even repeatedly. The Supervisory Board may remove a member of the Management Board prior to the expiration of his or her term only for cause, such as gross breach of duties (*grobe Pflichtverletzung*), the inability to manage the business properly (*Unfähigkeit zur ordnungsgemäßen Pflichtausübung*) or a vote of no-confidence during the shareholders' meeting (*Vertrauensentzug*). The shareholders themselves are not entitled to appoint or dismiss the members of the Management Board.

Under European law, a member of the Supervisory Board of a company may be elected for a term of up to six years. The articles of association may provide for a shorter term. Our Supervisory Board members are, if the general meeting does not resolve on a shorter term, elected for a period up to the end of the general meeting deciding on the discharge for the fourth financial year after the election. Reelection, including repeated reelection, is permissible. Members of the Supervisory Board may be removed with or without cause by way of a general meeting resolution, with the applicable majority requirement depending on the relevant company's articles of association.

Under Delaware law, any director or the entire board of directors may be removed, with or without cause, by the holders of a majority of the shares then entitled to vote at an election of directors, except (i) unless the certificate of incorporation provides otherwise, in the case of a corporation whose board of directors is classified, stockholders may effect such removal only for cause; or (ii) in the case of a corporation having cumulative voting, if less than the entire board of directors is to be removed, no director may be removed without cause if the votes cast against his removal would be sufficient to elect him if then cumulatively voted at an election of the entire board of directors, or, if there are classes of directors, at an election of the class of directors of which he is a part.

Vacancies on the Board of Directors	Under the law, vacant positions on the Management Board are filled by the Supervisory Board in accordance with the general rules of appointment, which provide that vacancies are filled by the simple majority of votes of Supervisory Board members present or represented by proxy at the vote (with, under certain circumstances, the chairman having a casting vote), unless otherwise provided by the company's articles of association. In case of emergencies, a vacant position on the Management Board may be filled by an individual appointed by the court. Vacant positions on the Supervisory Board are filled in accordance with the general rules of appointment.	Under Delaware law, vacancies and newly created directorships may be filled by a majority of the directors then in office (even though less than a quorum) or by a sole remaining director unless (i) otherwise provided in the certificate of incorporation or by-laws of the corporation or (ii) the certificate of incorporation directs that a particular class of stock is to elect such director, in which case a majority of the other directors elected by such class, or a sole remaining director elected by such class, will fill such vacancy.
Annual General Meeting	A European stock corporation which is governed by German law must hold an annual shareholders' meeting within six months of the end of its fiscal year. The annual shareholders' meeting must be held at a location determined by the articles of association. If the articles of association do not provide for a specific location, the shareholders' meeting shall be held at the company's seat or, if applicable, at the venue (in Germany) where its shares are listed.	Under Delaware law, the annual meeting of stockholders shall be held at such place, on such date and at such time as may be designated from time to time by the board of directors or as provided in the certificate of incorporation or by the bylaws.
General Meeting	Under the law, extraordinary shareholders' meetings, in addition to the annual shareholders' meetings, may be called by either the Management Board, or by the Supervisory Board. Shareholders holding at least 5% of the company's share capital are entitled to request that an extraordinary shareholders' meeting be convened. In the event that the meeting is not then so convened, a competent court may order that the meeting be convened or authorize the shareholders or their representative to convene the meeting themselves.	Under Delaware law, special meetings of the stockholders may be called by the board of directors or by such person or persons as may be authorized by the certificate of incorporation or by the bylaws.

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Notice of General Meetings	<p>Under applicable European and German law, unless a longer period is otherwise provided for in the articles of association or applies because of registration requirements stipulated in the articles of association, the shareholders must be given at least 30 days' advance notice of the shareholders' meeting. Such notices must at least specify the name of the company, the statutory seat of the company, and the location, date and time of the shareholders' meeting. In addition, the invitation must contain the agenda items as well as the Management Board's and the Supervisory Board's voting proposal for each agenda item and, depending on the circumstances, certain further information.</p> <p>If all shareholders entitled to attend the shareholders' meeting are present or represented and do not object to the meeting being held, the formalities of calling and holding of a shareholders' meeting do not apply.</p>	<p>Under Delaware law, unless otherwise provided in the certificate of incorporation or bylaws, written notice of any meeting of the stockholders must be given to each stockholder entitled to vote at the meeting not less than ten nor more than 60 days before the date of the meeting and shall specify the place, date, hour, and purpose or purposes of the meeting.</p>
Proxy	<p>A shareholder may designate another person to attend, speak and vote at a shareholders' meeting of the company on such shareholder's behalf by proxy.</p> <p>With respect to Management Board meetings, a Management Board member may transmit its (written or verbal) vote via another Management Board member.</p> <p>With respect to Supervisory Board meetings, a Supervisory Board member may participate in voting by issuing a written vote to another Supervisory Board member or any third party entitled to attend the Supervisory Board meeting.</p>	<p>Under Delaware law, at any meeting of stockholders, a stockholder may designate another person to act for such stockholder by proxy, but no such proxy shall be voted or acted upon after three years from its date, unless the proxy provides for a longer period. A director of a Delaware corporation may not issue a proxy representing the director's voting rights as a director.</p>
Preemptive Rights	<p>Under the law applicable to European stock corporations governed by German law, existing shareholders have a statutory subscription right for any additional issue of shares or any security convertible into shares pro rata to the nominal value of their respective holdings in the company, unless (i) shareholders representing three-quarters of the registered share capital present at the shareholders' meeting have resolved upon the whole or partial exclusion of the subscription right and (ii) there exists good and objective cause for such exclusion. No separate resolution on the exclusion of subscription rights is required if all shareholders waive their statutory subscription rights.</p>	<p>Under Delaware law, stockholders have no preemptive rights to subscribe to additional issues of stock or to any security convertible into such stock unless, and except to the extent that, such rights are expressly provided for in the certificate of incorporation.</p>

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## Authority to Allot

Under applicable European and German law, the Management Board may not allot shares, grant rights to subscribe for or to convert any security into shares unless a shareholder resolution to that effect has been passed at the company's shareholders' meeting granting the Management Board with such authority—subject to the approval of the Supervisory Board—in each case in accordance with the provisions of the German Stock Corporation Act.

Under Delaware law, if the corporation's certificate of incorporation so provides, the board of directors has the power to authorize the issuance of stock. It may authorize capital stock to be issued for consideration consisting of cash, any tangible or intangible property or any benefit to the corporation or any combination thereof. It may determine the amount of such consideration by approving a formula. In the absence of actual fraud in the transaction, the judgment of the directors as to the value of such consideration is conclusive.

## Liability of Directors and Officers

Under German law, any provision, whether contained in the company's articles of association or any contract or otherwise, that purports to exempt a Management or Supervisory Board member from any liability that would otherwise attach to such board member in connection with any negligence, default, breach of duty or breach of trust in relation to the company is void.

Under German law, members of both the Management Board and members of the Supervisory Board are liable to the company, and in certain cases to third parties or shareholders, for any damage caused to them due to a breach of such member's duty of care. Apart from insolvency or special circumstances, only the company has the right to claim damages from members of either board. The company may waive claims for damages against a negligent Management or Supervisory Board member only after the expiry of three years.

Under Delaware law, a corporation's certificate of incorporation may include a provision eliminating or limiting the personal liability of a director to the corporation and its stockholders for damages arising from a breach of fiduciary duty as a director. However, no provision can limit the liability of a director for:

- any breach of the director's duty of loyalty to the corporation or its stockholders;
  - acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law;
  - intentional or negligent payment of unlawful dividends or stock purchases or redemptions; or
  - any transaction from which the director derives an improper personal benefit.
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## Voting Rights

Under the relevant European and German law, each share, except for statutory non-voting preferred shares (*nicht stimmberechtigte Vorzugsaktien*), entitles its holder to vote at the shareholders' meeting with, in the case of no-par value shares, each share conferring one vote. While German law does not provide for a minimum attendance quorum for shareholders' meetings, the company's articles of association may so provide. In general, resolutions adopted at a shareholders' meeting may be passed by a simple majority of votes cast, unless a higher majority is required by law or under the company's articles of association.

Delaware law provides that, unless otherwise provided in the certificate of incorporation, each stockholder is entitled to one vote for each share of capital stock held by such stockholder.

## Shareholder Vote on Certain Transactions

Under applicable European and German law, certain shareholders' resolutions of fundamental importance require the vote of at least three-quarters of the share capital present or represented in the voting at the time of adoption of the resolution. Resolutions of fundamental importance include, in particular, capital increases with exclusion of subscription rights, capital decreases, the creation of authorized or conditional share capital, the dissolution of a company, a merger into or with another company, split-offs and split-ups, the conclusion of inter-company agreements (*Unternehmensverträge*), in particular domination agreements (*Beherrschungsverträge*) and profit and loss transfer agreements (*Ergebnisabführungsverträge*).

Generally, under Delaware law, unless the certificate of incorporation provides for the vote of a larger portion of the stock, completion of a merger, consolidation, sale, lease or exchange of all or substantially all of a corporation's assets or dissolution requires:

- the approval of the board of directors; and
- approval by the vote of the holders of a majority of the outstanding stock or, if the certificate of incorporation provides for more or less than one vote per share, a majority of the votes of the outstanding stock of a corporation entitled to vote on the matter.

## Standard of Conduct for Directors

Under applicable European and German law, both Management and Supervisory Board members must conduct their affairs with "the care and diligence of a prudent business man" and act in the best interest of the company. The scope of the fiduciary duties of Management and Supervisory Board members is generally determined by European and German legislation and by the courts.

Delaware law does not contain specific provisions setting forth the standard of conduct of a director. The scope of the fiduciary duties of directors is generally determined by the courts of the State of Delaware. In general, directors have a duty to act without self-interest, on a well-informed basis and in a manner they reasonably believe to be in the best interest of the stockholders.

Statutory and fiduciary duties of members of the Management Board to the company include, among others:

- to act in accordance with the law, the company's articles of association and the rules of procedure for the Management Board, if any;
- to report to the Supervisory Board on a regular basis as well as on certain important occasions;
- to exercise reasonable care, skill and diligence;
- to maintain a proper accounting system;
- to not compete, directly or indirectly, with the company without permission by the supervisory board; and
- to secure that no further transactions are made in case of insolvency.

Directors of a Delaware corporation owe fiduciary duties of care and loyalty to the corporation and to its stockholders. The duty of care generally requires that a director act in good faith, with the care that an ordinarily prudent person would exercise under similar circumstances. Under this duty, a director must inform himself of all material information reasonably available regarding a significant transaction. The duty of loyalty requires that a director act in a manner he reasonably believes to be in the best interests of the corporation. He must not use his corporate position for personal gain or advantage. In general, but subject to certain exceptions, actions of a director are presumed to have been made on an informed basis, in good faith and in the honest belief that the action taken was in the best interests of the corporation. However, this presumption may be rebutted by evidence of a breach of one of the fiduciary duties. Delaware courts have also imposed a heightened standard of conduct upon directors of a Delaware corporation who take any action designed to defeat a threatened change in control of the corporation.

Statutory and fiduciary duties of members of the Supervisory Board to the company include, among others:

- to effectively supervise the Management Board's handling of the company's affairs;
- to evaluate and issue a resolution on certain transactions which can only be conducted by the Management Board after approval of the Supervisory Board;
- to approve the company's financial statements;
- to appoint the Management Board members and to represent the company in transactions between the company and members of the Management Board; and
- to approve service contracts between individual members of the Supervisory Board and the company.

In addition, under Delaware law, when the board of directors of a Delaware corporation approves the sale or break-up of a corporation, the board of directors may, in certain circumstances, have a duty to obtain the highest value reasonably available to the stockholders.





Stockholder Actions

Under German law, generally, the company, rather than its shareholders, is the proper claimant in an action with respect to a wrong committed against the company, or in cases where there is an irregularity in the company's internal management or supervision. Therefore, such claims may only be raised by the company represented by its Management Board, or, in the case of a wrong committed by a member of the Management Board, by the Supervisory Board.

Additionally, pursuant to German case law, the Supervisory Board is obliged to pursue the company's claims against the Management Board, unless the interest of the company keeps them from doing so.

The Management Board, or, if a claim is against a member of the Management Board, the Supervisory Board, is obliged to pursue the company's claims against the designated individuals if so resolved by a simple majority of votes cast during a shareholders' meeting. With a simple majority of votes, shareholders can request that a representative pursues the claim on behalf of the company.

If the company is unable to fulfill its third-party obligations, the company's creditors may pursue the company's damage claims against members of the Management Board for certain wrongdoings.

Under certain circumstances, shareholders can bring forward damage claims of the company against its management on their own behalf. In order to bring forward such a claim one shareholder alone or together with other shareholders needs to hold at least one percent of the company's share capital or a participation of €100,000 in the share capital. Additionally, the claimant(s) need(s) to pass through special claim approval procedures.

Under Delaware law, a stockholder may initiate a derivative action to enforce a right of a corporation if the corporation fails to enforce the right itself. The complaint must:

- state that the plaintiff was a stockholder at the time of the transaction of which the plaintiff complains or that the plaintiff's shares thereafter devolved on the plaintiff by operation of law; and
- either (i) allege with particularity the efforts made by the plaintiff to obtain the action the plaintiff desires from the directors and the reasons for the plaintiff's failure to obtain the action, or (ii) or state the reasons for not making the effort.

Additionally, the plaintiff must remain a stockholder through the duration of the derivative suit. The action will not be dismissed or compromised without the approval of the Delaware Court of Chancery.

## American Depositary Shares

The Bank of New York Mellon, as depositary, will register and deliver the American Depositary Shares, or the ADSs. Each ADS will represent one share (or a right to receive one share) deposited with The Bank of New York Mellon SA/NV as custodian for the depositary in Germany. Each ADS will also represent any other securities, cash or other property which may be held by the depositary. The deposited shares together with any other securities, cash or other property held by the depositary are referred to as the deposited securities. The depositary's office at which the ADSs will be administered and its principal executive office are located at 240 Greenwich Street, New York, New York 10286.

You may hold ADSs either (i) directly (a) by having an American Depositary Receipt, or an ADR, which is a certificate evidencing a specific number of ADSs registered in your name, or (b) by having uncertificated ADSs registered in your name, or (ii) indirectly by holding a security entitlement in ADSs through your broker or other financial institution that is a direct or indirect participant in The Depository Trust Company, or DTC. If you hold ADSs directly, you are a registered ADS holder, or an ADS holder. This description assumes you are an ADS holder. If you hold the ADSs indirectly, you must rely on the procedures of your broker or other financial institution to assert the rights of ADS holders described in this section. You should consult with your broker or financial institution to find out what those procedures are.

Registered holders of uncertificated ADSs will receive statements from the depositary confirming their holdings.

As an ADS holder, we will not treat you as one of our shareholders and you will not have shareholder rights. European and German law governs shareholder rights. The depositary will be the holder of the shares underlying your ADSs. As a registered holder of ADSs, you will have ADS holder rights. A deposit agreement among us, the depositary, ADS holders and all other persons indirectly or beneficially holding ADSs sets out ADS holder rights as well as the rights and obligations of the depositary. New York law governs the deposit agreement and the ADSs.

The following is a summary of the material provisions of the deposit agreement. For more complete information, you should read the entire deposit agreement and the form of ADR. Those documents are filed as exhibits to the registration statement of which this prospectus forms a part.

### Dividends and Other Distributions

#### *How will ADS holders receive dividends and other distributions on the shares?*

The depositary has agreed to pay or distribute to ADS holders the cash dividends or other distributions it or the custodian receives on shares or other deposited securities, upon payment or deduction of its fees and expenses. You will receive these distributions in proportion to the number of shares your ADSs represent.

*Cash.* The depositary will convert any cash dividend or other cash distribution we pay on the shares into U.S. dollars, if it can do so on a reasonable basis and can transfer the U.S. dollars to the United States. If that is not possible or if any government approval is needed and cannot be obtained, the deposit agreement allows the depositary to distribute the foreign currency only to those ADS holders to whom it is possible to do so. It will hold the foreign currency it cannot convert for the account of the ADS holders who have not been paid. It will not invest the foreign currency and it will not be liable for any interest.

Before making a distribution, any withholding taxes, or other governmental charges that must be paid will be deducted. The depositary will distribute only whole U.S. dollars and cents and will round fractional cents to the nearest whole cent. *If the exchange rates fluctuate during a time when the depositary cannot convert the foreign currency, you may lose some of the value of the distribution.*

*Shares.* The depositary may distribute additional ADSs representing any shares we distribute as a dividend or free distribution. The depositary will only distribute whole ADSs. It will sell shares which would require it to deliver a fraction of an ADS (or ADSs representing those shares) and distribute the net proceeds in the same way as it does with cash. If the depositary does not distribute additional ADSs, the outstanding ADSs will also represent the new shares. The depositary may sell a portion of the distributed shares (or ADSs representing those shares) sufficient to pay its fees and expenses in connection with that distribution.

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*Rights to purchase additional shares.* If we offer holders of our securities any rights to subscribe for additional shares or any other rights, the depositary may (i) exercise those rights on behalf of ADS holders, (ii) distribute those rights to ADS holders or (iii) sell those rights and distribute the net proceeds to ADS holders, in each case after deduction or upon payment of its fees and expenses. To the extent the depositary does not do any of those things, it will allow the rights to lapse. **In that case, you will receive no value for them.** The depositary will exercise or distribute rights only if we ask it to and provide satisfactory assurances to the depositary that it is legal to do so. If the depositary will exercise rights, it will purchase the securities to which the rights relate and distribute those securities or, in the case of shares, new ADSs representing the new shares, to subscribing ADS holders, but only if ADS holders have paid the exercise price to the depositary. U.S. securities laws may restrict the ability of the depositary to distribute rights or ADSs or other securities issued on exercise of rights to all or certain ADS holders, and the securities distributed may be subject to restrictions on transfer.

*Other Distributions.* The depositary will send to ADS holders anything else we distribute on deposited securities by any means it thinks is legal, fair and practical. If it cannot make the distribution in that way, the depositary has a choice. It may decide to sell what we distributed and distribute the net proceeds, in the same way as it does with cash. Or, it may decide to hold what we distributed, in which case ADSs will also represent the newly distributed property. However, the depositary is not required to distribute any securities (other than ADSs) to ADS holders unless it receives satisfactory evidence from us that it is legal to make that distribution. The depositary may sell a portion of the distributed securities or property sufficient to pay its fees and expenses in connection with that distribution. U.S. securities laws may restrict the ability of the depositary to distribute securities to all or certain ADS holders, and the securities distributed may be subject to restrictions on transfer.

The depositary is not responsible if it decides that it is unlawful or impractical to make a distribution available to any ADS holders. We have no obligation to register ADSs, shares, rights or other securities under the Securities Act. We also have no obligation to take any other action to permit the distribution of ADSs, shares, rights or anything else to ADS holders. **This means that you may not receive the distributions we make on our shares or any value for them if it is illegal or impractical for us to make them available to you.**

#### **Deposit, Withdrawal and Cancellation**

##### ***How are ADSs issued?***

The depositary will deliver ADSs if you or your broker deposits shares or evidence of rights to receive shares with the custodian. Upon payment of its fees and expenses and of any taxes or charges, such as stamp taxes or stock transfer taxes or fees, the depositary will register the appropriate number of ADSs in the names you request and will deliver the ADSs to or upon the order of the person or persons that made the deposit.

##### ***How can ADS holders withdraw the deposited securities?***

You may surrender your ADSs to the depositary for the purpose of withdrawal. Upon payment of its fees and expenses and of any taxes or charges, such as stamp taxes or stock transfer taxes or fees, the depositary will deliver the shares and any other deposited securities underlying the ADSs to the ADS holder or a person the ADS holder designates at the office of the custodian. Or, at your request, risk and expense, the depositary will deliver the deposited securities at its office, if feasible. However, the depositary is not required to accept surrender of ADSs to the extent it would require delivery of a fraction of a deposited share or other security. The depositary may charge you a fee and its expenses for instructing the custodian regarding delivery of deposited securities.

##### ***How do ADS holders interchange between certificated ADSs and uncertificated ADSs?***

You may surrender your ADR to the depositary for the purpose of exchanging your ADR for uncertificated ADSs. The depositary will cancel that ADR and will send to the ADS holder a statement confirming that the ADS holder is the registered holder of uncertificated ADSs. Upon receipt by the depositary of a proper instruction from a registered holder of uncertificated ADSs requesting the exchange of uncertificated ADSs for certificated ADSs, the depositary will execute and deliver to the ADS holder an ADR evidencing those ADSs.

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## Voting Rights

### *How do ADS holders vote?*

ADS holders may instruct the depositary how to vote the number of deposited shares their ADSs represent. If we request the depositary to solicit your voting instructions (and we are not required to do so), the depositary will notify you of a shareholders' meeting and send or make voting materials available to you. Those materials will describe the matters to be voted on and explain how ADS holders may instruct the depositary how to vote. For instructions to be valid, they must reach the depositary by a date set by the depositary. The depositary will try, as far as practical, subject to the laws of the State of New York and the provisions of our articles of association or similar documents, to vote or to have its agents vote the shares or other deposited securities as instructed by ADS holders. If we do not request the depositary to solicit your voting instructions, you can still send voting instructions, and, in that case, the depositary may try to vote as you instruct, but it is not required to do so.

**Except by instructing the depositary as described above, you won't be able to exercise voting rights unless you surrender your ADSs and withdraw the shares. However, you may not know about the meeting enough in advance to withdraw the shares.** In any event, the depositary will not exercise any discretion in voting deposited securities and it will only vote or attempt to vote as instructed or as described in the following sentence. If (i) we asked the depositary to solicit your instructions at least 30 days before the meeting date, (ii) the depositary does not receive voting instructions from you by the specified date and (iii) we confirm to the depositary that:

- we wish the depositary to vote uninstructed shares;
- we reasonably do not know of any substantial shareholder opposition to a particular question; and
- the particular question is not materially adverse to the interests of shareholders,

the depositary will consider you to have authorized and directed it to vote the number of deposited securities represented by your ADSs in favor of any resolution that we proposed in the invitation to the shareholders' meeting.

We cannot assure you that you will receive the voting materials in time to ensure that you can instruct the depositary to vote your shares. In addition, the depositary and its agents are not responsible for failing to carry out voting instructions or for the manner of carrying out voting instructions. **This means that you may not be able to exercise voting rights and there may be nothing you can do if your shares are not voted as you requested.**

In order to give you a reasonable opportunity to instruct the depositary as to the exercise of voting rights relating to deposited securities, if we request the depositary to act, we agree to give the depositary notice of any such meeting and details concerning the matters to be voted upon at least 30 days in advance of the meeting date.

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**Fees and Expenses**

*Persons depositing or withdrawing shares or ADS holders must pay:*

*For:*

\$5.00 (or less) per 100 ADSs (or portion of 100 ADSs)

Issuance of ADSs, including issuances resulting from a distribution of shares or rights or other property

Cancellation of ADSs for the purpose of withdrawal, including if the deposit agreement terminates

\$.05 (or less) per ADS

Any cash distribution to ADS holders

A fee equivalent to the fee that would be payable if securities distributed to you had been shares and the shares had been deposited for issuance of ADSs

Distribution of securities distributed to holders of deposited securities (including rights) that are distributed by the depositary to ADS holders

\$.05 (or less) per ADS per calendar year

Depository services

Registration or transfer fees

Transfer and registration of shares on our share register to or from the name of the depositary or its agent when you deposit or withdraw shares

Expenses of the depositary

Cable and facsimile transmissions (when expressly provided in the deposit agreement)

Converting foreign currency to U.S. dollars

Taxes and other governmental charges the depositary or the custodian has to pay on any ADSs or shares underlying ADSs, such as stock transfer taxes, stamp duty or withholding taxes

As necessary

Any charges incurred by the depositary or its agents for servicing the deposited securities

As necessary

The depositary collects its fees for delivery and surrender of ADSs directly from investors depositing shares or surrendering ADSs for the purpose of withdrawal or from intermediaries acting for them. The depositary collects fees for making distributions to investors by deducting those fees from the amounts distributed or by selling a portion of distributable property to pay the fees. The depositary may collect its annual fee for depository services by deduction from cash distributions or by directly billing investors or by charging the book-entry system accounts of participants acting for them. The depositary may collect any of its fees by deduction from any cash distribution payable (or by selling a portion of securities or other property distributable) to ADS holders that are obligated to pay those fees. The depositary may generally refuse to provide fee-attracting services until its fees for those services are paid.

From time to time, the depositary may make payments to us to reimburse us for costs and expenses generally arising out of establishment and maintenance of the ADS program, waive fees and expenses for services provided to us by the depositary or share revenue from the fees collected from ADS holders. In performing its duties under the deposit agreement, the depositary may use brokers, dealers, foreign currency dealers or other service providers that are owned by or affiliated with the depositary and that may earn or share fees, spreads or commissions.

The depositary may convert currency itself or through any of its affiliates and, in those cases, acts as principal for its own account and not as agent, advisor, broker or fiduciary on behalf of any other person and earns revenue, including, without limitation, transaction spreads, that it will retain for its own account. The revenue is based on, among other things, the difference between the exchange rate assigned to the currency conversion made under the deposit agreement and the rate that the depositary or its affiliate receives when buying or selling foreign currency for its own account. The depositary makes no representation that the exchange rate used or obtained in any currency conversion under the deposit agreement will be the most

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favorable rate that could be obtained at the time or that the method by which that rate will be determined will be the most favorable to ADS holders, subject to the depositary's obligations under the deposit agreement. The methodology used to determine exchange rates used in currency conversions is available upon request.

#### **Payment of Taxes**

You will be responsible for any taxes or other governmental charges payable on your ADSs or on the deposited securities represented by any of your ADSs. The depositary may refuse to register any transfer of your ADSs or allow you to withdraw the deposited securities represented by your ADSs until those taxes or other charges are paid. It may apply payments owed to you or sell deposited securities represented by your ADSs to pay any taxes owed and you will remain liable for any deficiency. If the depositary sells deposited securities, it will, if appropriate, reduce the number of ADSs to reflect the sale and pay to ADS holders any proceeds, or send to ADS holders any property, remaining after it has paid the taxes.

#### **Tender and Exchange Offers; Redemption, Replacement or Cancellation of Deposited Securities**

The depositary will not tender deposited securities in any voluntary tender or exchange offer unless instructed to do by an ADS holder surrendering ADSs and subject to any conditions or procedures the depositary may establish.

If deposited securities are redeemed for cash in a transaction that is mandatory for the depositary as a holder of deposited securities, the depositary will call for surrender of a corresponding number of ADSs and distribute the net redemption money to the holders of called ADSs upon surrender of those ADSs.

If there is any change in the deposited securities such as a sub-division, combination or other reclassification, or any merger, consolidation, recapitalization or reorganization affecting the issuer of deposited securities in which the depositary receives new securities in exchange for or in lieu of the old deposited securities, the depositary will hold those replacement securities as deposited securities under the deposit agreement. However, if the depositary decides it would not be lawful and practical to hold the replacement securities because those securities could not be distributed to ADS holders or for any other reason, the depositary may instead sell the replacement securities and distribute the net proceeds upon surrender of the ADSs.

If there is a replacement of the deposited securities and the depositary will continue to hold the replacement securities, the depositary may distribute new ADSs representing the new deposited securities or ask you to surrender your outstanding ADRs in exchange for new ADRs identifying the new deposited securities.

If there are no deposited securities underlying ADSs, including if the deposited securities are cancelled, or if the deposited securities underlying ADSs have become apparently worthless, the depositary may call for surrender or of those ADSs or cancel those ADSs upon notice to the ADS holders.

#### **Amendment and Termination**

##### ***How may the deposit agreement be amended?***

We may agree with the depositary to amend the deposit agreement and the ADRs without your consent for any reason. If an amendment adds or increases fees or charges, except for taxes and other governmental charges or expenses of the depositary for registration fees, facsimile costs, delivery charges or similar items, or prejudices a substantial right of ADS holders, it will not become effective for outstanding ADSs until 30 days after the depositary notifies ADS holders of the amendment. **At the time an amendment becomes effective, you are considered, by continuing to hold your ADSs, to agree to the amendment and to be bound by the ADRs and the deposit agreement as amended.**

##### ***How may the deposit agreement be terminated?***

The depositary will initiate termination of the deposit agreement if we instruct it to do so. The depositary may initiate termination of the deposit agreement if:

- 60 days have passed since the depositary told us it wants to resign but a successor depositary has not been appointed and accepted its appointment;

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- we delist the ADSs from an exchange in the United States on which they were listed and do not list the ADSs on another exchange in the United States or make arrangements for trading of ADSs on the U.S. over-the-counter market;
- we delist our ordinary shares from an exchange outside the United States on which they were listed and do not list the shares on another exchange outside the United States;
- the depositary has reason to believe the ADSs have become, or will become, ineligible for registration on Form F-6 under the Securities Act;
- we appear to be insolvent or enter insolvency proceedings
- all or substantially all the value of the deposited securities has been distributed either in cash or in the form of securities;
- there are no deposited securities underlying the ADSs or the underlying deposited securities have become apparently worthless; or
- there has been a replacement of deposited securities.

If the deposit agreement will terminate, the depositary will notify ADS holders at least 90 days before the termination date. At any time after the termination date, the depositary may sell the deposited securities. After that, the depositary will hold the money it received on the sale, as well as any other cash it is holding under the deposit agreement, unsegregated and without liability for interest, for the pro rata benefit of the ADS holders that have not surrendered their ADSs. Normally, the depositary will sell as soon as practicable after the termination date.

After the termination date and before the depositary sells, ADS holders can still surrender their ADSs and receive delivery of deposited securities, except that the depositary may refuse to accept a surrender for the purpose of withdrawing deposited securities or reverse previously accepted surrenders of that kind that have not settled if it would interfere with the selling process. The depositary may refuse to accept a surrender for the purpose of withdrawing sale proceeds until all the deposited securities have been sold. The depositary will continue to collect distributions on deposited securities, but, after the termination date, the depositary is not required to register any transfer of ADSs or distribute any dividends or other distributions on deposited securities to the ADSs holder (until they surrender their ADSs) or give any notices or perform any other duties under the deposit agreement except as described in this paragraph.

#### **Limitations on Obligations and Liability**

##### ***Limits on our Obligations and the Obligations of the Depositary; Limits on Liability to Holders of ADSs***

The deposit agreement expressly limits our obligations and the obligations of the depositary. It also limits our liability and the liability of the depositary. We and the depositary:

- are only obligated to take the actions specifically set forth in the deposit agreement without negligence or bad faith, and the depositary will not be a fiduciary or have any fiduciary duty to holders of ADSs;
  - are not liable if we are or it is prevented or delayed by law or by events or circumstances beyond our or its ability to prevent or counteract with reasonable care or effort from performing our or its obligations under the deposit agreement;
  - are not liable if we or it exercises discretion permitted under the deposit agreement;
  - are not liable for the inability of any holder of ADSs to benefit from any distribution on deposited securities that is not made available to holders of ADSs under the terms of the deposit agreement, or for any special, consequential or punitive damages for any breach of the terms of the deposit agreement;
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- have no obligation to become involved in a lawsuit or other proceeding related to the ADSs or the deposit agreement on your behalf or on behalf of any other person;
- may rely upon any documents we believe or it believes in good faith to be genuine and to have been signed or presented by the proper person;
- are not liable for the acts or omissions of any securities depository, clearing agency or settlement system; and
- the depository has no duty to make any determination or provide any information as to our tax status, or any liability for any tax consequences that may be incurred by ADS holders as a result of owning or holding ADSs or be liable for the inability or failure of an ADS holder to obtain the benefit of a foreign tax credit, reduced rate of withholding or refund of amounts withheld in respect of tax or any other tax benefit.

In the deposit agreement, we and the depository agree to indemnify each other under certain circumstances.

#### **Requirements for Depository Actions**

Before the depository will deliver or register a transfer of ADSs, make a distribution on ADSs, or permit withdrawal of shares, the depository may require:

- payment of stock transfer or other taxes or other governmental charges and transfer or registration fees charged by third parties for the transfer of any shares or other deposited securities;
- satisfactory proof of the identity and genuineness of any signature or other information it deems necessary; and
- compliance with regulations it may establish, from time to time, consistent with the deposit agreement, including presentation of transfer documents.

The depository may refuse to deliver ADSs or register transfers of ADSs when the transfer books of the depository or our transfer books are closed or at any time if the depository or we think it advisable to do so.

#### **Your Right to Receive the Shares Underlying your ADSs**

ADS holders have the right to cancel their ADSs and withdraw the underlying shares at any time except:

- when temporary delays arise because (i) the depository has closed its transfer books or we have closed our transfer books, (ii) the transfer of shares is blocked to permit voting at a shareholders' meeting or (iii) we are paying a dividend on our shares;
- when you owe money to pay fees, taxes and similar charges; or
- when it is necessary to prohibit withdrawals in order to comply with any laws or governmental regulations that apply to ADSs or to the withdrawal of shares or other deposited securities.

This right of withdrawal may not be limited by any other provision of the deposit agreement.

#### **Direct Registration System**

In the deposit agreement, all parties to the deposit agreement acknowledge that the Direct Registration System, or DRS, and Profile Modification System, or Profile, will apply to the ADSs. DRS is a system administered by DTC that facilitates interchange between registered holding of uncertificated ADSs and holding of security entitlements in ADSs through DTC and a DTC participant. Profile is a feature of DRS that allows a DTC participant, claiming to act on behalf of a registered holder of uncertificated ADSs, to direct the depository to register a transfer of those ADSs to DTC or its nominee and to deliver those ADSs to the DTC account of that

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DTC participant without receipt by the depository of prior authorization from the ADS holder to register that transfer.

In connection with and in accordance with the arrangements and procedures relating to DRS/Profile, the parties to the deposit agreement understand that the depository will not determine whether the DTC participant that is claiming to be acting on behalf of an ADS holder in requesting registration of transfer and delivery as described in the paragraph above has the actual authority to act on behalf of the ADS holder (notwithstanding any requirements under the Uniform Commercial Code). In the deposit agreement, the parties agree that the depository's reliance on and compliance with instructions received by the depository through the DRS/Profile system and in accordance with the deposit agreement will not constitute negligence or bad faith on the part of the depository.

**Shareholder Communications; Inspection of Register of Holders of ADSs**

The depository will make available for your inspection at its office all communications that it receives from us as a holder of deposited securities that we make generally available to holders of deposited securities. The depository will send you copies of those communications or otherwise make those communications available to you if we ask it to. You have a right to inspect the register of holders of ADSs, but not for the purpose of contacting those holders about a matter unrelated to our business or the ADSs.

**Jury Trial Waiver**

The deposit agreement provides that, to the extent permitted by law, ADS holders waive the right to a jury trial of any claim they may have against us or the depository arising out of or relating to our shares, the ADSs or the deposit agreement, including any claim under the U.S. federal securities laws. If we or the depository opposed a jury trial demand based on the waiver, the court would determine whether the waiver was enforceable in the facts and circumstances of that case in accordance with applicable case law.

You will not, by agreeing to the terms of the deposit agreement, be deemed to have waived our or the depository's compliance with U.S. federal securities laws and the rules and regulations promulgated thereunder.

THE SYMBOL "[\*\*\*]" DENOTES PLACES WHERE CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH (i) NOT MATERIAL, AND (ii) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF PUBLICLY DISCLOSED

FIRST AMENDMENT TO THE COLLABORATION AGREEMENT

THIS FIRST AMENDMENT TO THE COLLABORATION AGREEMENT ("**First Amendment**") is made and entered into, effective as of June 1, 2018 ("**Amendment Effective Date**"), by and between BioNTech RNA Pharmaceuticals GmbH, a limited liability company organized under the laws of Germany ("**RNP**") and BioNTech AG, a stock corporation organized under the laws of Germany ("**BNT**") (RNP and BNT collectively, "**BioNTech**"), and Genentech, Inc., a corporation organized under the laws of the State of Delaware ("**GNE**") and F. Hoffmann-La Roche Ltd, a corporation organized under the laws of Switzerland ("**Roche**") (GNE and Roche, collectively, "**Genentech**"). BioNTech and Genentech are sometimes referred to herein individually as a "**Party**" and collectively as the "**Parties**."

BACKGROUND

WHEREAS, the Parties entered into a Collaboration Agreement dated as of September 20, 2016 pursuant to which BioNTech and Genentech agreed to collaborate in the research, development, and commercialization of Collaboration Products (the "**Agreement**");

WHEREAS, the Parties have agreed to amend the Agreement to add a patent to the list of BioNTech Core Patents as set forth herein.

NOW THEREFORE, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties agree as follows:

1. **Schedule 1.20 BioNTech Core Patents.** Schedule 1.20 shall be deleted and replaced in its entirety with the revised Schedule 1.20 attached hereto.

2. **Survival of Agreement Terms.** All terms and conditions of the Agreement not modified by this First Amendment shall continue in full force and effect in accordance with their terms. All capitalized terms not otherwise defined herein shall have the same definition as in the Agreement. In the event of any conflict between the terms and conditions of this First Amendment and the Agreement, the terms and conditions set forth in this First Amendment shall control with respect to the subject matter hereof.

[Signature page follows - the rest of this page intentionally left blank]

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IN WITNESS WHEREOF, the Parties have executed this First Amendment by their respective officers hereunto duly authorized, on the Amendment Effective Date.

**GENENTECH, INC.**

By: \_\_\_\_\_  
Name:  
Title:

**BIONTECH RNA  
PHARMACEUTICALS GMBH**

By: \_\_\_\_\_  
Name:  
Title:

**F. HOFFMANN-LA ROCHE LTD**

By: \_\_\_\_\_  
Name:  
Title:

**BIONTECH SE**

By: \_\_\_\_\_  
Name:  
Title:

**F. HOFFMANN-LA ROCHE LTD**

By: \_\_\_\_\_  
Name:  
Title:

BioNTech Core Patents

No.	Solely owned BioNTech Core	In-Licensed BioNTech Core
	Patents	Patents
***	***	***

<u>Neopeptide Prediction Algorithm</u>	
***	***

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THE SYMBOL “[\*\*\*]” DENOTES PLACES WHERE CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH (i) NOT MATERIAL, AND (ii) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF PUBLICLY DISCLOSED

SECOND AMENDMENT TO  
THE COLLABORATION AGREEMENT

This SECOND AMENDMENT (the “**Second Amendment**”) is made and entered into, effective as of December 6, 2019 (the “**Second Amendment Effective Date**”), by and between BioNTech RNA Pharmaceuticals GmbH, a limited liability company organized under the laws of Germany (“**RNP**”) and BioNTech SE, a European stock corporation (“**BNT**”) (RNP and BNT collectively, “**BioNTech**”), and Genentech, Inc., a corporation organized under the laws of the State of Delaware (“**GNE**”) and F. Hoffmann-La Roche Ltd, a corporation organized under the laws of Switzerland (“**Roche**”) (GNE and Roche, collectively, “**Genentech**”).

WHEREAS, the Parties entered into a Collaboration Agreement, dated as of September 20, 2016, as amended on June 1, 2018, pursuant to which BioNTech and Genentech agreed to collaborate in the research, development, and commercialization of Collaboration Products (the “**Agreement**”).

WHEREAS, BioNTech and Genentech wish to modify certain terms of the Agreement with respect to [\*\*\*] (i) certain RNA manufacturing projects within the CMC Development Plan and (ii) development of the commercial upstream manufacturing process.

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties agree as follows:

1. **Defined Terms.**

- a. Section 1.20 is hereby deleted in its entirety and replaced with the following:

“**BioNTech Core Patents**’ means (a) the Patents listed on Schedule 1.20, (b) [\*\*\*] and (c) all Patents claiming priority to any of the Patents described in clauses (a) or (b), or claiming priority to a priority document thereof.”

- b. Section 1.27 is hereby amended by adding the following sentence to the end of the Section:

“For clarity, BioNTech Know-How [\*\*\*].”

- c. Section 1.59 is hereby amended by adding the following clause to the end of the Section:

“; *provided*, however, that, notwithstanding anything to the contrary in this Agreement or the MDSA, Collaboration Know-How [\*\*\*]”

- d. The following definition is hereby added to the Agreement as Section 1.331:

“**External Sequencing Party**’ means an entity other than BioNTech or Genentech that is selected by Genentech to conduct some or all of the Sequencing Manufacturing Project.”

- e. The following definition is hereby added to the Agreement as Section 1.332:

“**RNA Manufacturing Know-How**’ means all Know-How that is discovered, generated, conceived or reduced to practice by a Party (or any authorized Third Party acting on a Party’s behalf) solely or jointly in the course of conducting the RNA Manufacturing Projects.”

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f. The following definition is hereby added to the Agreement as Section 1.333:

“**RNA Manufacturing Projects**’ means the work packages for the Collaboration Products concerning RNA manufacturing process, [\*\*\*] set forth in Schedule 1.333.”

g. The following definition is hereby added to the Agreement as Section 1.334:

“**Sequencing Manufacturing IP**’ means the Sequencing Manufacturing Know-How and all Patents that claim any such Sequencing Manufacturing Know-How.”

h. The following definition is hereby added to the Agreement as Section 1.335:

“**Sequencing Manufacturing Know-How**’ means all Know-How that is discovered, generated, conceived or reduced to practice by Genentech or by the External Sequencing Party on a Party’s behalf (whether solely or jointly with a Party) in the course of conducting any activities in connection with the Sequencing Manufacturing Project.”

i. The following definition is hereby added to the Agreement as Section 1.336:

“**Sequencing Manufacturing Project**’ means the development of the upstream portion of the Manufacturing Process for Commercial Manufacturing [\*\*\*].”

2. **Exhibits.** The schedule attached hereto as Exhibit A is hereby incorporated into the Agreement as Schedule 1.333.

3. **Amendment of the CMC Development Plan.** For each RNA Manufacturing Project, the Parties hereby agree that they will (a) agree upon a written project plan for such RNA Manufacturing Project, which will set forth the scope of work to be performed by each Party, deliverables, time schedule and budget (including required FTEs, equipment and other resources), (b) promptly amend the CMC Development Plan to include such agreed-upon project plan for such RNA Manufacturing Project, and (c) conduct such RNA Manufacturing Project in accordance with such project plan. Notwithstanding the foregoing, in the event that the Parties are unable to agree on such written project plan [\*\*\*].

4. **Decision-Making.** Section 2.8.2(g) is hereby amended by adding the following clause to the end of the Section:

“[\*\*\*]”

5. **Sequencing Manufacturing by the External Sequencing Party.** The following provision is hereby added to the Agreement as Section 7.4:

**“Sequencing Manufacturing by the External Sequencing Party.**

**7.4.1 Sequencing Manufacturing Project.** Notwithstanding anything to the contrary in this Agreement (including Sections 7.1 and 7.2) or the MDSA, Genentech shall have the sole right and responsibility for the performance of the Sequencing Manufacturing Project, at its discretion (subject to Sections 7.4.2 and 10.2.5), and may use the External Sequencing Party to conduct some or all of the Sequencing Manufacturing Project. Genentech shall ensure that the Sequencing Manufacturing Project is designed to deliver, and shall use commercially reasonable efforts to deliver, [\*\*\*].

**7.4.2 Use of External Sequencing Party by BioNTech.** If in connection with BioNTech’s Development of a BioNTech Indication or BioNTech’s Development or Commercialization of Reversion Products pursuant to Section 14.5.4, in each case, in accordance with (and subject to the terms and conditions

of) this Agreement, BioNTech desires to use the External Sequencing Party that Genentech is using to perform the sequencing for the upstream portion of the Manufacturing Process for Commercial Manufacturing [\*\*\*], Genentech will [\*\*\*] in the case of BioNTech Indications, or [\*\*\*] in the case of Reversion Products.’

6. **Costs.**

a. The following provision is hereby added to the Agreement as Section 8.2.8:

“**RNA Manufacturing Project Costs.** BioNTech shall be solely responsible for, and shall bear, all CMC Development Costs incurred by or on behalf of BioNTech or Genentech in the performance of activities pursuant to a RNA Manufacturing Project. In the event that Genentech incurs CMC Development Costs in connection with an RNA Manufacturing Project, such costs shall be reported to, and reimbursed by, BioNTech as part of the reconciliation process set forth in Sections 8.2.6 and 8.2.7. Genentech may offset the amounts of any invoices for such reconciled costs not paid in accordance with Section 8.2.7 from any payments due to BioNTech pursuant to Sections 8.4.1 and 8.7. Notwithstanding the foregoing, for any portion of such CMC Development Costs that both (a) are incurred by or on behalf of Genentech in excess of [\*\*\*] percent ([\*\*%]) of the budget set forth in the CMC Development Plan for activities allocated to Genentech pursuant to such RNA Manufacturing Project, and (b) have not been approved by BioNTech in advance, Genentech shall bear such portion of the CMC Development Costs. For clarity, the costs of implementing any processes or developments made under an RNA Manufacturing Project into the Manufacturing Process for a Collaboration Product shall be Shared Development Costs.”

b. The following provision is hereby added to the Agreement as Section 8.2.9:

“**Sequencing Manufacturing Project.** Genentech shall be solely responsible for, and shall bear, all Development Costs incurred by it and its Affiliates for the performance of the Sequencing Manufacturing Project by Genentech, its Affiliates or the External Sequencing Party.”

7. **Intellectual Property.**

a. The following is provision is hereby added to Section 10.2.1 as subsection (d):

“[\*\*\*]”

b. The following provision is hereby added to the Agreement as Section 10.2.5:

“[\*\*\*]”

8. **Survival of Agreement Terms.** All terms and conditions of the Agreement not modified by this Second Amendment shall continue in full force and effect in accordance with their terms. All capitalized terms not otherwise defined herein shall have the same definition as in the Agreement. In the event of any conflict between the terms and conditions of this Second Amendment and the Agreement, the terms and conditions set forth in this Second Amendment shall control with respect to the subject matter hereof.

*[Remainder of the page intentionally left blank; signature page follows.]*

IN WITNESS WHEREOF, the Parties have each caused this Second Amendment to be executed by their duly authorized representatives.

**GENENTECH, INC.**

By: \_\_\_\_\_

Name:

Title:

**F. HOFFMANN-LA ROCHE LTD**

By: \_\_\_\_\_

Name:

Title:

**F. HOFFMANN-LA ROCHE LTD**

By: \_\_\_\_\_

Name:

Title:

**BIONTECH RNA  
PHARMACEUTICALS GMBH**

By: \_\_\_\_\_

Name:

Title:

**BIONTECH SE**

By: \_\_\_\_\_

Name:

Title:





**JOINDER AND THIRD AMENDMENT TO THE COLLABORATION AGREEMENT**

This JOINDER AND THIRD AMENDMENT (the “**Third Amendment**”) is made and entered into, effective as of October 1, 2020 (the “**Third Amendment Effective Date**”), by and between (1) BioNTech RNA Pharmaceuticals GmbH, a limited liability company organized under the laws of Germany (“**RNP**”) and BioNTech SE, a European stock corporation (“**BNT**”) (RNP and BNT collectively, “**BioNTech**”), (2) Genentech, Inc., a corporation organized under the laws of the State of Delaware (“**GNE**”) and F. Hoffmann-La Roche Ltd, a corporation organized under the laws of Switzerland (“**Roche**”) (GNE and Roche, collectively, “**Genentech**”) and (3) BioNTech Manufacturing GmbH, a German limited liability company having its principal place of business at An der Goldgrube 12, 55131, Germany (“**BMG**”),

each a “**Party**” and together the “**Parties**”.

WHEREAS, BioNTech and Genentech entered into a Collaboration Agreement, dated as of September 20, 2016, as amended on June 1, 2018 and on December 6, 2019, and as supplemented by letters between BioNTech and Genentech dated June 1, 2020, June 24, 2020 and August 3, 2020, pursuant to which BioNTech and Genentech agreed to collaborate in the research, development and commercialization of Collaboration Products (as amended and supplemented, the “**Collaboration Agreement**”).

WHEREAS, BioNTech and Genentech further entered into a Manufacturing Development and Supply Agreement, dated as of September 20, 2016, pursuant to which BioNTech and Genentech agreed to collaborate on CMC development and related activities in support of (i) clinical supply of Collaboration Products that are Personalized Products through BioNTech’s Clinical Facilities and (ii) commercial supply of Collaboration Products that are Personalized Products through a joint Manufacturing Network (as such terms are defined in such agreement) (as amended, the “**MDSA**”).

WHEREAS, on the Third Amendment Effective Date, pursuant to an intra-group reorganization, RNP transferred the business and assets relating to its manufacturing operations to BMG, a wholly-owned subsidiary of BNT (the “**Manufacturing Asset Transfer**”). RNP further proposes to transfer all the assets, obligations and liabilities retained by it following the Manufacturing Asset Transfer (including the Collaboration Agreement and the MDSA) to BNT on 1 January 2021 (the “**Asset Transfer**”).

WHEREAS, BioNTech and Genentech, therefore, wish to modify certain terms of the Collaboration Agreement with respect to the above transactions and to join BMG as a party to the Collaboration Agreement.

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties agree as follows:

**1. Addition of BMG as a party to the Collaboration Agreement**

- a. BioNTech hereby represents and warrants that BMG is a wholly-owned subsidiary of BNT. Each of BMG and RNP will continue to be wholly-owned subsidiaries of BNT through the effective date of the Asset Transfer.
  - b. BMG (i) shall be made a party to the Collaboration Agreement; (ii) accepts and agrees to be subject to all terms, conditions and obligations of the Collaboration Agreement, including those amendments as set out in Sections 2 to 4 of this Third Amendment, and as may be further amended from time to time in accordance with its terms; and (iii) shall be entitled to the rights and benefits
-

and subject to the duties and obligations of BioNTech, as applicable, in each case as fully as if BMG were an original signatory to the Collaboration Agreement as a BioNTech party; and

- c. all references in the Collaboration Agreement to “BioNTech” shall collectively mean RNP, BNT and BMG.

**2. Change in Control**

- a. The words “BNT or RNP” in Section 1.42 (“Change in Control”) and Section 1.46 (“Class A Competition Change in Control”) of the Collaboration Agreement shall be deleted and replaced with the words “BNT, RNP or BMG”.
- b. The words “BNT and RNP” in paragraph (a) of the definition “Change in Control Firewall” in Schedule 1.43 (Firewalls) of the Collaboration Agreement shall be deleted and replaced with the words “BNT, RNP and BMG”.

**3. Manufacturing Development and Supply Agreement**

The words “That certain Manufacturing Development and Supply Agreement entered into by and among RNP, BNT, GNE and Roche as of even date herewith and effective as of the Effective Date (the “**Manufacturing Development and Supply Agreement**”)” in Section 7.1 of the Collaboration Agreement shall be deleted and replaced with the following:

“That certain Manufacturing Development and Supply Agreement by and among RNP, BNT, GNE and Roche dated as of September 20, 2016 and amended on October 1, 2020 to join BMG as a party thereto (as may be further amended from time to time, the “**Manufacturing Development and Supply Agreement**”)”

**4. Intellectual Property: Ownership; Assignment and Cooperation: Inventorship**

Section 10.2 of the Collaboration Agreement shall be amended by adding the following new paragraph (e):

“If BMG or any of its employees generate or create any BioNTech IP or Collaboration IP pursuant to or in connection with any activities carried out by it or any of them under this Agreement, BMG shall assign to, or shall procure that such BioNTech IP or Collaboration IP is Controlled by, BNT. BMG shall further comply with Section 10.2.2 to ensure that all necessary assignments and documentation are executed to implement the provisions of this Section 10.2(e).”

**5. Notices**

- a. Section 15.8.1 of the Collaboration Agreement is amended by deleting the final sentence in Section 15.8.1 and replacing it with the following:  
“For clarity, notice to Genentech shall require notice to both GNE and Roche, and notice to BioNTech shall require notice to each of BNT, RNP and BMG.”
- b. Section 15.8.2 is amended by adding the following paragraph after “BioNTech AG”:

"If to BMG, to:

BioNTech Manufacturing GmbH  
An der Goldgrube 12  
55131 Mainz  
Attn: Managing Director  
Fax: +49-6131-9084390

with a copy of any notice to (where applicable) BNT, RNP or BNG (which shall not constitute notice) to:

BioNTech SE  
An der Goldgrube 12  
55131 Mainz  
Attn: VP Legal  
Fax: +49-6131-9084390"

**6. Corporate Names**

Schedule 1.97 of the Collaboration Agreement shall be amended by adding the following at the end of the Schedule:

"For BMG:

"BioNTech Manufacturing GmbH"

**7. Assignment**

Pursuant to Section 15.4 of the Collaboration Agreement, each Party hereby consents to the assignment of the Collaboration Agreement by RNP to BNT in connection with the Asset Transfer, provided that both the Collaboration Agreement and the MDSA are assigned to BNT pursuant to such Asset Transfer, and provided further that RNP remains a wholly owned subsidiary of BNT through the effective date of such Asset Transfer. If the Asset Transfer is not consummated prior to March 31, 2021, or if RNP is no longer a wholly-owned subsidiary of BNT at any time prior to such Asset Transfer, this consent shall have no force or effect. RNP agrees to provide notice of and documentation relating to such transfer (subject to Genentech's reasonable and good faith review and comment) to Genentech not less than 10 Business Days prior to the effective date of the Asset Transfer.

**8. Survival of Agreement Terms**

All terms and conditions of the Collaboration Agreement not modified by this Third Amendment shall continue in full force and effect in accordance with their terms. All capitalized terms not otherwise defined herein shall have the same definition as in the Collaboration Agreement. In the event of any conflict between the terms and conditions of this Third Amendment and the Collaboration Agreement, the terms and conditions set forth in this Third Amendment shall prevail with respect to the subject matter hereof.

9. **Governing Law and Dispute Resolution**

- a. Governing Law and Service. Sections 15.6.1 and 15.6.2 of the Collaboration Agreement shall apply to this Third Amendment *mutatis mutandis*.
- b. Dispute Resolution. Section 15.7 of the Collaboration Agreement shall apply *mutatis mutandis* to any controversy, claim, legal proceeding or other dispute arising out of or relating to this Third Amendment.

*[Remainder of the page intentionally left blank. Signature page follows.]*

IN WITNESS WHEREOF, the Parties have each caused this Third Amendment to be executed by their duly authorized representatives.

**GENENTECH, INC.**

By /s/ Beth Odeh-Frikert

Name: Beth Odeh-Frikert

Title: Head Alliance & Asset Management, SSF

**F. HOFFMANN-LA ROCHE LTD**

By /s/ Stefan Arnold

Name: Stefan Arnold

Title: Head Legal Pharmaceuticals

By /s/ Melanie Wick

Name: Melanie Wick

Title: Authorized Signatory

**BIONTECH SE**

By /s/ Sean Marett

Name: Sean Marett

Title: Management Board Member

**BIONTECH RNA PHARMACEUTICALS GMBH**

By /s/ Dr. Sierk Poetting

Name: Dr. Sierk Poetting

Title: Managing Director

**BIONTECH MANUFACTURING GMBH**

By /s/ Dr. Sierk Poetting

Name: Dr. Sierk Poetting

Title: Managing Director

By /s/ Jan Kürschner

Name: Jan Kürschner

Title: Managing Director

THE SYMBOL “[\*\*\*]” DENOTES PLACES WHERE CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH (i) NOT MATERIAL, AND (ii) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF PUBLICLY DISCLOSED

FOURTH AMENDMENT TO  
THE COLLABORATION AGREEMENT

This FOURTH AMENDMENT (the “**Fourth Amendment**”) is made and entered into, effective as of October 26, 2020 (the “**Fourth Amendment Effective Date**”), by and between BioNTech RNA Pharmaceuticals GmbH, a limited liability company organized under the laws of Germany (“**RNP**”), BioNTech Manufacturing GmbH, a limited liability company organized under the laws of Germany (“**BMG**”) and BioNTech SE, a European stock corporation (“**BNT**”) (RNP, BMG and BNT collectively, “**BioNTech**”), and Genentech, Inc., a corporation organized under the laws of the State of Delaware (“**GNE**”) and F. Hoffmann-La Roche Ltd, a corporation organized under the laws of Switzerland (“**Roche**”) (GNE and Roche, collectively, “**Genentech**”).

WHEREAS, the Parties entered into a Collaboration Agreement, dated as of September 20, 2016, as amended on June 1, 2018, December 6, 2019 and October 1, 2020, and as supplemented by letters between the Parties dated June 1, 2020, June 24, 2020 and August 3, 2020, pursuant to which BioNTech and Genentech agreed to collaborate in the research, development, and commercialization of Collaboration Products (the “**Agreement**”).

WHEREAS, BioNTech and Genentech wish to revise the schedule of RNA Manufacturing Projects.

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties agree as follows:

1. **Schedule.** Schedule 1.333 is hereby deleted in its entirety and replaced with the schedule attached hereto as Exhibit A.
2. **Survival of Agreement Terms.** All terms and conditions of the Agreement not modified by this Fourth Amendment shall continue in full force and effect in accordance with their terms. All capitalized terms not otherwise defined herein shall have the same definition as in the Agreement. In the event of any conflict between the terms and conditions of this Fourth Amendment and the Agreement, the terms and conditions set forth in this Fourth Amendment shall control with respect to the subject matter hereof.

*[Remainder of the page intentionally left blank; signature page follows.]*

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IN WITNESS WHEREOF, the Parties have each caused this Fourth Amendment to be executed by their duly authorized representatives.

**BIONTECH SE**

By: \_\_\_\_\_

Name:

Title:

**BIONTECH RNA  
PHARMACEUTICALS GMBH**

By: \_\_\_\_\_

Name:

Title:

**BIONTECH MANUFACTURING GMBH**

By: \_\_\_\_\_

Name:

Title:

**GENENTECH, INC.**

By: \_\_\_\_\_

Name:

Title:

**F. HOFFMANN-LA ROCHE LTD**

By: \_\_\_\_\_

Name:

Title:

By: \_\_\_\_\_

Name:

Title:





**THE SYMBOL "[\*\*\*]" DENOTES PLACES WHERE CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH (i) NOT MATERIAL, AND (ii) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF PUBLICLY DISCLOSED**

**CELLSCRIPT, LLC**

Second Amendment to Patent Sublicense Agreement

This is the Second Amendment ("Second Amendment") to the Patent Sublicense Agreement which became effective on July 19, 2017, as amended in the First Amendment which became effective on February 10, 2020 (together, the "Agreement") by and between CELLSCRIPT, LLC, a Wisconsin company ("Cellscript") and BioNTech RNA Pharmaceuticals GmbH, a German corporation ("Company"). This Second Amendment is effective as of August 1, 2020 ("Second Amendment Effective Date"). Cellscript and Company may herein each be referred to as a "Party" or collectively as the "Parties".

WHEREAS, The Trustees of the University of Pennsylvania ("Penn") is the ultimate recipient of amounts of money that are payable by Company under the terms of the Agreement after the Second Amendment Effective Date; and

WHEREAS, the Parties wish to amend the Agreement in order to assure more timely payment and less risk of loss for said certain amounts of money that are payable to Penn by Cellscript or by Cellscript's sublicensor, mRNA RiboTherapeutics, Inc, ("mRNA") from Company's payments to Cellscript under the terms of the Agreement; and

WHEREAS, unless otherwise defined herein, capitalized terms will have the definitions given them in the Agreement.

NOW, THEREFORE, in consideration of the mutual obligations contained in the Agreement and in this Second Amendment, and intending to be legally bound, the Parties agree as follows:

- 1) From and after the Second Amendment Effective Date, all payments owed by Company to Cellscript under the Agreement shall be owed and paid directly to Penn, including but not limited to payments under sections [\*\*\*].
- 2) All references to payments to Cellscript are understood to mean payments to Penn.
- 3) All information, and reports concerning payments, including inventories, required under the Agreement shall be sent to both Cellscript and Penn, including under sections [\*\*\*]. Such information shall be delivered to Penn at pcifin@upenn.edu with paper copies to:

Penn Center for Innovation  
University of Pennsylvania

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3600 Civic Center Boulevard, Floor 9  
Philadelphia, PA 19104  
Attention: PCI Finance

- 4) Penn is a third-party beneficiary of the Agreement.
- 5) Under Section 6.3 termination, a failure to pay Penn is a failure to pay Cellsript.
- 6) Under Section 6.7, the obligations to pay Penn shall survive termination of the Agreement for any reason.
- 7) All amounts payable by Company to Penn pursuant to this Second Amendment shall be in U.S. Dollars and shall be subject to the same instructions, terms, conditions and deadlines for payment as stated with respect to payments to Cellsript in the Agreement, except that all such payments to Penn shall be paid to "The Trustees of the University of Pennsylvania" as follows:

By ACH/Wire:  
[\*\*\*]

By Check (lockbox):  
[\*\*\*]

*Payment should include the necessary amount to cover any bank charges incurred.*

- 8) The Agreement, together with this Second Amendment, constitute the entire agreement between the Parties. All other terms and provisions of the Agreement, except as expressly amended by this Second Amendment, remain in full force and effect.
- 9) This Second Amendment may be executed in two or more counterparts, each of which shall be deemed an original and together shall be deemed one and the same instrument.
- 10) Each Party's respective Notice Address, as provided under Section 15.6 of the Agreement is hereby updated and replaced by the Notice Address listed on the signature page of this Second Amendment.

*[Remainder of Page Intentionally Left Blank; Signature Page Follows]*

IN WITNESS WHEREOF, the Parties, intending to be legally bound, have caused this Second Amendment to be executed by their duly authorized representatives.

**CELLSCRIPT, LLC**

By: /s/ Gary A. Dahl, Ph.D.  
Name: Gary A. Dahl, Ph.D.  
Title: President and CEO

**Notices to:** CELLSRIPT, LLC  
726 Post Road  
Madison, WI 53713 USA  
Attn: President

**BioNTech RNA Pharmaceuticals GmbH**

By: /s/ Dr. Sierk Poetting  
Name: Gary A. Dahl, Ph.D.  
Title: President and CEO

**Notices to:** CELLSRIPT, LLC  
An der Goldgrube 12  
55131 Mainz, Germany  
Attn: Dr. Sierk Poetting

**THE SYMBOL "[\*\*]" DENOTES PLACES WHERE CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH (i) NOT MATERIAL, AND (ii) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF PUBLICLY DISCLOSED**

**mRNA RiboTherapeutics, Inc.**

Second Amendment to Patent Sublicense Agreement

This is the Second Amendment ("Second Amendment") to the Patent Sublicense Agreement which became effective on July 19, 2017, as amended in the First Amendment which became effective on February 10, 2020 (together, the "Agreement") by and between mRNA RiboTherapeutics, Inc., a Wisconsin company ("mRNA RiboTherapeutics") and BioNTech RNA Pharmaceuticals GmbH, a German corporation ("Company"). This Second Amendment is effective as of August 1, 2020 ("Second Amendment Effective Date"). mRNA RiboTherapeutics and Company may herein each be referred to as a "Party" or collectively as the "Parties".

WHEREAS, The Trustees of the University of Pennsylvania ("Penn") is the ultimate recipient of amounts of money that are payable by Company under the terms of the Agreement after the Second Amendment Effective Date; and

WHEREAS, the Parties wish to amend the Agreement in order to assure more timely payment and less risk of loss for said certain amounts of money that are payable to Penn by mRNA RiboTherapeutics from Company's payments to mRNA RiboTherapeutics under the terms of the Agreement; and

WHEREAS, unless otherwise defined herein, capitalized terms will have the definitions given them in the Agreement.

NOW, THEREFORE, in consideration of the mutual obligations contained in the Agreement and in this Second Amendment, and intending to be legally bound, the Parties agree as follows:

- 1) From and after the Second Amendment Effective Date, all payments owed by Company to mRNA RiboTherapeutics under the Agreement shall be owed and paid directly to Penn, including but not limited to payments under sections [\*\*].
- 2) All references to payments to mRNA RiboTherapeutics are understood to mean payments to Penn.

3) All information, and reports concerning payments, including inventories, required under the Agreement shall be sent to both mRNA RiboTherapeutics and Penn, including under sections [\*\*\*]. Such information shall be delivered to Penn at pcifin@upenn.edu with paper copies to:

Penn Center for Innovation  
University of Pennsylvania  
3600 Civic Center Boulevard, Floor 9  
Philadelphia, PA 19104  
Attention: PCI Finance

4) Penn is a third-party beneficiary of the Agreement.

5) Under Section 6.3 termination, a failure to pay Penn is a failure to pay mRNA RiboTherapeutics.

6) Under Section 6.7, the obligations to pay Penn shall survive termination of the Agreement for any reason.

7) All amounts payable by Company to Penn pursuant to this Second Amendment shall be in U.S. Dollars and shall be subject to the same instructions, terms, conditions and deadlines for payment as stated with respect to payments to mRNA RiboTherapeutics in the Agreement, except that all such payments to Penn shall be paid to "The Trustees of the University of Pennsylvania" as follows:

**By ACH/Wire:**

[\*\*\*]  
[\*\*\*]  
[\*\*\*]  
[\*\*\*]  
[\*\*\*]

**By Check (lockbox):**

[\*\*\*]  
[\*\*\*]  
[\*\*\*]  
[\*\*\*]  
[\*\*\*]

*Payment should include the necessary amount to cover any bank charges incurred.*

8) The Agreement, together with this Second Amendment, constitute the entire agreement between the Parties. All other terms and provisions of the Agreement, except as expressly amended by this Second Amendment, remain in full force and effect.

- 9) This Second Amendment may be executed in two or more counterparts, each of which shall be deemed an original and together shall be deemed one and the same instrument.
- 10) Each Party's respective Notice Address, as provided under Section 15.6 of the Agreement is hereby updated and replaced by the Notice Address listed on the signature page of this Second Amendment.

*[Remainder of Page Intentionally Left Blank; Signature Page Follows]*

IN WITNESS WHEREOF, the Parties, intending to be legally bound, have caused this Second Amendment to be executed by their duly authorized representatives.

**mRNA RIBOTHERAPEUTICS, Inc.**

By: /s/ Gary A. Dahl, Ph.D.  
Name: Gary A. Dahl, Ph.D.  
Title: President and CEO

**Notices to:** mRNA RiboTherapeutics, Inc.  
726 Post Road  
Madison, WI 53713 USA  
Attn: President

**BioNTech RNA Pharmaceuticals GmbH**

By: /s/ Dr. Sierk Poetting  
Name: Dr. Sierk Poetting  
Title: Managing Director

**Notices to:** BioNTech RNA Pharmaceuticals GmbH  
An der Goldgrube 12  
55131 Mainz, Germany  
Attn: Dr. Sierk Poetting



THE SYMBOL "[\*\*\*]" DENOTES PLACES WHERE CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH (i) NOT MATERIAL, AND (ii) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF PUBLICLY DISCLOSED

AMENDED AND RESTATED COLLABORATION AGREEMENT

by and between

**PFIZER INC.**

and

**BIONTECH SE**

**March 17, 2020**

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## AMENDED AND RESTATED COLLABORATION AGREEMENT

This Amended and Restated Collaboration Agreement (the "Agreement") is entered into with effect as of March 17, 2020 (the "Effective Date"), by and between Pfizer Inc., a corporation organized and existing under the laws of Delaware and having a principal place of business at 235 East 42nd Street, New York, New York, 10017 United States ("Pfizer") and BioNTech SE, a corporation organized and existing under the laws of Germany and having a place of business at An der Goldgrube 12, D-55131 Mainz, Germany ("BioNTech"). Pfizer and BioNTech are sometimes referred to herein individually as a "Party" and collectively as the "Parties".

WHEREAS, BioNTech owns or otherwise Controls (as defined below) certain patents, patent applications, technology, know-how, scientific and technical information and other proprietary rights and information relating to the identification, research and development of Candidates (as defined below) in the Field (as defined below) for delivery via Delivery Technology (as defined below);

WHEREAS, Pfizer has extensive experience and expertise in the development and commercialization of pharmaceutical and biopharmaceutical products;

WHEREAS, in view of the current COVID-19 crisis, Pfizer and BioNTech wish to engage in expedited collaborative research and development pursuant to the Research and Development Plan (as defined below) to identify and develop Candidates for inclusion in the Product, seek expedited regulatory approval for such Product, and launch such Product in all countries of the Territory (as defined below) as quickly as reasonably possible;

WHEREAS, Pfizer and BioNTech wish that Pfizer Commercializes the Product in all countries of the Territory, subject to BioNTech having the right to exclusively Commercialize the Product in the BioNTech Commercialization Territory;

WHEREAS, BioNTech and Pfizer have entered into a Collaboration Agreement effective as of March 17, 2020 (the "Original Collaboration Agreement") to govern their collaboration in the Development, Manufacturing and Commercialization of the Product in the Field;

WHEREAS, under Section 4 of Original Collaboration Agreement BioNTech and Pfizer have agreed upon a term sheet setting forth material terms for Commercialization of the Products which shall form the basis of a definitive commercialization agreement to be entered into after the signing of the Original Collaboration Agreement;

WHEREAS, BioNTech and Pfizer have decided to integrate the definitive terms of such commercialization agreement into the Original Collaboration Agreement and to replace the Original Collaboration Agreement by this Amended and Restated Collaboration Agreement which shall now include also the definitive terms for the commercialization of the Product; and

WHEREAS, in addition, BioNTech and Pfizer wish to amend or modify some of the terms of the Original Collaboration Agreement such that they are restated in their amended form in this Agreement.



NOW THEREFORE, in consideration of the premises and the mutual promises set forth herein, and intending to be legally bound, the Parties hereby agree to amend and restate the Original Collaboration Agreement as follows:

1. **DEFINITIONS**

As used in this Agreement, the following capitalized terms will have the meanings set forth below:

1.1 “**Affiliate**” means any entity directly or indirectly controlled by, controlling, or under common control with, a Person, but only for so long as such control will continue. For purposes of this definition, “control” (including, with correlative meanings, “controlled by”, “controlling” and “under common control with”) means (a) possession, direct or indirect, of the power to direct or cause direction of the management or policies of an entity (whether through ownership of securities or other ownership interests, by contract or otherwise), or (b) beneficial ownership of more than 50% of the voting securities or other ownership or general partnership interest (whether directly or pursuant to any option, warrant or other similar arrangement) or other comparable equity interests of an entity; *provided, however*, that where an entity owns a majority of the voting power necessary to elect a majority of the board of directors or other governing board of another entity, but is restricted from electing such majority by contract or otherwise, such entity will not be considered to be in control of such other entity until such time as such restrictions are no longer in effect. Notwithstanding the foregoing, for the purposes of this Agreement, AT Impf GmbH, having its place of business at Rosenheimer Platz 6, 81669 Munich, Germany, and any entity that directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with AT Impf GmbH (other than BioNTech SE or any entity that is directly or indirectly controlled by BioNTech SE) (collectively, the “Impf Group”) shall not be considered Affiliates of BioNTech.

1.2 “**Agreed Product Component**” is defined in Section 6.4.1.2.

1.3 “**Amendment Signing Date**” means 29 January 2021.

1.4 “**Annual Regional Commercialization Plan**” means, with respect to a Commercialization Region and having regard to the objectives and principles of the Global Commercialization Plan, the applicable plan as may be established by the applicable RCC, and as updated from time to time by the applicable RCC, in each case pursuant to Section 9.1, for the applicable Calendar Year during the Term. It is acknowledged that if each Party has countries within its Commercialization Territory that lie within the same Commercialization Region, two separate Annual Regional Commercialization Plans may exist with each covering only those countries within one Party’s Commercialization Territory.

1.5 “**Anti-Corruption Laws**” means all applicable anti-bribery and anti-corruption laws and regulations, including the U.S. Foreign Corrupt Practices Act of 1977, the U.K. Bribery Act 2010, and the local laws and regulations of any countries in which Candidates or Products, payments or services will be provided or procured under or pursuant to this Agreement.

1.6 “**Applicable Data Protection Law**” means all applicable personal data protection laws, rules and regulations, including the EU General Data Protection Regulation (“GDPR”).

1.7 “Bankruptcy Code” means Section 101(35A) of Title 11 of the United States Code, as amended, or such other legislation, Law or code with effect in another jurisdiction to which BioNTech or its Affiliates is subject having equivalent or reasonably similar purpose or provisions to the foregoing.

1.8 “Binding Obligation” means, with respect to a Party (a) any oral or written agreement or arrangement that binds or affects such Party’s operations or property, including any assignment, license agreement, loan agreement, guaranty, or financing agreement, (b) the provisions of such Party’s charter, bylaws or other organizational documents or (c) any order, writ, injunction, decree or judgment of any court or Governmental Authority entered against such Party or by which any of such Party’s operations or property are bound.

1.9 “Biologics License Application” or “BLA” means an application requesting permission from the FDA to introduce, or deliver for introduction, a biological product into interstate commerce, or any similar application or submission for marketing authorization of a product filed with a Regulatory Authority to obtain Regulatory Approval for such product in a country or group of countries, including an MAA.

1.10 “BioNTech Commercialization Territory” means (a) Germany and Turkey, until such time, on a country by country basis, a BioNTech Territory Exit Option is exercised by BioNTech in respect of one or both of those countries and (b) those countries, on a country by country basis, which become Pfizer Exit Countries (if any).

1.11 “BioNTech Commercial Materials” means any and all BioNTech Promotional Materials, BioNTech Training Materials, and all other literature or other information related to the Product and, in each case, created and provided by or on behalf of BioNTech hereunder.

1.12 “BioNTech House Marks” means (a) the corporate logo of BioNTech, (b) the trademark “BioNTech”, (c) any other Trademark, trade name or service mark (whether registered or unregistered) containing the word “BioNTech”, and (d) any other corporate logo or Trademark used by BioNTech to identify BioNTech or its Affiliates; and all intellectual property rights and goodwill associated with any and all of the foregoing in clauses (a) through (d).

1.13 “BioNTech Improvement” means any Research and Development Program Technology, regardless of inventorship, that is a modification or improvement made to the RNA Technology or RNA Process Technology and (a) would also be applicable to one or more candidates or products in addition to or other than the Candidates or Products (b) is not predominantly directed to the Pfizer Technology and (c) could have reasonably been developed without the aid, use or application of Pfizer Materials, Pfizer Improvements or Pfizer’s Confidential Information or any improvements or enhancements thereto.

1.14 “BioNTech Know-How” means [\*\*\*].

1.15 “BioNTech Materials” means any tangible materials (but not information about or contained in such materials) owned or Controlled by BioNTech that relate to or embody the BioNTech Know-How or BioNTech Patent Rights.

1.16 “BioNTech Patent Right” means any Patent Right (other than Pfizer Patent Rights or Patent Rights jointly owned by BioNTech and Pfizer pursuant to Section 11.2) in any form and

whether pending or issued that (a) is Controlled by BioNTech or any of its Affiliates as of the Effective Date or comes into the Control of BioNTech or any of its Affiliates during the Term (other than, in either case, through the grant of a license by Pfizer) and (b) claims any BioNTech Know-How.

1.17 “BioNTech Technology” means the BioNTech Patent Rights, BioNTech Materials, BioNTech Know-How. For avoidance of doubt, BioNTech Technology includes all Intellectual Property Rights Controlled by BioNTech pursuant to the Fosun Agreement.

1.18 “BioNTech Third Party Agreement” means any agreement between BioNTech (or any of its Affiliates) and any Third Party (such Third Party, a “Third Party Licensor”) that (a) relates to any of the BioNTech Technology or Research and Development Program Technology, or (b) otherwise grants a license or otherwise transfers any right to practice under any Patent Rights or Know-How, in each case that relate to the Candidates or Products or activities under this Agreement. For clarity, all Current Licenses shall be deemed BioNTech Third Party Agreements hereunder and all Current Licensors shall be deemed Third Party Licensors hereunder.

1.19 “Biosimilar Notice” means a copy of any application submitted by a Third Party to the FDA under 42 U.S.C. § 262(k) of the Public Health Service Act (or, in the case of a country of the Territory outside the United States, any similar law) for Regulatory Approval of a biopharmaceutical product, which application identifies a Product as the Reference Product with respect to such product, and other information that describes the process or processes used to manufacture the biopharmaceutical product.

1.20 “Business Day” means a day other than a Saturday, Sunday or bank or other public holiday in New York, New York, USA or Mainz, Germany.

1.21 “Candidate” means an immunogenic composition in the Field that comprises Unmodified RNA Technology, Modified RNA Technology or Replicon Technology that (a) is Developed pursuant to the Research and Development Plan, (b) is Controlled by BioNTech as of the Effective Date or from time to time during the Term or (c) is Exploited by any of the Parties or their Affiliates pursuant to this Agreement. Those Candidates Controlled by BioNTech and existing as of the Effective Date are set forth in Schedule 1.21.

1.22 “Calendar Quarter” means the respective periods of three consecutive calendar months ending on March 31, June 30, September 30 and December 31.

1.23 “Calendar Year” means any twelve (12) month period beginning on January 1 and ending on the next subsequent December 31.

1.24 “Capex Costs” means any capital expenditure costs associated with (a) the Research and Development Program or (b) the build-out, establishment, construction, expansion or investment in any Manufacturing facilities.

1.25 “Change of Control” means, with respect to a Party (a) the acquisition of beneficial ownership, directly or indirectly, by any Person (other than such Party or an Affiliate of such Party, and other than by virtue of obtaining irrevocable proxies) of securities or other voting interest of such Party representing of the combined voting power of such Party’s then outstanding securities or other voting interests, (b) any merger, reorganization, consolidation or business combination

involving such Party with a Third Party that results in the holders of beneficial ownership (other than by virtue of obtaining irrevocable proxies) of the voting securities or other voting interests of such Party (or, if applicable, the ultimate parent of such Party) immediately prior to such merger, reorganization, consolidation or business combination ceasing to hold beneficial ownership of at least fifty percent (50%) of the combined voting power of the surviving entity immediately after such merger, reorganization, consolidation or business combination, (c) any sale, lease, exchange, contribution or other transfer (in one transaction or a series of related transactions) of all or substantially all of the assets of such Party to which this Agreement relates, other than a sale or disposition of such assets to an Affiliate of such Party or (d) the approval of any plan or proposal for the liquidation or dissolution of such Party (other than in circumstances where such Party is deemed a Debtor pursuant to Section 14.9).

1.26 “Clinical Trial” means a human clinical study conducted on sufficient numbers of human subjects that is designed to (a) establish that a pharmaceutical product is reasonably safe for continued testing, (b) investigate the safety and efficacy of the pharmaceutical product for its intended use, and to define warnings, precautions and adverse reactions that may be associated with the pharmaceutical product in the dosage range to be prescribed or (c) support Regulatory Approval of such pharmaceutical product or label expansion of such pharmaceutical product. Without limiting the foregoing, Clinical Trial includes any Phase I Clinical Trial, Phase II Clinical Trial, Phase III Clinical Trial or other expedited clinical trial conducted by or on behalf of one or both Parties in connection with this Agreement.

1.27 “CMC” means chemistry, manufacturing and controls.

1.28 “Combination Product” means a product comprising a Candidate or Product in combination with one or more other therapeutically active ingredients (which includes any prophylactic activity) that are co-formulated as part of the same dosage form or packaged and administered to patient together. For the avoidance of doubt, adjuvants, including molecular adjuvants, are not considered therapeutically active ingredients for the purposes of this definition regardless of whether or not such adjuvant is packaged together with a Candidate or Product but in a separate container.

1.29 “Commercialization Activities” means those activities to be performed by each Commercializing Party with respect to the Commercialization of the Product in the Commercialization Territory, including those under Section 9 of this Agreement.

1.30 “Commercializing Party” shall mean, as applicable, (a) Pfizer (including Pfizer’s Affiliates) with respect to the countries included within the Pfizer Commercialization Territory or (b) BioNTech (including BioNTech’s Affiliates) with respect to the countries included with the BioNTech Commercialization Territory.

1.31 “Commercialization Territory” shall mean either the Pfizer Commercialization Territory or the BioNTech Commercialization Territory, as applicable.

1.32 “Commercialize” or “Commercializing” means to market, promote, distribute, offer for sale, sell, have sold, import, have imported, export, have exported or otherwise commercialize a compound or product. When used as a noun, “Commercialization” and “Commercialized” means any and all activities involved in Commercializing.

1.33 “Commercially Reasonable Efforts” means, with respect to the efforts to be expended by a Party with respect to any objective, those reasonable, good faith efforts to accomplish such objective as such Party would normally use to accomplish a similar objective under similar circumstances, in particular taking into account the then-current urgency of the COVID-19 crisis. With respect to any efforts relating to the Development, Regulatory Approval or Commercialization of a Candidate or Product by a Party, generally or with respect to any particular country in the Territory, a Party will be deemed to have exercised Commercially Reasonable Efforts if such Party has exercised those efforts normally used by such Party having regard to the circumstances, in the relevant country, with respect to a compound or protein, product or product candidate, as applicable (a) of similar modality Controlled by such Party, (b) to which such Party has similar rights, (c) which is of similar market potential in such country, and (d) which is at a similar stage in its development or product life cycle, as any Candidate or Product, in each case, taking into account all Relevant Factors in effect at the time such efforts are to be expended. Further, to the extent that the performance of a Party’s obligations hereunder is adversely affected by the other Party’s failure to perform its obligations hereunder, the impact of such performance failure will be taken into account in determining whether such Party has used its Commercially Reasonable Efforts to perform any such affected obligations.

1.34 “Committee” means one of the JSC, RCC, Patent Committee, Joint Safety Committee, JMC, JFC and JCC, and “Committees” means any two or more of the foregoing.

1.35 “Compassionate Use Purposes” means, with respect to the Product, providing Product under any compassionate use or expanded access programs or other gratis donations, but excluding any sales of Product for cash or non-cash consideration under any Emergency Use Authorization.

1.36 “Competitive Product” means a pharmaceutical product that incorporates an immunogenic composition comprising RNA in the Field that is intended to be, has been, or is being Exploited by a Third Party. For avoidance of doubt, Competitive Product does not include Product (a) Commercialized by or on behalf of BioNTech in the BioNTech Commercialization Territory pursuant to this Agreement; or (b) Commercialized outside of the Territory in accordance with the terms of the Fosun Agreement.

1.37 “Compliance” means the adherence by the applicable Party and its Affiliates in all material respects to all applicable Laws and Party Specific Regulations, in each case with respect to the activities to be conducted by or on behalf of that Party under this Agreement.

1.38 “Confidential Information” means, with respect to each Party, all Know-How or other information, including proprietary information and materials (whether or not patentable) regarding or embodying such Party’s or its Representatives’ technology, products, business information or objectives, that is communicated by or on behalf of the Disclosing Party to the Receiving Party or its permitted recipients, on or after the Effective Date, but only to the extent that: (a) such Know-How or other information in written form is marked in writing as “confidential” at the time of disclosure, (b) such Know-How or other information disclosed orally or in non-tangible form is identified by the Disclosing Party as “confidential” at the time of disclosure or within 30 days thereafter, or (c) such Know-How or other information (regardless of the form of disclosure) is disclosed in circumstances of confidence or would be understood by the Parties, exercising reasonable business judgment, to be confidential. Confidential Information does not

include any Know-How or other information to the extent the Receiving Party can demonstrate by competent proof that such Know-How or other information (a) was already known by the Receiving Party (other than under an obligation of confidentiality to the Disclosing Party) at the time of disclosure by or on behalf of the Disclosing Party, (b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the Receiving Party, (c) became generally available to the public or otherwise part of the public domain after its disclosure to the Receiving Party, other than through any act or omission of the Receiving Party in breach of its obligations under this Agreement, (d) was disclosed to the Receiving Party, other than under an obligation of confidentiality, by a Third Party who had no obligation to the Disclosing Party not to disclose such information to the Receiving Party or (e) was independently discovered or developed by or on behalf of the Receiving Party without the use of any Confidential Information belonging to the Disclosing Party. Joint Know-How shall be deemed Confidential Information of either Party and either Party shall be deemed the Receiving Party in respect of Joint Know-How.

1.39 “Contract Interest Rate” means one-half of one percent (0.5%) plus the rate for deposits in U.S. Dollars for a period of three-months as published by the ICE Benchmark Administration Limited, a United Kingdom Company (“LIBOR”); measured at 2 p.m. London/England time on the date payment is due. If the three-month LIBOR has been permanently discontinued, it will be replaced by a comparable or successor quoting service approved by the Parties. Interest will be calculated on a 365/360 basis.

1.40 “Control” or “Controlled” means with respect to any Intellectual Property Right or material (including any Patent Right, Know-How or other data, information or material), the ability (whether by sole, joint or other ownership interest, license or otherwise, other than pursuant to this Agreement) to, without violating the terms of any agreement with a Third Party, grant a license or sublicense or provide access or other right in as provided in this Agreement, to or under such Intellectual Property Right or material.

1.41 “Conversion Costs” means [\*\*\*].

1.42 “Copyright” means any copyright rights pertaining to the promotional materials and literature created or utilized by or on behalf of a Commercializing Party in connection with the Commercialization of Products in the by that Commercializing Party in its Commercialization Territory.

1.43 “Cover”, “Covered” or “Covering” means, with respect to (a) a given Candidate or Product and Patent Right, that a valid claim of such Patent Right would, absent a license thereunder or ownership thereof, be infringed by the making, sale, offer for sale or importation of such Candidate or Product and (b) a given Candidate or Product and Know-How, that such Know-How would, absent a license thereunder or ownership thereof, be misappropriated or misused by the use or making of such Candidate or Product.

1.44 “Current Good Manufacturing Practices” or “cGMP” means all applicable standards and applicable Laws relating to manufacturing practices for products (including ingredients, testing, storage, handling, intermediates) promulgated by the U.S. Food and Drug Administration and any other governmental authority (including, European Union or member state level and Japan), including, but not limited to, standards in the form of applicable Laws, guidelines, advisory opinions and compliance policy guides, and current interpretations of the applicable

authority or agency thereof (as applicable to pharmaceutical and biological products and ingredients), as the same may be updated, supplemented or amended from time to time, in each case of those jurisdictions in which the products are Manufactured.

1.45 “Current Licenses” means any agreement (a) that BioNTech or its Affiliates has entered into prior to the Effective Date with a Third Party and (b) pursuant to which BioNTech or its Affiliates are (i) granted rights to any BioNTech Technology as of the Effective Date or (ii) granted a license or otherwise transferred any right to practice under any Patent Rights or Know-How, in each case that relate to the Candidates or Products or activities under this Agreement. BioNTech’s Current Licenses are disclosed on Schedule 1.45.

1.46 “Current Licensor” means any Third Party that is a party to a Current License.

1.47 “Delivery Technology” means the BioNTech Know-How applicable to formulating nucleic acids to enable the delivery of such nucleic acids to target cells *in vivo*. For clarity, Delivery Technology does not [\*\*\*].

1.48 “Develop”, “Developed” or “Developing” means to discover, research or otherwise develop or improve a process, compound or product, including planning and conducting non-clinical and clinical research and development activities prior to grant of a Market Authorization Approval or any research or development conducted after receipt of a Market Authorization Approval, including those required by any Regulatory Authority to maintain any Market Authorization Approval. When used as a noun, “Development” means any and all activities involved in Developing.

1.49 “Developing Countries Territory” means, to the extent BioNTech or any of its Affiliates receive Third Party funding from [\*\*\*] to fund Development or Manufacturing of the Candidates or Products pursuant to this Agreement, those countries listed in Schedule 1.49 which are also defined in the relevant funding documents as “Developing Countries”; *provided* that if prior to the execution of such funding documents, the price of any medicinal product (including the Product) in any country within Schedule 1.49 is made relevant as a reference price for the sale of the Product in any country outside of the countries listed within Schedule 1.49, then such country shall be automatically removed as a country within Schedule 1.49, unless otherwise mutually agreed in writing by the Parties.

1.50 “Development Budget” means the budget to be agreed and updated [\*\*\*] by the JSC pursuant to Section 5.1 for all activities, costs and expenses that are to be funded as Shared Development Costs. The Development Budget existing on the signing of this Amended and Restated Collaboration Agreement is attached hereto as Schedule 1.50.

1.51 “EMA” means the European Medicines Agency or any successor agency thereto.

1.52 “Emergency Use Authorization” means an emergency use authorization, or any analogous approval for emergency situations, granted by a Governmental Authority or Regulatory Authority to warrant limited or conditional distribution of a pharmaceutical or vaccine product, including any granted pursuant to §564 of the FD&C Act (or any equivalent or comparable authorization granted by a Regulatory Authority elsewhere), in each case which is separate from a Market Authorization Approval.

1.53 “European Union” or “EU” means the countries of the European Union, as it is constituted as of the Effective Date, which consists of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden and, notwithstanding its departure from the European Union, shall for the purposes of this definition include the United Kingdom of Great Britain and Northern Ireland.

1.54 “Expedited Trial Pathway” means a Clinical Trial protocol or pathway recognized or authorized by any Regulatory Authority for the emergency or expedited approval of medicines for human use, as opposed to a traditional Clinical Trial.

1.55 “Exploit” means to Develop, Manufacture, Commercialize, use or otherwise exploit. Cognates of the word “Exploit” will have correlative meanings.

1.56 “FD&C Act” means the United States Federal Food, Drug, and Cosmetic Act, as amended, and the rules and regulations promulgated thereunder.

1.57 “FDA” means the United States Food and Drug Administration and any successor Governmental Authority having substantially the same function.

1.58 “Field” means immunogenic compositions comprising RNA encoding a SARS-CoV-2 polypeptide or fragment thereof, including naturally occurring or engineered variants thereof, for prophylaxis against COVID-19 in humans.

1.59 “First Commercial Sale” means, with respect to the Product in a given country in the Territory, the first shipment of the Product by the applicable Commercializing Party to a Third Party in such country for end use or consumption of the Product pursuant to an Emergency Use Authorization in such country or after grant of a Market Authorization Approval of such Product in such country or, if earlier, the invoicing of a Third Party for such shipment, excluding, however, any shipment or invoicing or other distribution of the Product for use in or for (a) a clinical trial, a Compassionate Use Purpose, named patient programs, sales under a treatment IND, test marketing, or any non-registrational studies or (b) any similar instance where the Product is supplied at or below the Commercializing Party’s Manufacturing Costs (excluding any margin) for such Product.

1.60 “Flu Collaboration License” means the separate research collaboration and license agreement between, inter alia, the Parties for the development and commercialization of immunogenic compositions comprising RNA that encodes at least one Antigen for prophylaxis against influenza in humans dated July 20, 2018, as amended.

1.61 “Fosun” means Shanghai Fosun Pharmaceutical Industrial Development, Co. Ltd, a company incorporated in China, and having a place of business at No. 1289 Yishan Road, Shanghai, China.

1.62 “Fosun Agreement” means the Development and License Agreement concluded between BioNTech and Fosun on March 13, 2020.

1.63 “Future License” means an agreement approved by the Parties (a) that BioNTech or its Affiliates enters into on or after the Effective Date with a Third Party or (b) that Pfizer or its Affiliates enters into on or after the Effective Date with a Third Party; which in the case of (a) and



(b) grants a license (sublicensable in accordance with the licenses granted hereunder) to that Third Party's ("Future Licensor") Intellectual Property Rights for the Development, Manufacture or Commercialization of the Candidates or Products by BioNTech and Pfizer in the Field, and which license is applicable to the Candidates or Products.

1.64 "GAAP" means the then-current generally accepted accounting principles in the United States as established by the Financial Accounting Standards Board or any successor entity or other entity generally recognized as having the right to establish such principles in the United States, in each case, consistently applied.

1.65 "GEIA" means the German Employee Invention Act.

1.66 "GEIA Technology," means all BioNTech Technology and Research and Development Program Technology invented by employees of BioNTech or its Affiliates (solely or jointly with employees of Third Parties) under the jurisdiction of GEIA.

1.67 "Global Commercialization Plan" means, the global plan established by the JCC pursuant to Section 9.1 with respect to the Territory as a whole, and as may be updated from time to time by the JCC for each Calendar Year during the Term, and from which any Annual Regional Commercialization Plan shall be derived.

1.68 "Global Trade Control Laws" include, but are not limited to, the U.S. Export Administration Regulations; the U.S. International Traffic in Arms Regulations; the economic sanctions rules and regulations implemented under statutory authority or President's Executive Orders and administered by the U.S. Treasury Department's Office of Foreign Assets Control; European Union (EU) Council Regulations on export controls, including Nos.428/2009, 267/2012; other EU Council sanctions regulations, as implemented in EU Member States; United Nations sanctions policies; all relevant regulations and legislative instruments made under any of the above; other relevant economic sanctions, export and import control laws, and other laws, regulations, legislation, orders and requirements imposed by a relevant Governmental Authority.

1.69 "Government" or "Governmental Authority," is to be broadly interpreted and includes (a) any national, federal, state, local, regional or foreign government, or level, branch, or subdivision thereof; (b) any multinational or public international organization or authority; (c) any ministry, department, bureau, division, authority, agency, commission, or body entitled to exercise any administrative, executive, judicial, legislative, police, regulatory, or taxing authority or power; (d) any court, tribunal, or governmental arbitrator or arbitral body; (e) any government-owned or controlled institution or entity; (f) any enterprise or instrumentality performing a governmental function; and (g) any political party.

1.70 "Government Official", to be broadly interpreted, means (a) any elected or appointed government official (e.g., a member of a ministry of health), (b) any employee or person acting for or on behalf of a government official, Governmental Authority, or other enterprise performing a governmental function, (c) any political party, candidate for public office, officer, employee, or person acting for or on behalf of a political party or candidate for public office, (d) any member of a military or a royal or ruling family, and (e) any employee or person acting for or on behalf of a public international organization (e.g., the United Nations). For clarity, healthcare

providers employed by Government-owned or -controlled hospitals, or a person serving on a healthcare committee that advises a Government, will be considered Government Officials.

- 1.71 "Gross Profit" means [\*\*\*].
- 1.72 "GxP" means, collectively, all relevant good practice quality guidelines and regulations, encompassing such internationally recognized standards as Good Manufacturing Practice (GMP), Good Clinical Practice (GCP), Good Laboratory Practice (GLP), Good Distribution Practice (GDP), and Good Review Practice (GRP).
- 1.73 "HCP" or "Healthcare Professional" includes any physician, nurse, pharmacist, or other person who may administer, prescribe, purchase or recommend pharmaceutical products or other healthcare products.
- 1.74 "House Marks" means the Pfizer House Marks or the BioNTech House Marks, as the case may be.
- 1.75 "Human Material" means any biological samples of one or more Subjects collected, provided or utilized by BioNTech during the Research and Development Plan pursuant to this Agreement.
- 1.76 "ICE" means an informed consent form that was approved by a qualified Institutional Review Board or Independent Ethics Committee ("IRB / IEC") in accordance with all applicable Laws and recognized international standards for the protection of human research subjects.
- 1.77 "IFRS" means International Financing Reporting Standards, as in effect from time to time, together with its pronouncements thereon from time to time, consistently applied.
- 1.78 "IND" means an Investigational New Drug Application submitted under the FD&C Act, or an analogous application or submission with any analogous agency or Regulatory Authority outside of the United States for the purposes of obtaining permission to conduct Clinical Trials.
- 1.79 "Intellectual Property Rights" means any and all (a) Patent Rights, (b) proprietary rights in Know-How, including trade secret rights, (c) proprietary rights associated with works of authorship and software, including copyrights, moral rights, and copyrightable works, and all applications, registrations, and renewals relating thereto, and derivative works thereof, (d) other forms of proprietary or intellectual property rights however denominated throughout the world, other than trademarks, service marks, trade names, trade dress, domain names and other indicators of origin.
- 1.80 "Internal Compliance Codes" means a Party's internal policies and procedures intended to ensure that such Party and its Affiliates comply with applicable Laws, Party Specific Regulations, and such Party's applicable internal policies and procedures, including such policies and procedures regarding compliance with such Party's ethical, medical and similar standards.
- 1.81 "Joint Commercialization Committee" or "ICC" has the meaning defined in Section 6.4.1.

- 1.82 “Joint Steering Committee” or “JSC” means the steering committee described in Section 6.3.1.
- 1.83 “Joint Know-How” means any Research and Development Program Know-How, whether or not patentable, made or created jointly by (a) BioNTech or any of its Representatives and (b) Pfizer or any of its Representatives, which does not constitute BioNTech Know-How, Product Know-How or Pfizer Know-How.
- 1.84 “Joint Patent Rights” means Research and Development Program Patent Rights that claim or disclose any invention included in Joint Know-How.
- 1.85 “Joint Steering Committee” or “JSC” means the steering committee described in Section 7.3.1 of this Agreement, and in the event the JSC is dissolved pursuant to Section 6.3.6 but this Agreement survives, all references to the JSC shall mean the Joint Commercialization Committee.
- 1.86 “Joint Technology” means the Joint Know-How and the Joint Patent Rights.
- 1.87 “Know-How” means any proprietary invention, discovery, development, data, information, process, method, technique, technology, result, cell line, cell, antibody or other protein, compound, probe, nucleic acid, (including RNAi) or other sequences or other know-how, whether or not patentable, and any physical embodiments of any of the foregoing or any information contained in any of the foregoing. Know-How does not include Patent Rights, Copyrights, Product Trademarks, Pfizer House Marks or BioNTech House Marks.
- 1.88 “Law” means any law, statute, rule, regulation, order, judgment or ordinance of any Governmental Authority, including all applicable Anti-Corruption Laws, Applicable Data Protection Laws, accounting and recordkeeping laws, and laws relating to interactions with HCPs and Government Officials. For the avoidance of doubt, any specific references to any applicable Law or any portion thereof shall be deemed to include all then-current amendments thereto or any replacement or successor law, statute, standard, ordinance, code, rule, regulation, resolution, promulgation, order, writ, judgment, injunction, decree, stipulation, ruling or determination thereto.
- 1.89 “MA Holder” means, on a country by country basis within the Territory, the Party (or its Affiliate or designee under its control) that holds the Regulatory Approval required for the Commercialization of the Product in such country.
- 1.90 “Major EU Market Country” means any of France, Germany, Italy, Spain or the United Kingdom.
- 1.91 “Major Market Country” means the Major EU Market Countries, the United States and Japan.
- 1.92 “Manufacture” or “Manufacturing” means to make, produce, manufacture, process, fill, finish, package, label, perform quality assurance testing, release, ship or store, and, for the purposes of further Manufacturing, distribute, import or export, a compound or product or any component thereof. When used as a noun, “Manufacture”, “Manufactured” or “Manufacturing” means any and all activities involved in Manufacturing a compound or protein, device or product or any component thereof.

- 1.93 “Manufacturing Costs” means [\*\*\*].
- 1.94 “Manufacturing Plan” means the plan for establishing Manufacturing and the Manufacturing facilities, as well as the Manufacturing obligations of each Party, in respect of the Candidates and Products, as such plan may be updated and modified from time to time pursuant to Section 5.1 and Section 6.4.4. The Manufacturing Plan existing on the signing of this Amended and Restated Collaboration Agreement is attached hereto as Schedule 1.94.
- 1.95 “Manufacturing Variances” means [\*\*\*].
- 1.96 “Market Authorization Approval” means the approval by all relevant Governmental Authorities of a Marketing Authorization Application in a given country or regulatory jurisdiction (but which will not include any Pricing and Reimbursement Approvals).
- 1.97 “Marketing Authorization Application” or “MAA” means an application to a Governmental Authority for approval to market the Product (but excluding Pricing and Reimbursement Approval) in a country or a regulatory jurisdiction including a BLA or an application for conditional use approval.
- 1.98 “Medical Activities” means MSL Activities and Global Medical Activities.
- 1.99 “Medical Science Liaison” or “MSL” means a field-based colleague that is part of a Party’s medical organization (whether or not such field-based colleagues are titled as such within the respective Party’s medical organization) and who will have no responsibility for promotion, detailing or marketing of the Product.
- 1.100 “Materials” means the Pfizer Materials or the BioNTech Materials, as the context requires.
- 1.101 “Modified RNA” means an mRNA that has been modified by the incorporation of one or more modified nucleosides, excluding the 5’ CAP.
- 1.102 “Modified RNA Technology,” means [\*\*\*].
- 1.103 “MSL Activities” means, for each country in the Territory, those activities not related to the promotion, detailing, or marketing of the Product, but which are otherwise set forth in the relevant medical section of the Annual Regional Commercialization Plan, if any, approved for such country, or where no such plan exists as determined by the applicable Commercializing Party, consisting of the following activities: (a) HCP-facing field-based medical communication activities utilizing Medical Education Materials and medical content approved by the applicable Commercializing Party to support the safe and effective use of the Product for approved indications, including indications authorized under an Emergency Use Authorization, or as permitted under applicable Laws other indications identified by the Commercializing Party for its Commercialization Territory; (b) responses to UMRs; (c) scientific exchange activities utilizing medical resources approved by the applicable Commercializing Party created for such purpose; (d) field-based medical support at medical congresses, including drafting post-congress summary reports for internal use; (e) gathering field-based customer insights for internal use and (f) other non-promotional activities approved for MSLs pursuant to the Parties’ compliance policies and

local laws and regulations. For clarity, MSL Activities specifically exclude Global Medical Activities.

- 1.104 “Mutation” means [\*\*\*].
- 1.105 “Net Sales” means with respect to a Product [\*\*\*]
- 1.106 “Packaging Configuration” means the number of vial boxes, vials per box, and doses of Product per vial in the commercial packaging presentation of the Product for sale or use in the Territory.
- 1.107 “Packaging and Labeling” means primary, secondary or tertiary packaging and labeling of Product (in its commercial packaging presentation) for sale or use in the Territory, including insertion of materials such as patient inserts, patient medication guides, and professional inserts and any other written, printed or graphic materials accompanying the Product and any brand security or anti-counterfeiting measures included in the packaging elements for the Product considered to be part of the finished packaged Product, and all testing and release thereof.
- 1.108 “Party Specific Regulations” means all non-monetary judgments, decrees, orders or similar decisions issued by any Governmental Authority specific to a Party, and all consent decrees, corporate integrity agreements, or other agreements or undertakings of any kind by a Party with any Governmental Authority, in each case as the same may be in effect from time to time and applicable to a Party’s activities contemplated by this Agreement.
- 1.109 “Patent Rights” means any and all (a) issued patents, (b) pending patent applications, including all provisional applications, non-provisional applications, substitutions, continuations, continuations-in-part, divisions and renewals, applications sharing a priority claim and all patents granted thereon, (c) patents-of-addition, reissues, reexaminations and extensions or restorations by existing or future extension or restoration mechanisms, including patent term adjustments, patent term extensions, supplementary protection certificates or the equivalent thereof, (d) inventor’s certificates, (e) other forms of government-issued rights substantially similar to any of the foregoing and (f) United States and foreign counterparts of any of the foregoing.
- 1.110 “Patient or HCP Support Program Trademark” means any Trademark (whether or not registered) which is solely for use on, with, or to refer to a Party’s patient or HCP support programs or patient assistance programs relating to the Product (where such Trademark does not incorporate a Product Trademark, the Pfizer House Marks or BioNTech House Marks, as applicable), and all intellectual property rights and goodwill associated with the foregoing.
- 1.111 “Person” means an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, incorporated association, joint venture or similar entity or organization, including a government or political subdivision or department or agency of a government.
- 1.112 “Personal Data” means any information relating to an identified or identifiable natural person as further specified in Art. 4 no. 1 of the GDPR.

1.113 “Pfizer Commercial Materials” means any and all Pfizer Promotional Materials, Pfizer Training Materials, and all other literature or other information related to the Product and, in each case, created and provided by or on behalf of Pfizer hereunder.

1.114 “Pfizer Commercialization Territory” means the Territory, except for countries within the BioNTech Commercialization Territory from time to time.

1.115 “Pfizer Exit Countries” means, on a country by country basis, those countries out of the United Arab Emirates, South-East Asia and the Developing Countries Territory where Pfizer elects, pursuant to this Agreement, not to Commercialize the Product pursuant to any Pfizer Country Exit Option as described in Section 3.12.2.

1.116 “Pfizer House Marks” means (a) the corporate logo of Pfizer, (b) the trademark “Pfizer”, (c) any other Trademark, trade name or service mark (whether registered or unregistered) containing the word “Pfizer”, (d) any other corporate logo or Trademark of Pfizer used by Pfizer to identify Pfizer or its Affiliates; and all intellectual property rights and goodwill associated with any and all of the foregoing in clauses (a) through (d).

1.117 “Pfizer Improvements” means any Research and Development Program Technology, regardless of inventorship, that is a modification or improvement to the Pfizer Technology and (a) would also be applicable to one or more candidates or products in addition to or other than the Candidates or Products, (b) is not predominantly directed to the Candidates or Products or the RNA Technology or RNA Process Technology and (c) could have reasonably been developed without the aid, use or application of BioNTech Materials, BioNTech Know-How or BioNTech’s Confidential Information or any improvements or enhancements thereto.

1.118 “Pfizer Know-How” means [\*\*\*].

1.119 “Pfizer Patent Right” means any Patent Right (other than Patent Rights jointly owned by BioNTech and Pfizer pursuant to Section 11.2) in any form and whether pending or issued that (a) is Controlled by Pfizer or any of its Affiliates on the Effective Date or that comes into the Control of Pfizer or any of its Affiliates during the Term (other than, in either case, through the grant of a license by BioNTech), and (b) claims any Pfizer Know-How.

1.120 “Pfizer Quarter” means each of the four (4) successive thirteen (13) week periods, the first such thirteen (13) week period (a) with respect to the United States, commencing on January 1 of any Pfizer Year and (b) with respect to any country in the Territory other than the United States, commencing on December 1 of any Pfizer Year. Wherever non-country specific timelines are specified in this Agreement in reference to a Pfizer Quarter, such reference shall be deemed to be made to the Pfizer Year applicable in the United States.

1.121 “Pfizer Technology” means the Pfizer Patent Rights, Pfizer Materials and Pfizer Know-How.

1.122 “Pfizer Year” means the twelve (12) month fiscal periods observed by Pfizer (a) commencing on January 1 with respect to the United States; and (b) commencing on December 1 with respect to any country in the Territory other than the United States.

1.123 “Phase I Clinical Trial” means a Clinical Trial that generally provides for the first introduction into humans of a pharmaceutical product with the primary purpose of determining safety, metabolism and pharmacokinetic properties and clinical pharmacology of such product, in a manner that is generally consistent with 21 CFR § 312.21(a), as amended (or its successor regulation), provided, however, a Phase I Clinical Trial does not include any study generally characterized by the FDA as an “exploratory IND study” in CDER’s Guidance for Industry, Investigators, and Reviewers Exploratory IND Studies, January 2006, irrespective of whether or not such study is actually performed in the United States or under an IND. A so-called Phase I/II Clinical Trial shall be deemed to be a Phase I Clinical Trial unless such trial, when completed, allows Pfizer to proceed directly to a Phase III Clinical Trial.

1.124 “Phase II Clinical Trial” means a Clinical Trial, the principal purpose of which is to make a preliminary determination as to whether a pharmaceutical product is safe for its intended use and to obtain sufficient information about such product’s efficacy, in a manner that is generally consistent with 21 CFR § 312.21(b), as amended (or its successor regulation), to permit the design of further Clinical Trials.

1.125 “Phase III Clinical Trial” means a pivotal Clinical Trial with a defined dose or a set of defined doses of a pharmaceutical product designed to ascertain efficacy and safety of such product, in a manner that is generally consistent with 21 CFR § 312.21(c), as amended (or its successor regulation), for the purpose of enabling the preparation and submission of an NDA.

1.126 “Price Approval” means, in any country where a Governmental Authority authorizes reimbursement for, or approves or determines pricing for, pharmaceutical products, receipt (or, if required to make such authorization, approval or determination effective, publication) of such reimbursement authorization or pricing approval or determination (as the case may be).

1.127 “Product” means any pharmaceutical product in a formulation suitable for administration to humans that [\*\*\*].

1.128 “Product Component” means any component or consumable additional to the Product (e.g., diluent, needles or syringes) that are supplied by on behalf of a Commercializing Party for use in the administration of the Product to a patient, other than where such components or consumables are supplied through a separate sale or as part of the same sale, but where the customer is charged for such components or consumables at cost or at greater than cost thereof.

1.129 “Product Know-How” means any Research and Development Program Know-How that is predominantly directed to the composition of matter, treatment with, or the delivery of, Manufacture, form, formulation, or use of a Candidate or Product in the Field and is not generally applicable to compositions or products in addition to or other than a Candidate or Product.

1.130 “Product Materials” means all raw or intermediate materials (including, without limitation, active pharmaceutical ingredients and excipients, vectors, plasmids and mRNA), labeling or packaging materials and components needed for the Manufacture and supply of a given Candidate or Product.

1.131 “Product Patent Rights” means any Patent Right that claims any invention included in Product Know-How.

- 1.132 “Product Shipping and Storage Costs” means [\*\*\*].
- 1.133 “Product Technology” means the Product Know-How and Product Patent Rights.
- 1.134 “Product Trademarks” means any Trademark, (whether registered or unregistered) selected with the mutual consent of the Parties through the JCC which is solely for use on, with, or to refer to the Product (other than Pfizer House Marks and BioNTech House Marks, as applicable), and all intellectual property rights and goodwill associated with the foregoing, but excluding any Patient or HCP Support Program Trademark.
- 1.135 “Professional Requirements” means (a) FDA’s regulations and guidelines concerning the advertising of prescription drug products, (b) the American Medical Association’s Guidelines on Gifts to Physicians, (c) the ACCME Standards for Commercial Support of Continuing Medical Education, (d) the European Federation of Pharmaceutical Industries and Associations (EFPIA), (e) the Pharmaceutical Supply Chain Initiative (PSCI) Pharmaceutical Industry Principles for Responsible Supply Chain Management, (f) the relevant Codes and Guidelines established by PhRMA relating to marketing practices and (h) all other accepted national and international pharmaceutical industry codes of practice in and for the relevant countries in the Territory.
- 1.136 “Professional Sales Representative” or “PSR” means a pharmaceutical sales representative employed (either full time or part time) by or on behalf of a Party or its Affiliates to promote and deliver details for the Product.
- 1.137 “Prosecution and Maintenance” means (a) the preparation, filing, and prosecution of patent applications and maintenance of Patent Rights, as well as re-examinations and reissues with respect to such Patent Rights, together with the conduct of interferences, post-grant proceedings (including post-grant review, inter-parties review, and derivation proceedings in the U.S.) and the defense of oppositions with respect to such Patent Rights and (b) the preparation, filing, and prosecution of Trademark applications and maintenance and renewal of Trademarks, the handling of office actions, objections or rejections issued by trademark offices, and the defense of oppositions with respect to such Trademark application or Trademark; and “Prosecute and Maintain” has the correlative meaning.
- 1.138 “Public Health Service Act” or “PHS Act” means the United States Public Health Service Act (42 U.S.C. 201 *et seq*), as amended from time to time (including any rules and regulations promulgated thereunder) or any subsequent or superseding law, statute or regulation.
- 1.139 “Recall Costs” means actual costs incurred by a Party or its Affiliates as the direct result of a recall or withdrawal of the Product in a country in the Territory, such as administrative costs associated with administering the recall or withdrawal, notification, packing, shipping, distribution and destruction costs, Product replacement costs and reimbursements, penalties payable to customers and other payments to Third Parties as a direct result of such recall or withdrawal, but will not include internal costs to the extent such costs are not included in Manufacturing Costs or indirect costs such as loss of reputation or goodwill or loss of indirect profits.
- 1.140 “Regional Commercialization Committee” or “RCC” means any of the regional committees established pursuant to Section 6.4.2.



1.141 “Regulatory Approval” means all technical, medical and scientific licenses, registrations, authorizations and approvals (including conditional use approvals and approvals of INDs, NDAs, MAAs, BLAs, supplements and amendments, pre- and post- approvals and labeling approvals) of any Regulatory Authority, necessary or useful for the use, Development, Manufacture, and Commercialization of a pharmaceutical or biopharmaceutical product in a regulatory jurisdiction, including commercially reasonable Price Approvals and commercially reasonable Third Party reimbursement approvals, including for the avoidance of doubt any Emergency Use Authorization.

1.142 “Regulatory Authority” means, with respect to a country in the Territory, any national (e.g., the FDA), supra-national (e.g., the European Commission, the Council of the European Union, or the European Medicines Agency), regional, state or local regulatory agency, department, bureau, commission, council or other Governmental Authority involved in the granting of any license, approval or authorization (including a regulatory approval or emergency use authorization) to Develop, Manufacture, Commercialize or Exploit pharmaceutical products in such country.

1.143 “Related Agreement” means the Pharmacovigilance Agreement entered into or to be entered into or amended pursuant to Section 8.3.3, supply agreements and quality agreements entered into or to be entered into or amended pursuant to Sections 7.4.1 and 7.4.2, and any other agreements entered into or to be entered into between the Parties or their Affiliates in connection with the Development, Regulatory Approval, Manufacture or Commercialization of a Candidate or Product.

1.144 “Relevant Factors” means all relevant factors that may affect the Development, Regulatory Approval or Commercialization of a Candidate or Product, including (as applicable): [\*\*\*].

1.145 “Replicon” means an RNA molecule(s) that comprises a gene encoding a polymerase that can, when the RNA molecule(s) is introduced into a cell, replicate the same or a different RNA molecule(s), that also comprises a gene or a sequence encoding at least one non-human polypeptide that is capable of eliciting an immune response (an “Antigen”) and does not comprise the full set of genes required to make an infectious virus and is capable, when introduced into a cell, of expressing detectable levels of the encoded Antigen.

1.146 “Replicon Product” means any Product comprising Replicon Technology.

1.147 “Replicon Technology” means the BioNTech Know-How applicable to Replicons. For clarity, Replicon Technology does not include Modified RNA Technology, Unmodified RNA Technology or Delivery Technology.

1.148 “Representatives” means (a) with respect to Pfizer, Pfizer, its Affiliates, its Sublicensees and subcontractors, and each of their respective officers, directors, employees, consultants, contractors and agents and (b) with respect to BioNTech, BioNTech, its Affiliates, its Sublicensees and subcontractors, and each of their respective officers, directors, employees, consultants, contractors and agents.

1.149 “Research and Development Plan” means the research and development plan to define the Development activities pursuant to the collaboration anticipated under this Agreement

(including, for the avoidance of doubt, any post-Marketing Authorization Approval Development activities but excluding any Medical Activities and Medical Affairs Studies) as may be amended from time to time pursuant to Section 5.1. The Research and Development Plan existing on the signing of this Amended and Restated Collaboration Agreement is attached hereto as Exhibit A.

1.150 “Research and Development Program” means the program of collaboration between the Parties to Develop and Manufacture (but not Commercialize) Candidates and Products in the Field, including the activities described in the Research and Development Plan.

1.151 “Research and Development Program Know-How” means any and all Know-How, Candidates and Products, whether or not patentable, made or created solely by or on behalf of either Party or its Representatives in the conduct of activities under the Research and Development Plan, made or created jointly by or on behalf of (a) BioNTech or its Representatives and (b) Pfizer or its Representatives in the conduct of activities under the Research and Development Plan.

1.152 “Research and Development Program Patent Rights” means any and all Patent Rights claiming or disclosing any invention included in Research and Development Program Know-How.

1.153 “Research and Development Program Technology” means the Research and Development Program Patent Rights and Research and Development Program Know-How.

1.154 “Residual Knowledge” means knowledge, techniques, experience and Know-How that (a) are, or are based on, any Confidential Information of the Disclosing Party and (b) are retained in the unaided memory of any authorized Representative of the Receiving Party after having access to such Confidential Information. An individual’s memory will be considered to be unaided if the individual has not intentionally memorized the Confidential Information for the purpose of retaining and subsequently using or disclosing it.

1.155 “RNA” means ribonucleic acid.

1.156 “RNA Process Technology” means the BioNTech Know-How used to Manufacture Candidates or Products.

1.157 “RNA Technology” means Replicon Technology, Unmodified RNA Technology, Modified RNA Technology and Delivery Technology that is, in each case, used by BioNTech in the Research and Development Program.

1.158 “Sales Manager” means a full or part time employee of a Commercializing Party (or a its subcontractor) that is responsible for the direct supervision of the PSRs of or on behalf of such Commercializing Party who detail the Product in the Territory under this Agreement.

1.159 “Shared Development Cost” means [\*\*\*].

1.160 “Signing Date” means April 9, 2020.

1.161 “South-East Asia” means [\*\*\*].

1.162 “Subject” means the individual donor of the Human Material or of the original tissues from which the Human Material was derived.

- 1.163 “Sublicensee” means any Person to whom a Party grants or has granted, directly or indirectly, a license or sublicense of any of the same Intellectual Property Rights licensed to such Party by the other Party under this Agreement in accordance with Section 3.7. For the avoidance of doubt, distributors used by a Commercializing Party to Commercialize Product in a country or region shall not be regarded a Sublicensee.
- 1.164 “Tax” means all corporation tax, advance corporation tax, income tax, capital gains tax, value added tax, customs and other import duties, inheritance tax, purchase tax, capital duties, social insurance contributions, foreign taxation and duties and all penalties, charges and interest relating to any of the foregoing or resulting from a failure to comply with the provisions of any enactment relating to any of the foregoing.
- 1.165 “Territory” means worldwide, except for the People's Republic of China (including Hong Kong SAR and Macau SAR) and Taiwan.
- 1.166 “Third Party” means any Person other than Pfizer, BioNTech or their respective Affiliates.
- 1.167 “Third Party License” means a Current License or a Future License.
- 1.168 “Third Party License Payment” shall mean a payment due to a Current Licensor or Future Licensor pursuant to a Current License or Future License, as applicable, that is [\*\*\*]. For the avoidance of doubt, [\*\*\*].
- 1.169 “Trademark” means any trademark, trade name, service mark, service name, brand, domain name, trade dress, logo, slogan or other indicia of origin or ownership, including the goodwill and activities associated with each of the foregoing.
- 1.170 “Transfer Price” shall mean [\*\*\*] of such Candidate or Product, subject to any different percentage between [\*\*\*] as determined by the JCC through mutual consent, to be applied for Products to be supplied to the Developing Countries Territory or to take account of any supply requirements of any Governmental Authority within the Territory or pursuant to the terms and conditions of any funding agreement with a Third Party Funder [\*\*\*].
- 1.171 “United States” or “U.S.” means the United States of America and its territories and possessions.
- 1.172 “Unmodified RNA” means an mRNA that [\*\*\*].
- 1.173 “Unmodified RNA Technology” means the BioNTech Know-How applicable to Unmodified RNA. For clarity, Unmodified RNA Technology does not include Replicon Technology, Modified RNA Technology or Delivery Technology.
- 1.174 “Unsolicited Medical Request” or “UMR” means unsolicited requests for medical information from any Third Party communicated to a Party in any manner addressing on-label use, off-label use or unapproved indications of a Product or Candidates under Development.
- 1.175 “UPC Agreement” means the treaty Agreement on the Unified Patent Court signed 19 February 2013, as may be amended or superseded from time.

1.176 “Vaccine Technical Committee” means a duly established and recognized multidisciplinary group of national medical and public health experts responsible for providing independent, evidence-based advice and recommendations to ministries of health or other relevant government policy makers on issues related to immunization and vaccines in a particular country or region.

The following terms are defined in the section of this Agreement listed opposite each term:

<b>Defined Term</b>	<b>Section in Agreement</b>
Acquirer	15.2.2
Acquisition Program	15.1.1
Additional Commitment Country	3.12.2
Additional Patent Jurisdictions	11.3.1.1
Affected Party	15.1
Agreement	Preamble
Alliance Managers	6.1
Annual Net Sales Level	4.8
Audited Party	4.14
Auditing Party	4.14
BARDA	4.5.1
Benefit Plans	17.16.2
BioNTech	Preamble
BioNTech Deferred Development Costs	4.4.2
BioNTech Enforcement Patent Rights	11.4.2
BioNTech Indemnified Party	16.2
BioNTech JSC Members	6.3.1
BioNTech Medical Training Materials	10.3.2
BioNTech Promotional Materials	9.5.3
BioNTech Prosecution Patent Rights	11.3.1.1
BioNTech Territory Exit Option	3.12.1
BioNTech Training Materials	9.5.2
Branded Prescription Drug Fee	4.11.5
Budget Deviation	6.4.1.1
Capex Funding	4.5.1
Change of Control Party	12.7
Commercialization Materials	9.12
Commercialization Region	6.4.2
Commercialization Sales Milestone Payment	4.8
Compliance Committee	6.4.5
Consequential Damages	16.1
Competitive Product Infringement	11.4.3
Continuing Party	11.3.2
Croda	7.4.2.4
Croda Agreement	7.4.2.4
Cure Plan	3.8.3

Debtor	14.9.1
Declining Party	11.3.2
Deferred Payment Period	4.4.2
Disputed Matter	6.5.2
Disclosing Party	12.1
Enforcement Action	11.4.1
Effective Date	Preamble
Equity Investment	4.2
Executive Officer	6.5.4
Expedited Milestone Refund	4.10.2.3
Force Majeure	17.3
Fosun Territory	3.13.1
FTO Action	11.7.1
Global Medical Activities	10.1
Hiring Party	17.16.2
Impf Group	1.1
Incremental Withholding Taxes	4.11.1
Indemnified Party	16.4.1
Indemnifying Party	16.4.1
Infringements	11.9.7.1
Infringement Claim	11.8
Investment Agreement	4.2
IRB / IEC	1.76
JCC	6.4.1
JFC	6.4.3
JMC	6.4.4
JSC Chair	6.3.2
Key Patent Jurisdictions	11.3.1.1
Lead Development Party	8.1.1
Lead Party	4.5.1
Lead Regulatory Party	8.2.1
Liabilities	16.2
Licensed Activities	11.7.1
Litigation Conditions	16.4.2
Losses	17.16.3
Medical Affairs Studies	10.6
Medical Education Materials	10.3.4
Medical Information Content	10.5
MSL Activities	10.1
NHP	17.16.3
NHP Indemnitees	17.16.3
Notice of Dispute	17.11.1
Notified Party	4.9.3
Original Collaboration Agreement	Preamble
Party or Parties	Preamble
Patent Committee	11.1
Patent Term Extension	11.3.4
Paying Party	4.10.2.2
Pfizer	Preamble

Pfizer Country Exit Option	3.12.2
Pfizer Indemnified Party	16.3
Pfizer JSC Members	6.3.1
Pfizer Materials	5.4.1
Pfizer Medical Training Materials	10.3.1
Pfizer Promotional Materials	9.5.3
Pfizer Training Materials	9.5.1
Pharmacovigilance Agreement	8.3
Pricing and Reimbursement Guidelines	9.6.1
Prosecution Proceedings	11.3.5
Program Director and Program Directors	6.2
Promotional Materials	9.5.3
Proportional Adjustment	4.10.2.3
Receiving Party	12.1
Reference Product Sponsor	11.4.6.2
Regulatory Approval Milestone	4.3
Relevant Line Item	6.4.1.1
Reporting Party	4.9.3
Restricted Market	17.10.1
Restricted Parties	17.10.2
Restricted Party List	17.10.2
Review Period	12.5.2
ROW	8.1.2
Standard Conversion Cost	1.93
Standard Product Materials Cost	1.93
Term	14.2
Termination Effective Date	14.8.5.1
Terminated Product Data	14.8.6.2
Terminated Territory	14.8.5.2
Third Party Claim	16.4.1
Third Party Funder	4.5.1
Third Party Licensor	1.18
Third Party Royalties	4.10.1.1
Transfer Price True Up Period	4.9.4
Upfront Payment	4.1
VAT	4.11.2
Violating Party	14.6.1
Withholding Taxes	4.11.1

2. **SCOPE AND SPIRIT OF COLLABORATION**

- 2.1 Scope of Collaboration. Subject to the terms and conditions of this Agreement, the Parties shall (a) cooperate in good faith to conduct their respective activities under the Agreement; and (b) establish one or more committees as described in Section 6 of this Agreement to oversee and coordinate the Development, Manufacture and Commercialization of Candidates and Products in the Territory.

2.2 **Spirit of Collaboration.** Without prejudice to the terms and conditions of this Agreement, each Party shall endeavor, in good faith, to conduct themselves in the collaboration hereunder, in all material respects, in the spirit of (i) honest and constructive good faith cooperation and (ii) with appropriate transparency between the Parties.

2.3 **Reviewing of and Commenting on Documents.** Subject to Section 2.2, but without prejudice to the terms and conditions of this Agreement, to the extent either Party has the right or obligation to review, comment or approve any documents, filings or other activities of the other Party pursuant to this Agreement, such Party shall endeavor to conduct such review, or provide its comments or approval (where required), within a timeline that is reasonable under the circumstances, and the Party requesting such review, comment or approval shall endeavor to make such request in a timely manner, in each case in order to endeavor to mitigate or avoid unreasonable disruptions or delays. Where comments have been requested, the requesting Party shall, in good faith, consider all reasonable comments made by the commenting Party in the requesting Party's further preparation or pursuit of such document, filing or activity. Where appropriate, and to the extent time permits, the Parties may discuss any material comment made by the other Party. The foregoing provisions however shall be interpreted in the general spirit of the collaboration set forth in Section 2.2 and the Parties recognize that the foregoing is not intended to (a) cause any unreasonably delay or impede or burden a Party's actions, activities or pursuit of the objectives under this Agreement, (b) modify any rights of a Party or decision making right set forth elsewhere in this Agreement, nor (c) give rise to any breach of this Agreement unless there is repeated, material and persistent uncured noncompliance with its provisions which has been raised through written notice and through the escalation procedure under Section 2.4.

2.4 **Escalation.** Without prejudice to the terms and conditions of this Agreement, to the extent one Party reasonably believes in good faith that the other Party is in material noncompliance with its obligations under Section 2.2 or 2.3, it shall escalate the relevant issues to the JSC or JCC, as applicable, and if such a relevant issue cannot be unanimously solved in such committee within [\*\*\*], it shall be escalated to the Executive Officers for further discussion and resolution.

### 3. **LICENSES**

#### 3.1 **Research Licenses.**

3.1.1 **Research License from BioNTech to Pfizer.** Subject to the terms and conditions of this Agreement, effective as of the Effective Date, BioNTech on behalf of itself and its Affiliates hereby grants (and will procure that its Affiliates grant) to Pfizer a sole license under the BioNTech Technology to use, have used, Develop, have Developed, Manufacture, and have Manufactured [\*\*\*] Candidates and Products within the Territory [\*\*\*].

3.1.2 **Research License from Pfizer to BioNTech.** Subject to the terms and conditions of this Agreement, effective as of the Effective Date, Pfizer on behalf of itself and its Affiliates hereby grants (and will procure that its Affiliates grant) to BioNTech a sole license under the Pfizer Technology to use, have used, Develop, have Developed, Manufacture, and have Manufactured [\*\*\*] (a) Candidates and Products and within the Territory [\*\*\*] and (b) Candidates or products identical to any Product within the Field for their Development (but not Manufacture) outside the Territory by or on behalf of BioNTech (including by Fosun or its Affiliates) pursuant to the Fosun Agreement. With respect to (b) above, such license shall (i) exclude and prohibit the disclosure and license by BioNTech of Pfizer Technology used for Manufacture or formulation of the Candidate

or Products, other than to the extent necessary for Fosun or its Affiliates to undertake fill/finish of a product identical to any Product in the Fosun Territory or to comply with information requirements of the China National Medical Products Administration (or equivalent), relating to such product required under applicable Law; and (ii) automatically terminate on the termination or expiration of the Fosun Agreement and will, unless earlier terminated, survive the termination or expiration of this Agreement in those circumstances described in Section 14.8.6.5.

3.1.3 **Scope of Research Licenses.** Each of the licenses granted under Section 3.1.1 and 3.1.2 is (a) a sole license, such that the applicable licensor Party shall not grant a Third Party (unless it is necessary for the Third Party undertaking a fee-for-service Development or Manufacturing activity on its behalf pursuant to this Agreement) a license under the same Intellectual Property Rights for any Exploitation within the Field and within the Territory in respect of any product, whether or not it is a Candidate or Product; (b) royalty-free; (c) sub-licensable in accordance with and subject to Section 3.7; (d) non-assignable, in whole or part, other than where a Party's benefit under this Agreement may be assigned pursuant to Section 17.1; and (e) granted subject to the provisions of this Agreement, and for the duration of the Term or until termination or expiry of this Agreement if earlier, unless otherwise specified herein.

3.2 **Licenses for Commercial Manufacturing.**

3.2.1 **License from BioNTech to Pfizer.** Subject to the terms and conditions of this Agreement, effective as of the Effective Date, BioNTech on behalf of itself and its Affiliates hereby grants (and will procure that its Affiliates grant) to Pfizer a non-exclusive license under the BioNTech Technology to Manufacture and have Manufactured Candidates and Products for use within the Territory and, subject to Section 3.4, Commercialization within the Territory in any indication.

3.2.2 **License from Pfizer to BioNTech.** Subject to the terms and conditions of this Agreement, effective as of the Effective Date, Pfizer on behalf of itself and its Affiliates hereby grants (and will procure that its Affiliates grant) to BioNTech a non-exclusive license under the Pfizer Technology to Manufacture and have Manufactured (a) Candidates and Products for Commercialization within the Territory in accordance with Section 3.4 in any indication and (b) Candidates and products identical to any Product within the Field for their use and Commercialization outside the Territory by BioNTech or Fosun and its Affiliates pursuant to the Fosun Agreement. With respect to (b) above, such license shall (i) exclude and prohibit the disclosure and license by BioNTech of Pfizer Technology used for Manufacture or formulation of the Candidate or Product, other than to the extent necessary for Fosun or its Affiliates to (x) undertake fill/finish of a product identical to any Product in the Fosun Territory or (y) comply with information requirements of the China National Medical Products Administration (or equivalent), relating to such product required under applicable Law; and (ii) shall automatically terminate on the termination or expiration of the Fosun Agreement and will, unless earlier terminated, survive the termination or expiration of this Agreement in those circumstances described in Section 14.8.6.5.

3.2.3 **Scope of Commercial Manufacturing Licenses.** Each of the licenses granted under Section 3.2.1 and 3.2.2 is (a) royalty-free; (b) sub-licensable in accordance with and subject to Section 3.7; (c) non-assignable, in whole or part, other than where a Party's benefit under this Agreement may be assigned pursuant to Section 17.1; and (d) granted subject to the provisions of



this Agreement, and for the duration of the Term or until termination or expiry of this Agreement if earlier, unless otherwise specified herein.

3.3 Regulatory Dossier Licenses.

3.3.1 **License from BioNTech to Pfizer.** Effective as of the Effective Date, in respect of the Drug Master Files, Regulatory Approvals and Regulatory Documentation (as each is defined in the Fosun Agreement), BioNTech hereby grants to Pfizer a sole license to rely upon and make reference to such Drug Master Files, Regulatory Approvals and Regulatory Documentation (and the data referenced therein), to use the same in respect of any application for, and maintaining, any Regulatory Approvals (as defined in this Agreement) filed by Pfizer pursuant to this Agreement in respect of Candidates or Products. The license granted under this Section 3.3.1 is (a) royalty-free; (b) sub-licensable in accordance with and subject to Section 3.7; (c) non-assignable, in whole or part, other than where a Party's benefit under this Agreement may be assigned pursuant to Section 17.1; and (d) granted subject to the provisions of this Agreement, and for the duration of the Term or until termination or expiry of this Agreement if earlier, unless otherwise specified herein. BioNTech shall procure disclosure of such Drug Master Files, Regulatory Approvals and Regulatory Documentation upon Pfizer's request. Without limiting any of the foregoing, but subject to Section 3.11, BioNTech shall be permitted to use such Drug Master Files, Regulatory Approvals and Regulatory Documentation (to the extent not comprising Pfizer's Technology or Pfizer's Confidential Information) with respect to any application for or maintenance of any Regulatory Approvals outside the Field.

3.4 Commercialization Licenses.

3.4.1 **License from BioNTech to Pfizer.** Subject to the terms and conditions of this Agreement, BioNTech on behalf of itself and its Affiliates hereby grants (and will procure that its Affiliates grant) to Pfizer an exclusive (even as to BioNTech) license under the BioNTech Technology to Commercialize and have Commercialized Products within the Pfizer Commercialization Territory in any indication.

3.4.2 **License from Pfizer to BioNTech.** Subject to the terms and conditions of this Agreement, Pfizer on behalf of itself and its Affiliates hereby grants (and will procure that its Affiliates grant) to BioNTech a license under the Pfizer Technology to Commercialize and have Commercialized (a) Products within the BioNTech Commercialization Territory in any indication, which license shall be granted on a sole basis; and (b) products identical to any Product within the Field but outside the Territory by BioNTech or by Fosun or its Affiliates pursuant to the Fosun Agreement. With respect to (b) above, such license shall (i) be sole; (ii) royalty-bearing; (iii) exclude and prohibit the disclosure and license by BioNTech of Pfizer Technology used for Manufacture or formulation of any Candidate or Product, other than to the extent necessary for Fosun or its Affiliates to (x) undertake fill/finish of a product identical to any Product in the Fosun Territory or (y) comply with information requirements of the China National Medical Products Administration (or equivalent), relating to such product required under applicable Law; and (iv) shall automatically terminate on the termination or expiration of the Fosun Agreement and will, unless earlier terminated, survive the termination or expiration of this Agreement in those circumstances described in Section 14.

3.4.3 **Scope of Commercialization Licenses.** Each of the licenses granted under Section 3.4.1 and 3.4.2 is (a) sub-licensable in accordance with and subject to Section 3.7; (b) non-assignable, in whole or part, other than where a Party's benefit under this Agreement may be assigned pursuant to Section 17.1; and (c) granted subject to the provisions of this Agreement and for the duration of the Term, unless otherwise specified herein. Furthermore, [\*\*\*].

3.4.4 **Financial Provisions for Commercialization.** The license under:

3.4.4.1 Sections 3.4.1 and 3.4.2(a) is royalty-free, but each is subject to the Gross Profit share set out in Section 4.9; and

3.4.4.2 Section 3.4.2(b) shall be royalty bearing at a rate of (i) [\*\*\*] percent of net sales of the product(s) sold pursuant to the Fosun Agreement where such product(s) is Covered by any Pfizer Patent Right or any Joint Patent Rights; or (ii) if, or when, (i) does not apply, then [\*\*\*] percent of net sales of the product(s) sold pursuant to the Fosun Agreement where such product(s) is Covered by any Pfizer Know-How or any Joint Know-How; with in each case of (i) or (ii) above, net sales having the same definition, *mutatis mutandis*, to Net Sales under this Agreement, with references under such Net Sales definition to "a Party" meaning BioNTech, its Affiliates and their respective licensees and "Product" meaning a product as described above, and with sales and royalty reporting every Pfizer Quarter, payments on a Pfizer Quarter basis, and Pfizer having audit rights comparable with those under this Agreement); *provided, however*, that (x) during the period in which a generic or biosimilar equivalent to such product(s) is Commercialized in any part of the territory that is the subject of the Fosun Agreement, the royalty under (i) above shall be reduced by [\*\*\*]; or (y) if the gross profit share earned by BioNTech in connection with sale of products under the Fosun Agreement is lower than the royalty amount to be paid to Pfizer hereunder in respect of those same sales, then no royalty shall be payable hereunder for those sales. The foregoing royalty obligations shall commence on the first commercial sale of the product(s) sold pursuant to the Fosun Agreement, and extend (x) with respect to the royalty under (i) for so long as such product(s) is Covered by any such Patent Rights (until such Patent Right expires, is surrendered, or is otherwise irrevocably revoked or declared invalid), and (y) with respect to the royalty under (ii), the [\*\*\*] anniversary of the date of the first commercial sale (having the same meaning, *mutatis mutandis*, to the definition of First Commercial Sale herein) of such product(s) in the territory that is the subject of the Fosun Agreement; and in each case, such provision shall survive the termination or expiry of this Agreement.

3.5 **Additional Licenses.**

3.5.1 **Additional License To Pfizer.** Without limiting any other license or sublicense granted under this Agreement and subject to the terms and conditions of this Agreement, BioNTech on behalf of itself and its Affiliates, effective as of the Effective Date, hereby grants (and will procure that its Affiliates grant) to Pfizer a non-exclusive, royalty-free, fully paid-up, sublicensable license under all BioNTech Improvements and Product Technology that were solely or jointly made or invented by Pfizer Representatives to use, have used, Develop, have Developed, Manufacture, have Manufactured, Commercialize, have Commercialized and otherwise Exploit any products or processes outside the Field. In addition to the obligations set forth in Section 3.11 for the avoidance of doubt, the license granted in this Section 3.5.1 shall not include or imply a right of Pfizer to use

any of BioNTech's Confidential Information (that is not a BioNTech Improvement or Product Technology) outside the Field.

3.5.2 Additional License To BioNTech.

3.5.2.1 Without limiting any other license or sublicense granted under this Agreement and subject to the terms and conditions of this Agreement, Pfizer, effective as of the Effective Date, hereby grants to BioNTech a non-exclusive, royalty-free, fully paid-up, sublicensable license under all Pfizer Improvements that were solely or jointly invented by BioNTech Representatives to use, have used, Develop, have Developed, Manufacture, have Manufactured, Commercialize, have Commercialized and otherwise Exploit any products or processes outside the Field.

3.5.2.2 Without limiting any other license or sublicense granted under this Agreement and subject to the terms and conditions of this Agreement, Pfizer, effective as of the Effective Date, hereby grants to BioNTech a non-exclusive, royalty-free, fully paid-up, sublicensable license under Pfizer's interest in the Research and Development Program Technology to use, have used, Develop, have Developed, Manufacture, have Manufactured, Commercialize, have Commercialized and otherwise Exploit any products or processes outside the Field.

3.5.2.3 For the avoidance of doubt, the licenses granted in this Section 3.5.2 shall not include or imply a right of BioNTech to use any Pfizer Confidential Information (that is not a Pfizer Improvement or Research and Development Program Technology) outside the Field, but remain subject to the obligations set forth in Section 3.11.

3.5.3 The licenses granted pursuant to Section 3.5.1 and Section 3.5.2 may be sublicensed by the licensee Party pursuant to the terms of those applicable licenses, *provided* that (a) the sublicensing Party shall be responsible for failure by its Sublicensees to comply with the relevant terms and conditions of this Agreement applicable to such licenses and (b) [\*\*\*] without BioNTech's prior consent (such consent not to be unreasonably withheld). For the avoidance of doubt, Section 3.7 shall not apply to the sublicensing of those rights licensed under this Section 3.5.

3.6 Trademark Licenses. Trademark Licenses are set forth in Section 11.9.5.

3.7 Sublicensees. Either Party shall have the right to grant sublicenses and, as applicable, sub-sublicenses under and subject to the rights granted to it under Sections 3.1 to 3.4 and 11.9.5 to (a) its Affiliates; (b) permitted Third Party subcontractors which such Party uses to undertake services for, or to perform its obligations under this Agreement; (c) Sublicensees in respect of Manufacturing, provided that, other than where a sublicense is required by a Governmental Authority or pursuant to a Third Party Funder agreement, the sublicensing Party shall (i) discuss the proposed use of a Third Party with the other Party, and take into account any reasonable views, objections or comments with respect to the proposed Third Party; (ii) impose industry standard obligations of confidentiality and non-use on the Third Party with respect to the other Party's Confidential Information, and limit the disclosure of that other Party's Confidential Information so far as is reasonably necessary; and (iii) not, where Pfizer is the sublicensing Party, [\*\*\*] without BioNTech's prior consent (such consent not to be unreasonably withheld); and (d) distributors of the Product in the Territory; and (e) in the case of BioNTech, and subject to the restrictions

in Sections 3.1, 3.2, and 3.4 and the terms of Section 12 and excluding any rights under Section 11.9.5, Fosun and any of Fosun's Affiliates pursuant to the Fosun Agreement for Commercialization in the Field outside the Territory. In respect of any and all such sublicenses (or sub-sublicenses):

3.7.1 the sublicensing Party shall be responsible for failure by its Sublicensees to comply with the terms and conditions of this Agreement;

3.7.2 the rights sublicensed under the sublicense may not be further sublicensed by the Sublicensee;

3.7.3 the sublicensing Party shall notify the other Party in writing of any sublicenses granted to Third Parties (other than Fosun);

3.7.4 in the event of a sublicense in respect of the Commercialization of Product, shall provide a copy of the relevant sublicense agreement to the other Party upon request which may be redacted to delete provisions not applicable to the calculation of Gross Profits; *provided, however*, that the Sublicensing Party shall not be required to provide copies of any sublicense agreement between such Sublicensing Party and its Affiliates;

3.7.5 unless otherwise agreed between the Parties on a case-by-case basis, all sublicenses shall automatically terminate (and the sublicensing Party shall ensure that all sublicenses automatically terminate) upon termination (for whatever reason) or expiry of a license granted hereunder, but only to the extent necessary to terminate the sublicense in so far as it corresponds to any terminated or expired licenses granted in this Agreement; and

3.7.6 in respect of Trademarks, the Party granting the sublicense shall ensure that all goodwill arising from use of the sublicensed Trademarks enures for the benefit of the Party that owns the applicable Trademark.

3.8 BioNTech Current Licenses.

3.8.1 **Maintenance of Current Licenses.** BioNTech will maintain in full effect and will perform all of its obligations in a timely manner under each of the Current Licenses. Absent Pfizer's prior written consent (which may be provided, conditioned or withheld in Pfizer's sole discretion), BioNTech will not terminate, modify or amend any Current License in any manner that would adversely affect any of the rights granted or that may be granted to Pfizer under this Agreement or that would impose any obligations upon Pfizer hereunder (including any increase in Third Party License Payments) that are in addition to those obligations that would exist under this Agreement based on the Current Licenses as they exist on the Effective Date or adversely affect BioNTech's ability to perform its obligations under this Agreement. Further, BioNTech will not take any action or omit to take any action that would cause it to be in breach of any Current License or that would give rise to a right of any Current Licensor to terminate the applicable Current License.

3.8.2 **Communications and Performance.** Notwithstanding anything to the contrary in this Agreement, BioNTech will use Commercially Reasonable Efforts to facilitate any communications between Pfizer and any Current Licensor required for Pfizer to exercise the rights granted to it pursuant to this Section 3 and will use Commercially Reasonable Efforts to cause each applicable Current Licensor to perform all of its obligations under the applicable Current License.

3.8.3 **Breach of Current License by BioNTech.** If BioNTech receives notification of any actual or potential breach or otherwise becomes aware of its breach of any Current License (and if uncured, such breach could give rise to the termination of the applicable Current License), then BioNTech will immediately notify Pfizer of such breach. To the extent that any act or omission on the part of Pfizer is the cause of such breach of a Current License, Pfizer will take all actions and provide BioNTech with all cooperation necessary to cure such breach, in each case as reasonably requested by BioNTech and at Pfizer's sole cost and expense. To the extent that Pfizer is not the cause of such breach of a Current License, BioNTech will have the first opportunity to cure such breach in accordance with a plan to be mutually agreed upon by the Parties in writing, acting reasonably (each, a "Cure Plan"). If (a) BioNTech, at any time, is not using diligent efforts to cure such breach pursuant to the applicable Cure Plan or (b) BioNTech is unable to cure such breach in accordance with the applicable Cure Plan or it becomes reasonably apparent that BioNTech will not be able to cure such breach pursuant to the applicable Cure Plan, then Pfizer may, at its election and in its sole discretion and without prejudice to its other remedies against BioNTech, act reasonably to cure such breach and BioNTech will take all actions and provide Pfizer with all cooperation to cure such breach, in each case as directed by Pfizer. Further, if Pfizer is not the cause of such breach of a Current License, then BioNTech will, at Pfizer's sole election, (i) reimburse Pfizer for all out-of-pocket costs and expenses incurred by or on behalf of Pfizer or any of its Representatives in connection with curing such breach; or (ii) permit Pfizer, under the Agreement, to offset any such costs and expenses incurred by or on behalf of Pfizer or any of Pfizer's Representatives in connection with curing such breach against Pfizer's future payment obligations to BioNTech (or any of its successor or assigns) under this Agreement.

3.8.4 **Termination of any Current License.** In the event that any Current License is terminated by the applicable Current Licensor and this Agreement, as of the effective date of such termination, has not otherwise expired or been terminated, Pfizer, to the extent permitted by such Current License (or if not permitted or addressed in such Current License, to the extent permitted by the applicable Current Licensor), will have the right without prejudice to its other remedies against BioNTech, at Pfizer's election, to convert the sublicenses granted under this Agreement by BioNTech to Pfizer under such Current License to a direct license from the applicable Current Licensor to Pfizer on the terms and conditions contained in such Current License (with Pfizer assuming the applicable obligations of BioNTech thereunder) or such other terms and conditions as may be negotiated by Pfizer and the applicable Current Licensor; *provided* that Pfizer shall negotiate in good faith reasonable terms and conditions, including with respect to royalties or other payments due in connection with the Candidates or Products. In the event Pfizer enters into any such direct license with a Current Licensor pursuant to this Section 3.8.4, BioNTech will, at Pfizer's sole election and without prejudice to its other remedies hereunder:

3.8.4.1 in respect of royalties and other payments payable by Pfizer under such direct license to the Current Licensor, to the extent such royalties and payments are due in connection with the Candidates or Products hereunder, reimburse to Pfizer the difference between (a) the amount that is payable under any direct license with Pfizer and (b) the amount that would have to be reimbursed by Pfizer to BioNTech in accordance with Section 4.10.1 with respect to the Current License if the Current License had not been terminated; or

3.8.4.2 permit Pfizer to offset any such reimbursement amounts (to the extent not reimbursed pursuant to clause (a) above) against Pfizer's future payment obligations to BioNTech (or any of its successor or assigns) under this Agreement (including BioNTech's share of Gross Profits) until Pfizer has fully recovered all such reimbursement amounts.

3.8.5 **Consents and Waivers.** BioNTech represents, warrants and covenants to Pfizer that, to the extent any terms and conditions of this Agreement do not (or will not at any time during the Term) conform to any requirements relating to the grant of sublicenses under any Current License, it has obtained the irrevocable consent (or, if applicable, the waiver of any resultant conflict) from the applicable Current Licensor that is necessary to permit the activities contemplated under this Agreement, including such that BioNTech may grant the applicable sublicenses granted or to be granted hereunder and perform all of its obligations hereunder and Pfizer may exercise all of its rights and perform all of its obligations hereunder, in each case, without breaching the applicable Current License. In the event that any provision in any Current License which conflicts with this Agreement or adversely impacts the activities contemplated under this Agreement comes to the attention of either BioNTech or Pfizer or which otherwise, at any time during the Term, would cause the representation, warranty and covenant set forth in the preceding sentence to be untrue, BioNTech, in consultation with Pfizer, will obtain any and all additional required consents or waivers from the applicable Current Licensor(s) which may be necessary to align the conflicting provision(s) of the applicable Current License with this Agreement and to permit the activities contemplated by this Agreement.

3.8.6 **Exceptions to the Fosun Agreements.** If BioNTech (as opposed to Pfizer) has breached the Fosun Agreement [\*\*\*]. In addition, in respect of the Fosun Agreement (i) [\*\*\*]; and (ii) [\*\*\*].

3.8.7 **Reduction in Royalties.** [\*\*\*]

3.9 **Third Party Agreements.** Subject to Section 4.10, each Party will be solely responsible for all obligations (including royalty and payment obligations) that relate to Candidates, Products, BioNTech Technology or Pfizer Technology under its or its Affiliates' own agreements with Third Parties that are in effect on or prior to the Effective Date, including the Current Licenses for which BioNTech has sole responsibility.

3.10 **No Implied Rights.** Except as expressly provided in this Agreement, neither Party will be deemed to have granted the other Party (by implication, estoppel or otherwise) any right, title, license or other interest in or with respect to any Patent Rights, Know-How, Trademarks or other Intellectual Property Rights or information Controlled by such Party.

3.11 **Exclusivity.**

3.11.1 **Mutual Exclusivity.** Except if otherwise permitted by the unanimous consent of the JSC, during the Term, neither Party shall, and shall procure that its Affiliates shall not, itself or with or on behalf of a Third Party, Develop, have Developed, Manufacture, have Manufactured, Commercialize, have Commercialized or otherwise Exploit or have Exploited any [\*\*\*] in the Field within the Territory, except that each Party may continue any agreement existing as of the Effective Date with a Third Party for non-clinical research within the Field with academic institutions and

consortia. For avoidance of doubt, the foregoing exclusivity obligation shall not apply to (a) [\*\*\*]; (b) [\*\*\*]; (c) [\*\*\*]; or (d) [\*\*\*].

3.11.2 **Exclusivity of the Licenses.** Without prejudice to the licenses granted by BioNTech pursuant to this Section 3, BioNTech shall not, and shall procure that its Affiliates shall not, grant any license, permission, waiver, covenant not to sue, or other right to use or Exploit any of the BioNTech Technology within the Field and within the Territory that would conflict with or erode any of Pfizer's rights hereunder.

3.11.3 **Exclusivity in the Product.** Except pursuant to this Agreement, neither Party shall, and shall procure that its respective Affiliates shall not, itself or with or on behalf of a Third Party, Develop, have Developed, Manufacture, have Manufactured, Commercialize, have Commercialized or otherwise Exploit (a) any Candidate Controlled by BioNTech as of the Effective Date within the Field; or (b) any Candidate that, as a consequence of the Development under this Agreement, becomes Controlled by BioNTech after the Effective Date, for any field; or (c) any Product for any field or application; in each case (a), (b) and (c) other than for non-clinical research purposes, or within the Field pursuant to the Fosun Agreement.

3.12 **Adjustments to Commercialization Territories.**

3.12.1 **BioNTech Territory Exit Option:** BioNTech shall have the option to opt-out of Commercializing the Product in any country of the BioNTech Commercialization Territory (excluding any Additional Commitment Country which has become part of the BioNTech Commercialization Territory pursuant to Section 3.12.2), whereupon Pfizer shall take over Commercialization of the Product in any such country (the "BioNTech Territory Exit Option"). BioNTech may exercise the BioNTech Territory Exit Option, on a country by country basis, upon no less than [\*\*\*] prior written notice to Pfizer, *provided, however*, that the Parties agree upon a transition plan within the first [\*\*\*] of such notice, which plan may require BioNTech to conduct distribution, Commercialization, promotional and supply activities beyond the expiration of the [\*\*\*] period, however. In the event of any such option exercise, (a) the Parties will work together to transition to Pfizer the responsibilities for distribution, Commercialization and promotion of the Product and (b) as of the option exercise effective date, the Pfizer Commercialization Territory under this Agreement shall be extended accordingly and (c) prior to Pfizer fully transitioning as the exclusive distributor and licensee in the applicable country, where the Product has already been launched, BioNTech shall ensure that the Product continues to be supplied in such country.

3.12.2 **Pfizer Country Exit Option:** On a country by country basis in relation to [\*\*\*] that obliges Commercialization of the Product in such country; (each such country under (a) and (b) being an "Additional Commitment Country"), BioNTech shall request in writing from Pfizer a decision as to whether Pfizer wishes to Commercialize in such Additional Commitment Country in accordance with the Commercialization requirements [\*\*\*] of its receipt of such notice or [\*\*\*] prior to the date of the planned initiation of Commercialization following full Market Authorization Approval (for clarity, not Emergency Use Authorization or any conditional Market Authorization Approval) in such Additional Commitment Country [\*\*\*]. If Pfizer notifies BioNTech that it wishes to Commercialize the Product in such Additional Commitment Country, then Pfizer shall Commercialize the Product in such Additional Commitment [\*\*\*].

3.13 Expansion of the Territory.

3.13.1 **Right of First Negotiation to Expand into Fosun Territory.** If the Fosun Agreement expires or is otherwise terminated for any reason, BioNTech shall promptly (and in any event within [\*\*\*] of the earlier of expiration or termination of the Fosun Agreement or BioNTech receiving notice of expiration or termination of the Fosun Agreement) notify Pfizer in writing and Pfizer shall [\*\*\*] such rights to be exercised by Pfizer within [\*\*\*] of Pfizer's receipt of BioNTech's notice provided in accordance with this Section 3.13.1.

3.13.2 **Election; Negotiation.** If Pfizer elects to negotiate for such rights in the Fosun Territory, the Parties shall in good faith and acting reasonably exclusively negotiate for a period of no less than [\*\*\*] after Pfizer's notice of its intent to negotiate for those rights and BioNTech shall disclose to Pfizer if, at any time during such period, BioNTech is concurrently negotiating with one or more permitted Third Parties for such rights; provided, however, that BioNTech shall not be required to disclose the identity of such Third Party.

3.13.3 **BioNTech Negotiation [\*\*\*].** Prior to exhaustion of Pfizer's exclusive negotiation right, BioNTech shall not engage in negotiations for, or license, or grant any option to the Product for the Fosun Territory [\*\*\*]. The terms and discussions around, as well as the existence of, any negotiation activities between Pfizer and BioNTech shall be confidential information of each Party which neither shall disclose to a Third Party.

3.13.4 **Interim Assistance in Fosun Territory.** During the period from termination of the Fosun Agreement until BioNTech concludes an agreement for the commercialization of the Product in the Fosun Territory with a Third Party (and provided that neither BioNTech nor Fosun are able and willing to distribute the Product in the Fosun Territory during such time period), Pfizer shall be free but not obligated to distribute Product in the Fosun Territory (pursuant to the Regulatory Approval held for the Product by or on behalf of BioNTech) if it believes it is necessary or desirable at such time, for public health reasons, for the Product to be made available in the Fosun Territory (which sales shall be included in the Gross Profits calculation). For clarity, Pfizer shall have no obligation to distribute or Commercialize the Product in the Fosun Territory.

4. PAYMENTS, FUNDING, FINANCIAL MATTERS.

4.1 **Upfront Payment.** The Parties acknowledge and agree that Pfizer made a one-time, non-refundable (without limiting Pfizer's right to claim for damages under this Agreement) payment of Seventy-Two Million US Dollars (US \$72,000,000) to BioNTech on or about 21 May 2020 ("Upfront Payment"), which payment has been and shall be dedicated to activities to be performed under the Research and Development Plan.

4.2 **Equity Investment.** The Parties acknowledge and agree that Pfizer and BioNTech entered into an "Investment Agreement" on 9 April 2020 in conjunction with this Agreement pursuant to which Pfizer subscribed for shares in BioNTech in consideration for an investment amount of One Hundred and Thirteen Million US Dollars (US \$113,000,000) based on a price per share of US \$47.53, subject to the conditions as prescribed in such Investment Agreement ("Equity Investment").

4.3 **Regulatory Milestone Payment.** Within the later of (a) [\*\*\*] of the date upon which either BioNTech or Pfizer first obtains all Regulatory Approvals required for the Commercialization of the



Product in a Major Market Country in the Territory or (b) following achievement of the milestone under (a) above [\*\*\*] after the Amendment Signing Date, Pfizer shall pay BioNTech a one-time, non-refundable (without limiting Pfizer's right to claim for damages under this Agreement) milestone payment of [\*\*\*] US Dollars (US \$[\*\*\*]) ("Regulatory Approval Milestone").

4.4 Sharing of Development Costs.

4.4.1 **Shared Development Costs.** Except as otherwise provided herein, each Party shall bear fifty percent (50%) of all Shared Development Costs.

4.4.2 **BioNTech Deferred Development Costs.** The Parties acknowledge and agree that from the Effective Date until December 31, 2020 (the "Deferred Payment Period"), BioNTech's share of the Shared Development Costs incurred in accordance with the binding parts of the Development Budget, Research and Development Plan and the Manufacturing Plan, and this Agreement were initially funded by way of an interest free repayable loan from Pfizer ("BioNTech Deferred Development Costs"). BioNTech shall make a payment to reimburse Pfizer the BioNTech Deferred Development Costs incurred during the Deferred Payment Period within [\*\*\*] of receipt of Pfizer's invoice for the same. The Parties shall exchange reasonable documentation of all relevant Shared Development Costs in accordance with Section 4.4.4 applicable to such invoice. Pfizer may offset any BioNTech Deferred Development Costs (to the extent not reimbursed to Pfizer), against Pfizer's future payment obligations to BioNTech (or any of its successors or assigns) under this Agreement. Following the end of the Deferred Payment Period, BioNTech shall thereafter itself fund its share of the Shared Development Costs in accordance with Section 4.4.4.

4.4.3 **Budgeting of Shared Development Costs.** The Parties shall agree on, at least once per Calendar Year, and regularly update (if required), the Development Budget through the JSC. As soon as either Party determines that it is likely to overspend on the binding part of the Development Budget that is allocated to that Party by more than [\*\*\*], it shall inform the JSC accordingly, and shall only be entitled to incur such overrun costs as Shared Development Costs pursuant to Section 4.4.1 and 4.4.2 upon the JSC's mutual consent.

4.4.4 **Reporting and Reconciliation.** After the end of the Deferred Payment Period, all Shared Development Costs incurred in accordance with the binding parts of the Development Budget shall initially be borne by the Party incurring such costs and shall thereafter be subject to reimbursement in accordance with this Section 4.4.4. Each Party shall report to the other Party, within [\*\*\*] after the end of each Pfizer US Quarter, the Shared Development Costs incurred by such Party during such Pfizer Quarter. Such report shall specify in reasonable detail all amounts included in such Shared Development Costs during such Pfizer Quarter (broken down by activity), and out-of-pocket costs shall be allocated to the extent possible to a specific activity in the applicable binding part of the Research and Development Plan. Each such report shall enable the receiving Party to compare the reported Shared Development Costs against the applicable binding part of the Development Budget previously approved by the JSC, on both a quarterly basis and a cumulative basis for each activity. The Parties shall seek to resolve any questions related to such accounting statements within [\*\*\*] following receipt by each Party of the other Party's report hereunder. Following such resolution, BioNTech shall prepare a reconciliation report for the Shared Development Costs for such Pfizer Quarter (including as against the binding parts of the Development Budget) and shall either (a) deliver an invoice to Pfizer for any amounts due to BioNTech as a result of reconciliation or (b) notify Pfizer that it should issue an invoice to

BioNTech for any amounts due to Pfizer as a result of reconciliation. Any such invoice from BioNTech to Pfizer shall be payable within [\*\*\*] from receipt by Pfizer. Any such invoice from Pfizer to BioNTech shall be payable within [\*\*\*] from receipt by Pfizer.

4.4.5 **Capex Costs.** Notwithstanding anything else in this Agreement, each Party shall be solely responsible for its own Capex Costs and any capital expenditures required in connection with this Agreement.

4.4.6 **Other Costs.** Except as expressly set forth otherwise in this Agreement), each Party will bear all costs and expenses it incurs in connection with its activities under this Agreement.

4.5 Third Party Funding.

4.5.1 **Third Party Funders.** Pfizer and BioNTech shall, in good faith and acting collaboratively, seek funding from one or more Third Parties for such Third Party to provide financial support to the collaboration between the Parties under this Agreement (each, a "**Third Party Funder**"). For each potential Third Party Funder, the Parties will agree on (a) the Party to lead the communications and discussions with such Third Party Funder (the "**Lead Party**") and (b) the activities, costs or expenses for which funding support shall be sought (e.g. funding for Development costs, funding in support of a Party's Capex Costs ("**Capex Funding**") or both). An initial list of potential Third Party Funders and their allocation as between the Parties is set forth in Schedule 4.5. Notwithstanding the foregoing, Pfizer shall be entitled to secure funding from, and shall be the Lead Party in discussions with [\*\*\*], in the event that Pfizer, in its sole discretion [\*\*\*] and BioNTech shall be entitled to secure funding from, and shall be the Lead Party in discussions with [\*\*\*], in the event that BioNTech, in its sole discretion, chooses to seek funding from [\*\*\*].

4.5.2 **Discussions with Funders.** The Lead Party will lead any discussions with such Third Parties in any country, provided that the Lead Party will provide regular updates to the JSC and keep the JSC reasonably informed of the status and any developments in such discussions, and shall, at the other Party's reasonable request, update the other Party on any such discussions. The Lead Party shall conduct any such discussions and draft and file any applications for any Third Party Funding in good faith and acting reasonably with respect to its requests for such funding. Where legally possible and unless otherwise agreed between the Parties, each application for any Third Party funding shall be made in both Parties' name unless the Parties have agreed in advance pursuant to Section 4.5.1 that such application shall be in respect of one Party's Capex Funding alone, in which case such application may be made in that Party's own name alone. The Lead Party shall not enter into a written agreement with any Third Party Funder without prior written consent of the other Party (such consent not to be unreasonably withheld, conditioned or delayed) unless the Parties have agreed in advance pursuant to Section 4.5.1 that such agreement shall be in respect of that Lead Party's Capex Funding alone, in which case the Lead Party can conclude such Third Party Funder agreement without consent from the other Party. Notwithstanding the foregoing, (a) Pfizer shall be entitled to seek any funding from [\*\*\*] without requiring BioNTech's consent; (b) BioNTech shall be entitled to seek any funding from [\*\*\*] without requiring Pfizer's consent; and (c) neither Party shall agree as a party to any agreement with any Third Party Funder or in consequence of such agreement to commit any particular allocation of supply of Product for any country or government without the prior consent of the JCC pursuant to Section 7.4.2.5. Pfizer and BioNTech acknowledge and agree that there is no guaranty that any Lead Party will be successful

in securing any funding from any Third Party Funder or that any specific amount of funding will be obtained.

4.5.3 **Allocation of Funds and Balancing Payment.** To the extent possible, any Third Party funding to the extent it relates to activities in relation to which the Parties have agreed to treat the associated Development costs as Shared Development Cost shall be shared equally between the Parties. If such sharing is not possible, a balancing adjustment shall be made in favor of the other Party to the Shared Development Costs to reflect [\*\*\*] percent of such funding that that Party receives from the Third Party Funder provided that doing so does not breach any applicable Laws or the terms of such funding. Each Party shall promptly report to the other Party in writing if and when it receives any payments from any Third Party Funder funding that relates to activities, costs or expenses that are Shared Development Costs.

4.5.4 **Not Applicable to Loans.** For the avoidance of doubt, this Section 4.5 shall not apply to any traditional loans provided by any Third Party to a Party provided that (a) such loans are repayable by the borrower Party and not, directly or indirectly, by the other Party; (b) this Agreement, any other agreement ancillary to this Agreement, the BioNTech Technology, Product Technology and Product are not provided as security for, or otherwise encumbered by way of, such loan (excluding, for clarity, any tangible assets). Each Party shall be entitled to seek any such loans from any Third Party without any obligations to the other Party.

4.5.5 **Documentation.** To the extent the conditions agreed by the Lead Party with any Third Party Funder require the disclosure or delivery of specific documentation relating to Shared Development Costs (e.g. invoices from Third Parties or calculation of internal costs) in order to obtain funding or reimbursement for such Shared Development Costs from such Third Party Funder, upon the Lead Party's request, the other Party will use Commercially Reasonable Efforts to provide such documentation to the Lead Party within [\*\*\*] from the request, *provided* that the Lead Party shall pay all reasonably necessary costs and expenses of the other Party which are directly incurred in connection with provision of any documentation to the extent it is beyond the documentation or the efforts required pursuant to Section 4.4.4, *provided, further*, [\*\*\*].

4.6 **Accounting Principles.** Each Party shall determine Shared Development Costs using its standard accounting procedures, consistently applied and in accordance with GAAP or IFRS, as applicable (provided that the application of such procedures results, on balance, in outcomes that are fair and equitable to both Parties taking into consideration the interests of both Parties as reflected in this Agreement). All personnel costs of either Party or its Affiliates are excluded from Shared Development Costs.

4.7 **Commercialization Costs.** Each Party will be solely responsible for the costs it incurs in Commercializing the Product within its respective Commercialization Territory and such costs shall not be included in the calculation of Gross Profits as described in Section 4.9 below.

4.8 **Commercialization Sales Milestones.** Pfizer shall pay BioNTech the following one off Commercialization Sales Milestone Payments within [\*\*\*] of the end of the Pfizer Quarter in which the annual Net Sales of the Product within the Territory pursuant to this Agreement in a Pfizer Year first achieve the relevant level described below. For the avoidance of doubt, the Parties recognize that more than one Commercialization Sales Milestone Payment may become due in any particular Pfizer Quarter or Pfizer Year; however, each of the Commercial Sales Milestones Payments set forth below shall be payable one

time only, regardless of the number of Pfizer Years in which the applicable Annual Net Sales Level is achieved.

Milestone	Annual Net Sales Level in the Territory (US\$)	Amount to be Paid to BioNTech (US\$) (each a "Commercialization Sales Milestone Payment")
1	\$[***]	\$[***]
2	\$[***]	\$[***]
3	\$[***]	\$[***]
4	\$[***]	\$[***]
5	\$[***]	\$[***]
6	\$[***]	\$[***]

4.9 Gross Profit Sharing.

4.9.1 **Sharing of Gross Profits.** Subject to Section 4.4.2, BioNTech and Pfizer will share the Gross Profits generated through the Commercialization of the Product in the Territory pursuant to this Agreement on a fifty-fifty (50:50) basis calculated on a Pfizer Quarter basis. In reflecting that principle, it is agreed that all Product Shipping and Storage Costs incurred for Products, as well as Agreed Product Component costs incurred in acquiring or Manufacturing Agreed Product Components supplied or provided to customers in connection with Commercialization of the Product (if applicable) shall be shared on a fifty (50:50) basis.

4.9.2 **Calculation of Net Sales.** In calculating Net Sales for the purposes of this Section 4, [\*\*\*].

4.9.3 **Quarterly Reporting of Net Sales and Payments.** Within [\*\*\*] after the end of each US Pfizer Quarter, each Party (a "Reporting Party") shall deliver to the other Party (a "Notified Party") a report setting forth, for the most recent Pfizer Quarter, the following information, on a country-by-country and Territory-wide basis: [\*\*\*].

4.9.4 **Manufacturing Variances and True-Up of Transfer Pricing.** Each Party shall, [\*\*\*].

4.9.5 **Quarterly Consolidated Report.** Within the later of (i) [\*\*\*] after exchange of all the reports and amounts pursuant to Section 4.9.3 or (ii) [\*\*\*] of the end of the applicable US Pfizer Quarter, Pfizer shall prepare and provide to BioNTech a consolidated report, with respect to the applicable Pfizer Quarter, setting forth:

[\*\*\*]

4.9.6 **Payment of Gross Profit Share.** To the extent Pfizer, with respect to any Pfizer Quarter, is to make a payment to BioNTech for its Gross Profit portion as set forth in the consolidated financial report prepared pursuant to Section 4.9.5, such payment shall be made by Pfizer to BioNTech as provided in Section 4.13. To the extent BioNTech is to make a payment to Pfizer for its Gross Profit portion as set forth in the consolidated financial report prepared pursuant to Section 4.9.5, such payment shall be made by BioNTech to Pfizer as provided in Section 4.13. Such payments under this Section 4.9.6 for any Pfizer Quarter shall be made within [\*\*\*] after

Pfizer, pursuant to Section 4.9.5, delivers to BioNTech the consolidated financial report for such Pfizer Quarter.

4.10 Third Party License Payments.

4.10.1 **Third Party Royalties.**

4.10.1.1 [\*\*\*].

4.10.1.2 Following the consolidated financial report for each Pfizer Quarter prepared by Pfizer and delivered to BioNTech pursuant to Section 4.9.5 above

[\*\*\*].

4.10.2 **Other Third Party License Payments.** Subject to Section 3.8.4, for Third Party License Payments due under Third Party Agreements, the following rules, as applicable, shall apply:

4.10.2.1 [\*\*\*];

4.10.2.2 [\*\*\*]; and

4.10.2.3 [\*\*\*].

4.10.2.4 [\*\*\*].

4.10.3 **Exclusion of Certain Payments.** [\*\*\*].

4.11 Taxes.

4.11.1 **Withholding Taxes.** The Parties agree to use reasonable efforts to cooperate with one another and use commercially reasonable efforts to avoid or reduce, to the extent permitted by applicable Law, tax withholding or similar obligations in respect of royalties, milestone payments, and other payments made by the paying Party to the receiving Party under this Agreement ("Withholding Taxes"). If Withholding Taxes are imposed on any payment under this Agreement, the liability for such Withholding Taxes shall be the sole responsibility of the receiving Party, and the paying Party shall (a) deduct or withhold such Withholding Taxes from the payment made to the receiving Party, (b) timely pay such Withholding Taxes to the proper taxing authority, and (c) send proof of payment to the receiving Party within [\*\*\*] following such payment. Each Party shall comply with (or provide the other Party with) any certification, identification or other reporting requirements that may be reasonably necessary in order for the paying Party to not withhold Withholding Taxes or to withhold Withholding Taxes at a reduced rate under an applicable bilateral income tax treaty. Each Party shall provide the other with commercially reasonable assistance to enable the recovery, as permitted by applicable Law, of Withholding Taxes or similar obligations resulting from payments made under this Agreement, such recovery to be for the benefit of the Party bearing the cost of such Withholding Taxes under this Section 4.11.1 (Taxes and Withholding). Notwithstanding the foregoing, if as a result of any assignment or sublicense by the paying Party, any change in the paying Party's tax residency, any change in the entity that originates the payment, or any failure on the part of the paying Party to comply with applicable Law with respect to Withholding Taxes (including filing or record retention requirements), Withholding Taxes are imposed that would not otherwise have been imposed ("Incremental Withholding Taxes"), then the paying Party shall be solely responsible for the amount of such Incremental

Withholding Taxes and shall increase the amounts payable to the receiving Party so that the receiving Party receives a sum equal to the sum which it would have received had there been no such imposition of Incremental Withholding Taxes.

4.11.2 **Value Added Tax.** All payments between the Parties under this Agreement are exclusive of applicable statutory value added tax or similar taxes ("VAT"), if any, which shall be listed separately on each invoice. If and to the extent any VAT will become payable due to any supplies or services rendered under this Agreement and if and to the extent such VAT is to be paid by the Party providing the supply or service to the competent tax authorities, the receiving Party shall pay an amount equal to such VAT to the providing Party upon receipt of a valid invoice allowing for the recovery of such VAT.

4.11.3 **Taxes of Co-Entrepreneurship.** If and to the extent the Parties are considered to be partners of a co-entrepreneurship for tax purposes because of their collaboration governed by this Agreement and taxes allocated to the co-entrepreneurship (e.g. German trade tax, but excluding any taxes imposed on or with respect to net income other than German trade tax) are owed by either of the Parties, such tax (as well as any related cost of reporting and preparation of relevant tax returns) shall be [\*\*\*]. In deviation of the foregoing, if and to the extent such tax (including related cost) is increased or reduced by circumstances that are exclusively attributable to one of the Parties (Causing Party) (in particular due to so-called special trade tax effects), any increased tax (including related costs) shall exclusively be allocated to and be borne by the Causing Party and any saved tax shall be credited to the Causing Party. The Parties shall cooperate in good faith to agree on a mutual tax filing position for their collaboration governed by this Agreement in due course after the Effective Date. Each Party shall have the right to assign any or all of its contractual position under this Agreement to a wholly owned corporate subsidiary ("Blocker Entity") provided that the relevant Party (i) remains secondarily liable for any liabilities of the Blocker Entity under this Agreement in respect of the contractual position assigned and (ii) shall indemnify the other Party from any taxes triggered by the transfer of such contractual position to the Blocker Entity.

4.11.4 **Other.** Except as otherwise set forth in this Section 4.11, each Party shall be solely responsible for the payment of all Taxes imposed on such Party's income arising directly or indirectly from the activities of the Parties under this Agreement and each Party shall be solely responsible for taxes based on, imposed on or calculated by reference to any employees employed by that Party.

4.11.5 **Branded Prescription Drug Fee.** Under the provisions of the U.S. Patient Protection and Affordable Care Act, Pub. L. No. 111-14 (as amended), Pfizer is subject to the annual fee on prescription drug manufacturers, hereinafter referred to as the "Branded Prescription Drug Fee". [\*\*\*]

4.12 **Currency, Source of Payments.** All amounts payable and calculations under this Agreement will be in United States dollars [\*\*\*]. As applicable, all costs and expenses will be translated into United States dollars at the exchange rate used by the relevant Party for public financial accounting purposes. If, due to restrictions or prohibitions imposed by national or international authority, a given payment cannot be made as provided under this Section 4.12, the Parties will consult with a view to finding a prompt and acceptable solution. If the Parties are unable to identify a mutually acceptable solution regarding such

payment, then the Party owing the relevant payment may elect, in its sole discretion, to deliver such payment in the relevant jurisdiction and in the local currency of the relevant jurisdiction.

4.13 **Method of Payment.** Except as permitted pursuant to Section 4.12, each payment hereunder will be made by electronic transfer in immediately available funds via either a bank wire transfer, an ACH (automated clearing house) mechanism, or any other means of electronic funds transfer, at the paying Party's election, to such bank account as the receiving Party will designate in writing to the other Party within [\*\*\*] of the Signing Date, and thereafter at least [\*\*\*] before the payment is due. All invoice or billing related questions in relation to Pfizer should be referred to Pfizer's Accounting Department at [\*\*\*] or go to the Accounts Payable Invoice Portal at [\*\*\*]. Unless otherwise specified herein, each invoice is payable within [\*\*\*] of receipt of the relevant invoice.

4.14 **Record Keeping and Audits.**

4.14.1 **Record Keeping.** Each Party shall keep and maintain and shall cause its Affiliates to keep and maintain books and accounts of record in sufficient detail to enable the determination of [\*\*\*] and any other financial provisions of or applicable to this Agreement. Such records will be maintained for up to [\*\*\*] after the end of the year to which they pertain or such longer period of time required under a Current License, insofar as applicable to the rights sublicenses pursuant to such Current License.

4.14.2 **Right to Audit.** Upon [\*\*\*] prior notice from a Party (the "Auditing Party"), the other Party (the "Audited Party") will permit an independent certified public accounting firm of nationally recognized standing selected by the Auditing Party and reasonably acceptable to the Audited Party, to examine [\*\*\*] the relevant books and records of the Audited Party and its Affiliates (and where possible, its subcontractors) as may be reasonably necessary to verify the amounts reported by the Audited Party in accordance with Sections 4.4 to 4.10. An examination by the Auditing Party under this Section 4.14 will occur not more than [\*\*\*] and will be limited to the pertinent books and records for any Calendar Year ending not more than [\*\*\*] before the date of the request. The accounting firm will be provided access to such books and records at the Audited Party's or its Affiliates' facility(ies) where such books and records are normally kept and such examination will be conducted during the Audited Party's or its Affiliates' normal business hours. The Audited Party may require the accounting firm to sign a reasonably acceptable non-disclosure agreement before providing the accounting firm with access to the Audited Party's or its Affiliates' facilities or records. Upon completion of the audit, the accounting firm will provide both Pfizer and BioNTech the same written report disclosing any discrepancies in the reports submitted by the Audited Party, and, in each case, the specific details concerning any discrepancies. No other information will be provided to the Auditing Party.

4.14.3 **Underpayments/Overpayments.** If such accounting firm concludes that there are errors in how Shared Development Costs, Third Party funding, BioNTech Deferred Development Costs, Net Sales, Gross Profits, Transfer Prices, Third Party License Payments, Expedited Milestone Refunds or Proportional Adjustments have been calculated, allocated, paid or reclaimed, then adjustments shall be made in accordance with the accounting firm's recommendations in a reconciliation of such amounts and any overpayment or underpayment by the Audited Party shall be rectified either by a refund to, or payment by, the Audited Party from or to the Auditing Party within [\*\*\*] of the date the Audited Party receives such accountant's written report. Further, if the

amount of any overpayment or overallocation to the Audited Party exceeds more than [\*\*\*] of the amount that was properly payable due or allocated to the Audited Party, then the Audited Party will reimburse the Auditing Party for the Auditing Party's out-of-pocket costs in connection with the audit.

4.14.4 **Confidentiality.** Notwithstanding any provision of this Agreement to the contrary, all reports and financial information of the Audited Party or its Affiliates which are provided to or subject to review by the Auditing Party will be deemed to be Confidential Information of the Audited Party and subject to the provisions of Section 12.1.

4.15 **No Guaranty of Success.**

4.15.1 Pfizer and BioNTech acknowledge and agree that any milestone payments payable hereunder: (a) have been included in this Agreement on the basis that they are only payable or otherwise relevant if a certain Product is successfully Developed or Commercialized in accordance with the applicable milestone or event, as applicable; (b) are solely intended to allocate amounts that may be achieved upon successful Development or Commercialization of such Product as applicable, between Pfizer and BioNTech; (c) are not intended to be used as a measure of damages if this Agreement is terminated for any reason; and (d) will only be triggered, and will only be relevant as provided, in accordance with the terms and conditions of such provisions.

4.15.2 Pfizer and BioNTech further acknowledge and agree that nothing in this Agreement, or in any document or presentation provided by Pfizer to BioNTech prior to the Effective Date will be construed as representing any estimate or projection of (a) the successful Development or Commercialization of any Product under this Agreement, (b) the number of Products that will or may be successfully Developed or Commercialized under this Agreement, (c) the number of countries in the Territory in which the Product will receive Regulatory Approval, (d) anticipated sales or the actual value of any Products that may be successfully Developed or Commercialized under this Agreement or (e) the damages, if any, that may be payable if this Agreement is terminated for any reason.

4.15.3 Neither Party makes any representation, warranty or covenant, either express or implied, to the other Party that (a) it will successfully Develop, Manufacture, Commercialize or continue to Develop, Manufacture or Commercialize any Product in any country, (b) it will secure Regulatory Approval for the Product in any country in the Territory, (c) if Commercialized, that any Product will achieve any particular sales level, whether in any individual country or cumulatively throughout the Territory or (d) it will devote, or cause to be devoted, any level of diligence or resources to Developing, Manufacturing or Commercializing any Product in any country, or in the Territory.

4.16 **No Other Compensation.** Other than as explicitly set forth in this Agreement, neither Party will be obligated to pay any additional fees, milestone payments, royalties or other payments of any kind to the other Party under this Agreement or any Related Agreement.

4.17 **Late Payment.** Any payments or portions thereof due hereunder which are not paid when due will bear interest at the Contract Interest Rate, compounded annually, calculated on the number of days



such payment is delinquent. This Section 4.17 will in no way limit any other remedies available to either Party.

4.18 **No Double Counting.** There will be no double counting of any payments, costs or revenue item in the calculation of any amounts under this Agreement or any Related Agreement, and to the extent a cost or expense has been included in one category or sub-category, it will not be included in another; similarly, to the extent any revenue has been taken into account in one category or sub-category it will not be taken into account in another. For clarity, [\*\*\*].

## 5. **RESEARCH AND DEVELOPMENT PLAN**

5.1 **Scope of Development and Updating of Plans** Pfizer and BioNTech will collaborate during the Term to conduct research to identify, Develop and evaluate Candidates and Products within the Field in accordance with the binding parts of the Research and Development Plan, the Development Budget, the Manufacturing Plan, and the terms and conditions set forth in this Section 5. The Research and Development Plan may be modified by agreement and approval of the JSC pursuant to Section 6, provided that the JSC shall have no right or authority to (a) modify the Research and Development Plan in a way not permitted under Section 6.3; or (b) modify the Research and Development Plan so as to amend the contractual provisions of this Agreement. The Parties acknowledge and agree that the initial [\*\*\*] of each of the Research and Development Plan, the Manufacturing Plan and the Development Budget have been agreed between the Parties, the first [\*\*\*] of each binding upon the Parties and the second [\*\*\*] indicative but non-binding. At least [\*\*\*] prior to the expiration of such initial [\*\*\*] binding period, the JSC shall decide and mutually agree on the following [\*\*\*] period of each of the Research and Development Plan and the Development Budget which period, upon agreement, shall be binding upon the Parties subject to Section 6.3.4. At least [\*\*\*] prior to the expiration of the initial [\*\*\*] period following the Effective Date, the JSC shall establish a rolling [\*\*\*] process to decide on and update each of the Research and Development Plan and the Development Budget for subsequent [\*\*\*] periods, each of which shall be updated by the JSC no later than [\*\*\*] prior to the expiration of the then binding [\*\*\*] period.

5.2 **Research and Development Plan.** The Research and Development Plan shall (a) include a broad non-binding overview of the first [\*\*\*] of the planned Development program (specifying in reasonable detail all material Development activities) to generate the preclinical, clinical, CMC, regulatory and other information required for submitting a marketing authorization application for Regulatory Approval for the Candidate or Product and to achieve such Regulatory Approval for the Candidate or Product in one or more selected country(ies) of the Territory; (b) include a more detailed and binding part of the plan for the initial binding period described in Section 5.1, which will be updated in accordance with Section 5.1; and (c) set forth those obligations assigned to each Party with respect to the performance of the Development activities contemplated by such Research and Development Plan.

### 5.3 **Allocation of Responsibilities.**

5.3.1 **General.** Each Party will use Commercially Reasonable Efforts to perform its obligations and activities identified under the binding parts of the Research and Development Plan or as allocated to it by the JSC in a professional manner in accordance with any target dates set forth in Research and Development Plan. Further, each Party will perform its obligations under the binding parts of the Research and Development Plan or as allocated to it by the JSC in compliance with all Laws applicable to its activities under the Research and Development Plan.

5.3.2 **Mutations.** If and to the extent Mutations of the SARS-CoV-2 virus arise [\*\*\*].

5.3.3 **Label Extensions.** If a Party wishes to extend the label or approved indication of any Product Developed hereunder to other indications (including any outside of the Field), it may so notify the JSC. In such event, the JSC shall discuss such label extension in good faith. If the JSC agrees by unanimous consent that Development should be undertaken to support the label extension, the Parties shall include the Development activities required to be undertaken to support such label extension in the Research and Development Plan and, if appropriate, amend the Field accordingly to cover such extension. Any external cost or expense (other than Capex Cost) incurred by either Party (or its Affiliates) solely and specifically in connection with such Development activities [\*\*\*].

5.3.4 **Subcontractors.** Either Party may subcontract its responsibilities under the binding parts of the Research and Development Plan or those allocated to it by the JSC without the other Party's prior written consent; *provided* that such Party shall be responsible for the management of all permitted subcontractors (which will include any Affiliate of a Party). The engagement of any Third Party subcontractor by a Party shall be in writing. The engagement of any subcontractor (whether Affiliate or Third Party) shall not relieve such Party of its obligations under this Agreement or the binding parts of the Research and Development Plan. Any agreement between the Party or its Affiliate and a subcontractor pertaining to the Research and Development Plan activities shall be consistent with the provisions of this Agreement including (a) an obligation to assign all Intellectual Property Rights generated during its performance of such Research and Development Plan to the Party free of any encumbrance such that the Party may fulfil its obligations hereunder and (b) terms and conditions under which such Third Party is obligated to preserve the confidentiality of the Research and Development Program, Research and Development Program Technology and any Confidential Information are at least as restrictive as those described in Section 12.2.1.

5.3.5 **Flexibility of Resources.** Due to practical consequences arising from the outbreak of the virus that is the subject of the Field, it may become difficult or temporarily impossible (including as classified as a force majeure event) for a Party to fulfil all of its responsibilities under the Research and Development Plan or as allocated to it by the JSC. Accordingly, a Party, in its effort to collaborate, may therefore agree to swap, substitute or perform any of the other Party's responsibilities that were allocated to it in the Research and Development Plan or by the JSC. The JSC shall be responsible for coordinating any such changes, which must be finally approved in writing by the Parties where the change results in a Party taking on additional financial cost and responsibility.

5.3.6 **Personnel Matters.** Each Party acknowledges and agrees that it is solely responsible for the compensation of its personnel assigned to the Research and Development Plan, and shall be responsible for withholding all national, state, local or other applicable taxes and similar items for such personnel. Each Party also shall be responsible for all other of its employer related obligations, including providing appropriate insurance coverage and employee benefits, and making all other deductions required by law affecting the gross wages of each of its employees. BioNTech personnel assigned to the Research and Development Plan activities are not nor shall they be deemed to be employees of Pfizer, and Pfizer personnel assigned to the Research and Development Plan activities are not nor shall they be deemed to be employees of BioNTech.

#### 5.4 Materials and Permitted Activities.

5.4.1 **Transfer.** From time to time during the Term, Pfizer shall provide BioNTech with tangible chemical or biological materials (the "**Pfizer Materials**") and BioNTech may provide Pfizer with BioNTech Materials for the other Party's use in accordance with binding parts of the Research and Development Plan. The Party providing its Materials represents and warrants to the other Party that, as of the date of delivery of the Material (a) to the providing Party's knowledge, such Party has the right to provide such Material to the other Party for the uses in accordance with the binding parts of the Research and Development Plan, (b) the Materials comply with any requirements set forth in the Research and Development Plan or otherwise mutually agreed between the Parties (if any) in writing and (c) to the providing Party's knowledge, the use of the Materials authorized herein does not infringe any Third Party rights. Except as expressly set forth in the preceding sentence, the Materials are provided by the providing Party on an "as-is" basis without any representation or warranty of any type, express or implied, including any representation or warranty of merchantability or fitness for a particular purpose, each of which is hereby expressly disclaimed by the receiving Party.

5.4.2 **Title to Materials.** All right, title and interest in and to the providing Party's Materials (including any modifications or progeny thereof) will remain the sole and exclusive property of such Party notwithstanding the transfer to and use by other Party of the same.

5.4.3 **Permitted Activities.** Notwithstanding anything to the contrary in this Agreement save for each Party's exclusivity obligations and restrictions (including those at Sections 3.1 and 3.11), nothing in this Agreement shall be deemed to prevent or restrict in any way the ability of either Party or its Affiliates to conduct any activities in the Territory, which activities would be allowed under any safe harbor, research exemption, government or executive declaration of urgent public health need, or similar right available in law or equity if conducted by a Third Party.

5.4.4 **Return of Proprietary Materials.** Upon termination or expiration of the Term, each Party receiving the other Party's Materials hereunder shall, either destroy or return all unused Materials to the providing Party.

5.5 **Human Materials.** To the extent a Party holds and controls Human Materials that have been collected as part of any Clinical Trial in relation to the Product or a product identical to the Product, upon the other Party's reasonable request for access to such Human Materials for purposes of obtaining Marketing Authorization Approval or other Development purposes for, in the case of Pfizer, the Product or, in the case of BioNTech, a product identical to the Product in the Fosun Territory, the Parties shall negotiate in good faith with respect to an agreement under which the Party holding and controlling such Human Materials could provide such Human Materials.

#### 6. CONTRACT GOVERNANCE

6.1 **Alliance Managers.** Each Party will appoint a (i) single individual to act as the primary point of contact between the Parties to support the activities under the Research and Development Plan and the Manufacturing Plan and (ii) single individual to support matters relating to the Commercialization of, and regulatory and Compliance issues regarding pharmaceutical products (all persons under (i) and (ii) being the "Alliance Managers"). A Party's Alliance Manager for Research and Development and Manufacturing may be the same or different than the Alliance Manager for Commercialization. Each Party

may change its designated Alliance Managers at any time upon written notice to the other Party. The Alliance Managers will:

6.1.1 act as a key point of contact between the Parties to facilitate a successful collaboration hereunder;

6.1.2 use good faith efforts to attend (either in person or by telecommunications) and actively participate in all meetings of the JSC or JCC, as applicable, and as agreed by the Alliance Managers, any meetings of any RCC or any subcommittees established hereunder, but will be non-voting members at such meetings; and

6.1.3 be the first point of referral for all matters of conflict resolution and bring disputes to the attention of the JSC in a timely manner.

6.2 **Program Directors.** Each Party will appoint a program director to oversee all activities conducted under the Research and Development Plan and all activities related to Commercialization, including regulatory and Compliance activities (each, a "Program Director"). A Party may appoint a different Program Director for activities under the Research and Development Plan and activities related to Commercialization. Each Party may change its designated Program Director at any time upon written notice to the other Party. The Program Directors will coordinate the efforts of their respective Party in conducting activities under the Research and Development Plan.

6.3 **Joint Steering Committee.**

6.3.1 **Composition.** As of the Effective Date, the Parties will establish a Joint Steering Committee, comprised of at least [\*\*\*] representatives of BioNTech (including the Alliance Manager for BioNTech) and at least [\*\*\*] representatives of Pfizer (including the Alliance Manager for Pfizer). The JSC representatives for each of Pfizer and BioNTech will be referred to herein as the "Pfizer JSC Members" and the "BioNTech JSC Members" respectively.

Each Party may replace its representatives to the JSC at any time upon notice to the other Party, *provided that* at all times an equal number of representatives from each Party are appointed to the JSC and each Party shall be responsible for ensuring any replaced representative is fully briefed and apprised of the Research and Development Program. Each Party shall procure that its JSC representatives shall make themselves available to attend JSC meetings upon reasonable notice and in accordance with this Agreement. Each Party may invite non-voting employees and consultants to attend meetings of the JSC. All members of the JSC and any invitees of either Party described above will agree in writing to be bound to obligations of confidentiality and assignment of Intellectual Property Rights no less restrictive than those that bind the Parties under this Agreement.

6.3.2 **Committee Chair.** The JSC will be chaired by a BioNTech JSC Member (the "JSC Chair"). BioNTech may replace the JSC Chair at any time upon notice to Pfizer. The responsibilities of the JSC Chair will be:

6.3.2.1 to notify each Party at least [\*\*\*] Business Days in advance of each JSC meeting;

6.3.2.2 to collect and organize agenda items for each JSC meeting; and

6.3.2.3 to prepare the written minutes of each JSC meeting and circulate such minutes for review and approval by the Parties and identify action items to be carried out by the Parties.

6.3.3 **Meetings.** Until the initiation of a Phase I Clinical Trial or Expedited Trial Pathway, the JSC shall meet at least weekly, unless otherwise unanimously agreed. Thereafter, the JSC will meet on at least bi-weekly basis (or less or more frequently as the JSC so determines), either in-person or by audio or video teleconference. Meetings of the JSC will occur at such times and places as mutually agreed by the Parties. Any sub-committees or working groups established in accordance with Section 6.3.4 may meet via audio or video teleconference on a regular basis and in-person at such times and places as the Parties may agree. Meetings of the JSC will only occur if at least two representatives of each Party are present at the meeting or participating by teleconference or videoconference. Each Party will be responsible for, and will not be entitled to any reimbursement from the other Party with respect to, any and all personnel costs or expenses (including travel expenses) which are incurred by or on behalf of its personnel in connection with participation in any JSC meetings or sub-committee or working group meetings, or any other travel required to be undertaken by either Party's personnel in connection with the performance of the Agreement. The JSC Chair will use good faith efforts to (a) prepare and circulate to BioNTech and Pfizer each JSC meeting agenda on or before the day prior to the scheduled date for each JSC meeting and (b) circulate for review and approval by BioNTech and Pfizer written minutes of each JSC meeting within [\*\*\*] Business Days after such meeting. The Parties will agree on the minutes of each meeting promptly, but in no event later than the day before the next meeting of the JSC.

6.3.4 **Responsibilities.** The JSC will coordinate and provide operational and strategic oversight of the Development and Manufacturing activities to be performed under the Research and Development Plan and the Manufacturing Plan by each Party and, within such scope will:

- 6.3.4.1 review and approve all proposals of whether to seek funding from a Third Party Funder, and the terms of any proposed agreement with a Third Party Funder, which (with the exceptions specified in Section 4.5.2 for [\*\*\*] and [\*\*\*]) will require unanimous consent of the JSC;
- 6.3.4.2 monitor and assess the progress of activities under the Research and Development Plan and the Manufacturing Plan;
- 6.3.4.3 decide on the Candidates or Products that will be studied in the Clinical Trials;
- 6.3.4.4 decide on the design of the Clinical Trials, including the protocol governing the Clinical Trials;
- 6.3.4.5 decide on and revise and approve any revisions of the Research and Development Plan and the Development Budget (including in accordance with the mechanism described in Section 5.1 and any adjustments pursuant to Section 5.3.3 and 5.3.5), each of which shall require unanimous consent of the JSC except as expressly set forth in Section 6.4.9;
- 6.3.4.6 discuss any Intellectual Property Rights of a Third Party which may be relevant to Candidates and Products;

- 6.3.4.7 oversee the Development of Manufacturing processes relating to the Candidates or Products, establishment of Manufacturing capacity, and endorse a strategy for Manufacturing Candidates and Product for both the Clinical Trials and planned Commercialization;
- 6.3.4.8 review and discuss all preclinical data and data arising from Clinical Trials investigating the Candidate or Product in the Territory, including adverse events;
- 6.3.4.9 review and discuss all preclinical data and data arising from Clinical Trials under the Fosun Agreement, including adverse events;
- 6.3.4.10 form such other Committees and sub-committees as the JSC may deem appropriate within its area of responsibility, such as a Joint Development Committee and the like, *provided* that the JSC may, with unanimous consent, delegate decision-making authority (that is within the JSC's own authority) relevant to such committee's and sub-committee's area of expertise only;
- 6.3.4.11 address such other matters relating to the activities of the Parties under the Research and Development Plan as either Party may bring before the JSC, including any matters that are expressly for the JSC to decide as provided in this Agreement;
- 6.3.4.12 review and discuss any proposals by either Party relating to permitting a Third Party to perform research involving the Product;
- 6.3.4.13 agree on a Development Budget, as well as any amendments to such budgets, provided that the Development Budget and any amendments to it shall require unanimous consent of the JSC;
- 6.3.4.14 discuss, collaborate on and oversee any applications for Regulatory Approvals in respect of the Candidates and Products, both within and outside the Territory;
- 6.3.4.15 discuss, collaborate on and agree on mutations pursuant to Section 5.3.2 or any label extension pursuant to Section 5.3.3, each of which must be agreed by unanimous consent of the JSC; and
- 6.3.4.16 attempt to resolve any disputes between the Parties with respect to (a) the performance of activities under the Research and Development Plan on an informal basis or (b) matters before the Patent Committee, in each case subject to Section 6.5.

6.3.5 **Limits on JSC Authority.** Notwithstanding any provision of this Section 6 to the contrary, (a) each Party will retain the rights, powers and discretion granted to it under this Agreement and no such rights, powers, or discretion will be delegated to or vested in the JSC unless such delegation or vesting of rights is expressly provided for in this Agreement or the Parties expressly so agree in writing, (b) except with respect to modifications to the Research and Development Plan permitted as set forth in Section 6.3.4.5, the JSC will not have the power to amend this Agreement or otherwise modify or waive compliance with this Agreement in any manner and (c) neither Party will require the other Party to (i) breach any obligation or agreement that such other Party may have with or to a Third Party to the extent such obligation or agreement existed prior to the Effective Date or (ii) perform any activities that are materially different or

greater in scope or more costly than those provided for in the Research and Development Plan then in effect.

6.3.6 **JSC Term.** The JSC may be dissolved upon mutual agreement between the Parties.

6.4 Other Committees.

6.4.1 **Joint Commercialization Committee.** The Parties shall establish a Joint Commercialization Committee (the "JCC") to (a) develop and oversee strategies on a global level for the Commercialization of the Product in the Territory, including reviewing and overseeing Packaging and Labeling and establishing global pricing guidelines, and marketing and patient access programs and strategies for the Product, (b) establish and oversee the implementation of a Global Commercialization Plan and, if the JCC so elects, review and oversee any Annual Regional Commercialization Plans in accordance with Section 9.1.1, and oversee the Commercialization Activities under the collaboration, in each case ((a) and (b)), on a global and, as applicable, on a Commercialization Region basis, and (c) establish and, if appropriate, amend guidance for the appropriate Packaging Configuration that may be used by either Commercialization Party, *provided* that the Parties acknowledge and agree that [\*\*\*]. The JCC shall be composed of [\*\*\*] senior executives of each Party; *provided* that the total number of representatives may be changed upon mutual agreement of the Parties (so long as each Party has an equal number of representatives). One representative of each party on the JCC shall be designated by such Party to be a co-chairperson of the JCC. As part of its responsibilities, but subject to the decision making processes at Section 6.5.4 in the event agreement cannot be reached, the JCC shall also perform the following:

6.4.1.1 Within each annual planning cycle, the JCC shall discuss and seek to agree on the forward-looking Gross Profit budget for the following year to be set forth in the applicable Global Commercialization Plan by reference to the following year's profit and loss forecast [\*\*\*]. Relevant items for such review and discussion shall include: [\*\*\*]. Each Party shall promptly notify the JCC if it becomes aware that there is a deviation in the immediately preceding Pfizer Quarter of more than [\*\*\*] of the actual Gross Profit as compared against the budget for the Gross Profit in the profit and loss forecasts pursuant to the above (a "Budget Deviation") and specify the reason for such Budget Deviation. Following such Budget Deviation notice, the JCC shall discuss the reasons for such deviation on a Relevant Line Item by Relevant Line Item basis and seek to agree on any potential measures to be taken to address and improve the situation. In addition, from [\*\*\*] onwards, the Parties shall review, each Pfizer Quarter, the profit and loss statement compared to the Gross Profit level pursuant to (i) and (ii) above for such Pfizer Quarter and such year-to-date against the equivalent Pfizer Quarter in the previous year and the equivalent year-to-date period in the previous year.

6.4.1.2 The JCC shall review, discuss and agree by mutual consent all aspects relating to Product Components in any market or region, including [\*\*\*].

6.4.2 **Regional Commercialization Committee(s).** The JCC may elect, at its discretion, to establish individual regional commercialization committees for the following regions located within a Party's Commercialization Territory (or such regions as may be amended by Pfizer from time to time): [\*\*\*], (each a "Commercialization Region") in the Territory (each an "RCC").

provided that [\*\*\*]. Each RCC will oversee and monitor the activities of the applicable Commercializing Party for such Commercialization Region. Each RCC will review the Annual Regional Commercialization Plan for the Commercialization Region for which such RCC is responsible, provided that [\*\*\*]. To the extent an RCC is not established for a Commercialization Region (i) within the Pfizer Commercialization Territory, Pfizer shall establish its own Commercialization plan for such Commercialization Region, or (ii) within the BioNTech Commercialization Territory, BioNTech shall establish its own Commercialization Plan for such Commercialization Region, provided that in each case of (i) and (ii), any such Commercialization Plan must not be inconsistent with the global positioning and the Global Commercialization Plan agreed in the JCC or pursuant to Section 6.5.4. Each RCC shall be composed of [\*\*\*] representatives from each Party. One of the Pfizer representatives on each RCC established for Commercialization Regions within the Pfizer Commercialization Territory shall be designated by Pfizer to be the chairperson of such RCC and one of the BioNTech representatives of each RCC established for the Commercialization Regions within the BioNTech Commercialization Territory shall be designated by BioNTech to be the chairperson of such RCC; provided that for any RCC established for a Commercialization Region that incorporates countries in both the BioNTech Commercialization Territory and the Pfizer Commercialization Territory, the chairperson of such RCC shall be designated by the Party having more countries in its Commercialization Territory in such Commercialization Region unless the JCC elects to establish two RCC's for such Commercialization Region where each such RCC only has responsibility for countries with in either the BioNTech Commercialization Territory or the Pfizer Commercialization Territory, but not both.

6.4.3 **Joint Finance Committee.** The Parties shall establish a Joint Finance Committee (the "**JFC**") to work with the other Committees to assist in financial, forecasting, budgeting and planning matters as required, including (a) assisting the JCC and the Joint Manufacturing Committee established pursuant to this Agreement in developing the long-range forecast for commercial supply of the Products; (b) recommending and approving procedures, formats and timelines consistent with this Agreement for reporting pursuant to Sections 4.9 and 4.10 financial data and assist in resolving differences that relate to the financial terms of this Agreement; provided that no Party shall be required to make any material changes to its internal accounting and reporting systems and standards; (c) reviewing calculations of the amount of any payments to be made by the Parties (or their Affiliates) hereunder, reviewing the reconciliation of payments; (d) coordinating audits of financial data where appropriate and required or allowed by this Agreement; and (e) establishing the inter-party procedures, contracts (if necessary), and financial structure necessary to effect that economic result contemplated by this Agreement and monitoring and maintaining such structure. Furthermore, the JFC shall establish reporting procedures for the sharing of information reasonably required by the other Party for its financial reporting. Such reporting shall as a minimum include reasonable detail with respect to [\*\*\*]. The JFC shall be composed of [\*\*\*] representatives from each Party, wherein one representative has expertise on research and development matters and the other on commercial matters, provided that the total number of representatives may be changed upon mutual agreement of the Parties (so long as each Party has an equal number of representatives).

6.4.4 **Joint Manufacturing Committee.** The Parties shall establish a Joint Manufacturing Committee (the "**JMC**") to plan, decide on, develop, amend, revise and oversee the execution of the Manufacturing Plan, to help the Parties establish adequate Manufacturing



facilities, capacity and capability for the Product, to address such other matters relating to the activities of the Parties under the Manufacturing Plan as either Party may bring before it and, subject to Section 6.5, to attempt to resolve any disputes between the Parties with respect to the performance of activities under the Manufacturing Plan on an informal basis. The JMC shall agree and decide on an initial Manufacturing Plan within [\*\*\*] of the Amendment Signing Date. The JMC shall work with the JCC and the JFC in respect of Manufacturing activities. The JMC shall be composed of [\*\*\*] from each Party, provided that the total number of representatives may be changed upon mutual agreement of the Parties (so long as each Party has an equal number of representatives).

6.4.5 **Compliance Committee.** Pfizer and BioNTech agree to establish a Compliance Committee (the "Compliance Committee") promptly after the Amendment Signing Date. The Compliance Committee shall be comprised of [\*\*\*] from each Party or such other number as may be mutually agreed by the Parties, provided that each Party at all times shall have an equal number of representatives on the Compliance Committee. The Compliance Committee shall report to the JCC. Subject to the terms and conditions of this Agreement, the Compliance Committee shall have overall responsibility for resolving discrepancies between the Parties' respective compliance policies; managing compliance with corporate integrity agreements and deferred prosecution agreements (or similar agreements/settlement documents) to which either of the Parties are subject; and ensuring a process to monitor the Parties' activities under this Agreement for compliance with all applicable Laws relating to healthcare and all Anti-Corruption Laws.

6.4.6 **Committee Membership – General.** Each Party will ensure that the members appointed by it to serve on any Committee, including the JSC or JCC, have, as applicable: (a) the appropriate level of seniority and decision-making authority commensurate with the responsibilities of the Committee to which they are appointed; and (b) a range of expertise, as applicable, in the Commercialization of pharmaceutical or vaccine products to enable an efficient cross-functional Committee structure. If any Committee member becomes unwilling or unable to fulfil his or her duties hereunder, then the Party that appointed such member will promptly appoint a replacement by written notice to the other Party. Further, each Party may replace any of its designated Committee representatives at any time on written notice to the other Party. The chairperson or co-chairpersons, as applicable, of each Committee will be responsible for calling meetings, preparing and circulating an agenda in advance of each meeting of such Committee; provided that the Committee chairperson(s) will call a meeting of the applicable Committee promptly upon the written request of the most senior representative from the other Party serving on such Committee to convene such a meeting.

6.4.7 **Secretary; Minutes.** Each Committee will have a secretary (who need not be a voting member of such Committee), which will alternate yearly between the Parties. The hosting Party's secretary (or designee) for a given Committee will be responsible for preparing reasonably detailed written minutes of all meetings of such Committee that reflect, without limitation, material decisions made, action items identified and unresolved matters discussed at such meetings. The initial draft of the meeting minutes for a given Committee meeting, reflecting key decisions, action items and unresolved matter, among other details, will be completed by the end of such meeting and circulated to the Committee's members for subsequent review and approval.

6.4.8 **Meetings.** Each Committee will meet at such times as it elects to do so; *provided* that the JCC and each RCC will meet at least once every [\*\*\*], via teleconference or videoconference or otherwise (with at least [\*\*\*] per calendar year being in person if feasible), or as otherwise agreed by the JCC or the relevant RCC, as applicable. Additionally, either Party may call a meeting of the JCC or any RCC at any time; *provided* that the requesting Party provides at least [\*\*\*] prior written notice to the chair of such Committee and such notice includes a proposed agenda for such meeting. Any and each subcommittee established hereunder will establish a meeting frequency and meeting protocol necessary to coordinate and conduct the activities for which it is responsible, as mutually agreed by the Parties. Any in-person meetings of the JCC and any RCC will be held on an alternating basis between a location designated by BioNTech and Pfizer, unless otherwise agreed by the Parties. Each Party will be solely responsible for its own expenses relating to attending and participating in all Committee meetings. As appropriate, other employee representatives of the Parties may attend such meetings as non-voting participants, but no Third Party personnel may attend unless otherwise agreed by each of the Parties. All Committee meetings will be conducted in English, and all documents (including all Committee meeting minutes and Annual Regional Commercialization Plans) will be in English.

6.4.9 **Reporting.** Each Commercializing Party will keep the JCC or applicable RCC informed of progress and results of the Commercialization Activities and Medical Activities for which such Commercializing Party is responsible through its members on such Committee at each regularly scheduled meeting thereof and as otherwise provided herein.

6.4.10 **No Authority to Amend or Modify.** Notwithstanding anything herein to the contrary, no Committee will have any authority to amend, modify or waive compliance with this Agreement or any Related Agreement. Subject to Section 17.6, the Parties agree to periodically review the operation of the JCC and the provisions of Article 9 and mutually agree any changes which are considered necessary or appropriate in light of prevailing circumstances and to ensure the Agreement, its operation and that of the JCC continues to comply with applicable Laws

6.5 Committee Decision-Making.

6.5.1 **Consensus Decision Making.** Each Party shall procure that its respective Committee members shall act reasonably and in good faith to take action by unanimous consent of the Parties, with each Party having a single vote, irrespective of the number of Committee representatives actually in attendance, *provided* that at least [\*\*\*] from each Party is in attendance at any meeting in which a decision is made.

6.5.2 **Joint Steering Committee Deadlocks.** If, despite good faith efforts, the JSC is unable to reach unanimous agreement on a particular matter, within [\*\*\*] after the JSC first meets to consider such matter, or such later date as may be mutually acceptable to the Parties (each such matter, a "Disputed Matter"), then:

6.5.2.1 [\*\*\*]; and

6.5.2.2 [\*\*\*]; and

6.5.2.3 [\*\*\*].

The Parties agree that the JSC will further refine the details of the decision-making rights and processes in accordance with Schedule 6.5.2 and the terms of this Agreement.

6.5.3 **Regional Commercialization Committees Deadlocks.** All deadlocks arising in any RCC will be referred to the JCC for resolution and the JCC shall attempt to resolve such matter within ten (10) Business Days of the matter being referred to it.

6.5.4 **Joint Commercialization Committee Deadlocks.** Either Party may elect to refer a deadlock arising in the JCC (including deadlocks referred to it by the RCC) to [\*\*\*]. If [\*\*\*] are not able to resolve the dispute, then:

6.5.4.1 [\*\*\*];

6.5.4.2 [\*\*\*]; and

6.5.4.3 [\*\*\*],

provided that [\*\*\*].

6.5.5 **Joint Manufacturing Committee Deadlocks.** All deadlocks arising from the JMC will be referred to the Parties' respective [\*\*\*] for resolution and such respective [\*\*\*] shall use good faith efforts to discuss and resolve such deadlock within [\*\*\*] of the matter being referred to them.

6.5.6 **Other Deadlocks.** All deadlocks arising from any other Committee described in Section 6.4 shall be referred to the JSC or JCC, depending on whether the issue subject to the deadlock is primarily related to Research and Development or Commercialization, for resolution and the JSC or JCC, as applicable, shall attempt to resolve such matter within [\*\*\*] of the matter being referred to it, *provided* that the JSC or JCC, as applicable, may elect to consult with members of the other Committee (that is, the JCC or JSC, as applicable), or include such members in decision-making, where such matter is related to the expertise of such other Committee or its members.

6.5.7 **Dispute Resolution.** For the avoidance of doubt Section 6.5 concerns resolution of any committee deadlocks relating to operational matters to be determined by the applicable committee, and any other dispute or deadlock, including any dispute as to questions of contractual interpretation under this Agreement, shall only be determined and resolved pursuant to Section 17.11.

## 7. MANUFACTURING

7.1 **Development of Manufacture Process.** BioNTech and Pfizer shall jointly Develop a scalable process for Manufacture of Candidates and Products in the Field in the Territory in accordance with the binding parts of the Research and Development Plan and the Manufacturing Plan.

7.2 **Manufacture of Candidates Products.** Each Party will use Commercially Reasonable Efforts to perform its obligations and activities identified under the binding parts of the Manufacturing Plan or as allocated to it by the JSC, or the JMC, once established, in a professional manner in accordance with any target dates set forth in the Manufacturing Plan. Further, each Party will perform its obligations under the binding parts of the Manufacturing Plan or as allocated to it by the JSC or the JMC, once established, in compliance with all Laws applicable to its activities under the Manufacturing Plan. Pfizer and BioNTech

will collaborate in the build-up of Manufacturing capacity for the Manufacturing of Candidates and Products for clinical and commercial purposes in accordance with the binding parts of the Manufacturing Plan and the terms and conditions set forth in this Section 7. The Manufacturing Plan may be modified by unanimous consent of the JSC or the JMC, once established, pursuant to Section 6. Unless otherwise agreed in the Manufacturing Plan, at a minimum Pfizer will be responsible for the build-up of its Manufacturing site(s) in the USA for quantities of Product to be agreed as part of the Manufacturing Plan and the commercial supply agreement for such site, and at a minimum BioNTech will be responsible for the extension of its Manufacturing sites in Mainz and Idar-Oberstein for quantities of Product to be agreed as part of the Manufacturing Plan and the commercial supply agreement for such sites. [\*\*\*] The Manufacturing Plan may also consider one or both Parties engaging Third Party contract manufacturing organizations as a source of Manufacturing. In addition, promptly after the Effective Date, the Parties will agree on a technology transfer plan and continue to perform the technology transfer that the Parties have already started prior to the Effective Date to enable Manufacturing by Pfizer. For the avoidance of doubt, to the extent the technology transferred under this Agreement is identical to the technology to be transferred pursuant to the Flu Collaboration License, the Parties shall cooperate to minimize any duplication of technology transfer efforts under the Flu Collaboration License that unreasonably would be duplicative, wasteful or unnecessary.

7.3 **Quality Requirements.** Each Party that undertakes or subcontracts any Manufacturing activities in respect of the Candidates or Products, whether for the purposes of this Agreement, the Clinical Trials or pursuant to the commercial supply agreements shall ensure (a) that all Manufacturing activities are undertaken in accordance with (i) applicable cGMP standards, applicable Laws, and other regulatory and manufacturing good practice (including record and sample keeping, deviation reporting, testing and quality requirements and post-marketing regulatory guidelines from the FDA and the EMA); (ii) the requirements of the applicable quality agreement; and (iii) the requirements of the applicable supply agreement entered into pursuant to Section 7.4, and (b) that such Product manufactured by it is (i) in conformance with the specifications therefor in effect at the time of shipment by such Party to the other Party or to any Third Party distributor or customer, such that the Product is not, at the time of shipment from such Party to the other Party or to any distributors or customers in the Territory, adulterated or misbranded within the meaning of the FD&C Act or any analogous applicable Law outside of the United States; and (ii) in conformance, at such time of shipment by such Party, in all material respects with the certificates of analysis accompanying such Product when shipped.

7.4 **Manufacturing Agreements.**

7.4.1 **Clinical Supply.** Within [\*\*\*] following the Effective Date, the Parties shall enter into an agreement for clinical supply, as required to ensure the Clinical Trials planned can proceed on the timelines set forth in the binding parts of the Research and Development Plan. All clinical supply of Candidates and Products shall be charged as Shared Development Costs at the Manufacturing Costs. In addition, the Parties have agreed on quality agreements with respect to such clinical supply agreement.

7.4.2 **Commercial Supply.** Furthermore, the Parties will negotiate in good faith and mutually agree on one or more commercial supply agreement(s) and quality agreement(s) simultaneously with the negotiation of the Commercialization Terms. The commercial supply agreement(s) shall be in accordance with the following commercial terms:

7.4.2.1 The Manufacturing Party shall be entitled to charge (i) the Transfer Price for each batch of Product delivered in accordance with the relevant commercial supply agreement, or (ii) where intermediates, drug substance or bulk drug product is supplied for Manufacturing the Product, the Manufacturing Costs (as further defined in Section 1.93) for any such intermediates, drug substance or bulk drug product, but in each case of (i) and (ii), all supplies shall be made by the Manufacturing Party on a buy/sell model. Such Transfer Price (or Manufacturing Cost) shall be invoiced by the Manufacturing Party upon delivery of the Products and shall be payable by the other Party within [\*\*\*] from receipt of such invoice.

7.4.2.2 The Transfer Price (or Manufacturing Cost) shall be adjusted on a yearly basis for all commercial supply agreements in accordance with relevant cost developments.

7.4.2.3 The Parties will work together, subject to and observing applicable Laws, and agree the volumes of Product Materials to be purchased from Third Party suppliers for the purposes of this Agreement and to [\*\*\*] of either Party to source the other Party's requirements for such Product Materials for its Manufacturing activities pursuant to this Agreement, which sourced Product Materials shall then be sold, at cost, to that other Party [\*\*\*].

7.4.2.4 [\*\*\*].

7.4.2.5 The Parties will cooperate and use Commercially Reasonable Efforts to manufacture or cause to be manufactured and continuously supply the Product for distribution and use in the Field by customers and patients in the Territory. The JCC shall determine, by mutual consent, the allocation of supplies of Product in the Territory on a fair and equitable basis, subject also to any applicable Law, export controls, any government supply obligations, supply obligations included in any Third Party Funder agreements, supply obligations pursuant to advance purchase agreements, including agreements with any Governmental Authority, as well as supplies reasonably required by BioNTech for product identical to the Product in the Fosun Territory; *provided, however*, that the allocation of supplies required for the purposes of this Agreement shall take precedence over supplies for other uses, which priority shall be the primary consideration for such determination. Notwithstanding the foregoing, neither Party will have liability to the other Party by virtue of any shortage or allocation.

7.4.3 The supply agreements to be entered into between the Parties pursuant to Sections 7.4.1 and 7.4.2 shall include appropriate accounting mechanisms to allow for true-up payments in respect of (i) Manufacturing Costs, including to account for any mark up on the Manufacturing Costs of Product Materials where permitted in the definition of Manufacturing Costs or costs paid to Third Party manufacturers for the manufacture and supply of Candidates or Products or components thereof, and (ii) Manufacturing Variances.

7.5 **Allocation of Responsibilities.** Section 5.3.1 and Sections 5.3.4 to 5.3.6 shall apply *mutatis mutandis* in respect of each Party's responsibilities under the Manufacturing Plan.

7.6 **Quality Audits.** The Parties shall negotiate in good faith and mutually agree on appropriate and customary audit rights of the other Party and any relevant Third Party contractor of such Party with respect to manufacturing quality matters in the commercial supply agreement(s) or quality agreement(s).

## 8. **DEVELOPMENT, REGULATORY AND PHARMACOVIGILANCE**

### 8.1 **Development Matters.**

8.1.1 **Allocation of Development and Regulatory Responsibility.** The Development of Candidates and Products shall be conducted by the Parties, under the direction and oversight of the JSC (and, as applicable, the Joint Development Committee), in accordance with the applicable Research and Development Plan and Development Budget. Pursuant to the initial Research and Development Plan, the Parties shall identify a strategy for Development of the Candidates and Products in the Territory that identifies the Party that is leading the clinical Development of the Candidates or Products in a country in the Territory (the "**Lead Development Party**"). Notwithstanding the foregoing, the Parties have agreed that (a) Pfizer shall lead the clinical aspects of Development of Candidates and Products in the USA, and (b) BioNTech shall lead the clinical aspects of Development of Candidates and Products in the EU. BioNTech shall be the sponsor and IND/CTA holder for all Clinical Trials in the Territory, in each case, subject to a mutually agreeable strategy with respect to the Development of Candidates and Products. For any Clinical Trial for which Pfizer is the Lead Development Party (but is not the sponsor of such Clinical Trials), BioNTech shall have delegated to Pfizer operational and day-to-day Development activities, decision-making authority and responsibility for such Clinical Trial, including those activities described in **Schedule 8.1.1**, subject to a protocol approved by unanimous consent by the JSC. For avoidance of doubt, the Lead Development Party shall conduct its Development activities in collaboration with and with active review of the other Party.

8.1.2 **Appointment of Lead Development Party for Future Clinical Trials.** At any time during the Term, the JSC may determine by mutual consent that additional clinical Development of the Candidate and Product are warranted and, in such event, unless otherwise agreed by the JSC, (a) Pfizer shall be the Lead Development Party for each additional Clinical Trial in the USA, (b) BioNTech shall be the Lead Development Party for each additional Clinical Trial in the EU and (c) the JSC shall mutually agree on the appointment of one of the Parties to be the Lead Development Party for each additional Clinical Trial on a Clinical Trial-by-Clinical Trial basis in a country or region in the Territory other than the USA and EU ("**ROW**"), and subject to the mutually agreed upon strategy.

8.1.3 **Clinical Trials.** In respect of Clinical Trials for the Candidates or Products pursuant to this Agreement, the following shall apply:

8.1.3.1 **GxP Standards.** Subject to Section 8.1.3.8, BioNTech as the sponsor for any Clinical Trial in respect of any Candidate or Product pursuant to this Agreement shall ensure the Clinical Trial is conducted in accordance with GxP and all applicable Laws, and will provide to the other Party any significant GxP or non-compliance issues relating to the protocol for such Clinical Trial, which arise or may be identified through monitoring,

8.1.3.2 *Monitoring Plans.* A high-level strategy for monitoring Clinical Trials in respect of any Candidate or Product pursuant to this Agreement will be agreed by the JSC within [\*\*\*] following the Effective Date. The Lead Development Party of the Clinical Trial will notify the other Party if there are any amendments required to such monitoring plan, and provide such other Party with an opportunity to review and comment on any such amendments, and any amendments shall only be made following approval by the JSC.

8.1.3.3 *Sponsor Oversight Plan.* The Parties shall mutually agree on a sponsor oversight plan to set forth the accountabilities and oversight of all Clinical Trials conducted by the Lead Development Party, consistent with that certain GCP Quality Agreement, dated December 10, 2020, including Appendix D, Roles and Responsibilities.

8.1.3.4 *IRB/IEC Approval.* BioNTech as the sponsor and Regulatory Approval holder of the Clinical Trials shall ensure that the Clinical Trial is approved by and subject to continuing oversight by an appropriate Institutional Review Board (IRB) or Independent Ethics Committee (IEC), except that BioNTech shall delegate this responsibility to Pfizer for any Clinical Trial for which Pfizer is the Lead Development Party. The Lead Development Party shall provide documentation of both the initial IRB/IEC approval of the final protocol to the other Party and annual renewals of that approval if such renewals are required. To the extent a Party receives notice of any withdrawal or suspension of IRB/IEC approval during the Term, it will promptly inform the other Party.

8.1.3.5 *Informed Consent.* BioNTech as the sponsor and Regulatory Approval holder for each applicable Clinical Trial will obtain informed consent for each Clinical Trial subject in accordance with the applicable informed consent document and applicable Law and will inform and obtain express consent from each Clinical Trial subject that the data, including Personal Data, arising from such Clinical Trial may be used in accordance with the terms of this Agreement (including its export from the European Union and its processing by Pfizer or other Third Parties in accordance with the terms of this Agreement and Law), provided however, that BioNTech shall delegate this responsibility to Pfizer for those Clinical Trials for which Pfizer is the Lead Development Party. Notwithstanding the foregoing, the Lead Development Party will share the informed consent document with the other Party for such other Party's review and comment prior to its use in a Clinical Trial in a country in the Territory.

8.1.3.6 *Sponsorship.* Where the Lead Development Party (or its Affiliate or designee) is not the sponsor of a Clinical Trial or Regulatory Approval holder, such Lead Development Party shall not represent to any Third Party, including any Clinical Trial subjects, that the Lead Development Party or its Affiliates are a sponsor.

8.1.3.7 *Reporting.* BioNTech is solely responsible for any and all safety reporting and regulatory obligations associated with the conduct of the Clinical Trial for which it is the sponsor, including, but not limited to, obtaining and maintaining Regulatory Approvals for the conduct of the Clinical Trials, provided, however, that BioNTech shall delegate the safety reporting and regulatory obligations associated with the conduct of each Clinical Trial in the Territory to Pfizer subject to Section 8.3.7.

8.1.3.8 *Delegation.* Notwithstanding the responsibilities of BioNTech as IND/CTA holder or sponsor of Clinical Trials, where Pfizer is the Lead Development Party for a Clinical Trial Pfizer shall conduct its activities in compliance with GxP and applicable Law with respect to each of the activities which have been delegated to Pfizer pursuant to Schedule 8.1.1.

8.2 Regulatory Matters.

8.2.1 **Lead Regulatory Party.** The JSC shall agree on a strategy to allocate operational responsibility for regulatory activities relating to each Candidate or Product to one of the Parties (the "Lead Regulatory Party") which shall, as a default initial allocation, be by reference to the country or region where such Party is the Lead Development Party. The JSC's initial allocation shall be that Lead Regulatory Party for regulatory activities relating to each Candidate or Product in the EU shall be BioNTech, and the Lead Regulatory Party for regulatory activities relating to each Candidate or Product in the USA shall be Pfizer. Subject to the JSC's mutual consent to seek Regulatory Approval in one or more countries or regions in the ROW, Pfizer shall be the Lead Regulatory Party for regulatory activities relating to each Candidate or Product in such country or region in the ROW. If the JSC cannot agree on whether Regulatory Approval shall be sought for any country or region in the ROW, the Party that wishes to seek Regulatory Approval in such country or region shall be entitled to be the Lead Regulatory Party for regulatory activities relating to each Candidate or Product in such country or region and seek such Regulatory Approval at its own cost. The JSC may vary from the foregoing allocations by mutual consent. The other Party shall cooperate with the Lead Regulatory Party, at its reasonable request, with respect to any regulatory matters for which the Regulatory Approval holder is responsible or to whom regulatory matters have been delegated. Notwithstanding the foregoing, for matters relating to any Vaccine Technical Committee, Price Approval or reimbursement approval in a country, such matters shall be handled by the Party in whose Commercialization Territory such country is located irrespective of whether they are the Lead Regulatory Party.

8.2.2 **Regulatory Communications and Filings.** The Lead Regulatory Party shall use Commercially Reasonable Efforts to prosecute to grant and maintain all applications for Regulatory Approvals for the Product, including any supplements or amendments thereto and all Regulatory Approvals obtained therefrom. The Lead Regulatory Party shall make all filings with the Regulatory Authority that are necessary to maintain the Regulatory Approvals for the Product in good standing, including any regulatory reporting. In accordance with Section 8.2.1, each Party shall cooperate with the other Party with respect to any and all regulatory matters for which the other Party is responsible pursuant to this Agreement or the Research and Development Plan. Unless exigent action is required with respect to a given filing before a Regulatory Authority concerning a Candidate or Product, or a material communication with a Regulatory Authority concerning the same, the Lead Regulatory Party shall provide the other Party with copies of all filings relating to such Marketing Authorization Application prior to submission within a reasonable amount of time (but not less than [\*\*\*]) to allow such Party to review and comment on such filings, and the Party submitting such filing shall consider all comments and proposed revisions from the other Party in good faith prior to submission. The Lead Regulatory Party shall consult with the other Party regarding, and keep the other Party informed of, the status of the preparation of all Marketing Authorization Applications and the prosecution or maintenance thereof, including any material communications that it receives with respect to the same. The Lead



Regulatory Party shall provide to the other Party copies of all final Marketing Authorization Applications and filings relating thereto that it submits within [\*\*\*] from filing (unless access to such Marketing Authorization Applications or filing is reasonably required earlier in which case the Lead Regulatory Party shall make such Marketing Authorization Applications and filings available earlier than [\*\*\*] to the extent reasonably possible). The foregoing provisions of this Section 8.2.2 shall also apply to material and substantive communications with Regulatory Authorities. Both Parties will cooperate with respect to any and all regulatory matters with respect to the Product, including the implementation of any of the foregoing in any country in the Territory. For the avoidance of doubt, where Pfizer is the Lead Regulatory Party, all filing, prosecution and maintenance activities to be made by Pfizer under this Section 8.2.2 shall be made in the name of BioNTech or its Affiliate, unless otherwise agreed pursuant to Section 8.2.6, and Pfizer shall submit or make available to BioNTech within [\*\*\*] copies of all filings and other material correspondence submitted to any Regulatory Authority, Governmental Authority or Government Official worldwide in BioNTech's name or on BioNTech's behalf in connection with such Regulatory Approvals and applications therefor.

8.2.3 **Requests by Associations or Competitors.** The JCC shall, in good faith, seek to agree and align on the types of complaints, inquiries or other requests for information with respect to the Product from any trade or industry association or any competitor that may merit standard responses. Either Party shall use such standard responses in response to any such complaint, inquiry or request on which the JCC aligns. Furthermore, either Party will promptly notify the respective other Party if it or its Affiliates receive any complaint, inquiry or request, including situations for which such standard responses are not applicable or appropriate. If such standard responses are not sufficient, where such complaint, inquiry or request relates to or primarily impacts only one Party's Commercialization Territory, such Party will have control and discretion with respect to determining the appropriate response thereto, subject to applicable Law; *provided, however*, that if any such complaint, inquiry or request (i) relates to the safety or efficacy of the Product, subject to the terms of the applicable Pharmacovigilance Agreement, the Party that is the applicable MA Holder will have control and discretion (having regard to the other Party's input and recommendations) with respect to determining the appropriate response thereto or (ii) relates to or impacts both Parties' Commercialization Territory, the Party in receipt of such complaint, inquiry or request shall refer it to the JCC and the JCC will have control and discretion with respect to determining the appropriate response thereto, subject to applicable Law.

8.2.4 **Regulatory Meetings.** The Lead Regulatory Party shall consult with the other Party reasonably in advance of the date of any anticipated meeting with a Regulatory Authority relating to any Marketing Authorization Applications or Regulatory Approvals in respect of any Candidate or Product for which it is responsible and shall consider any timely and reasonable recommendations made by the other Party in preparation for such meeting. The Parties agree that the Lead Regulatory Party shall lead interactions with respect to countries or regions in the Territory for which such Party is the Lead Regulatory Party. Upon the request of the other Party, and to the extent legally permissible and not opposed by the relevant Regulatory Authority, the Lead Regulatory Party shall permit the other Party to attend any and all meetings with the applicable Regulatory Authority concerning the Candidate or Product. [\*\*\*]

8.2.5 **Manufacturing Matters.** Where a Party is the Lead Regulatory Party and responsible for preparing and maintaining the filings for Regulatory Approval, the other Party shall

provide all reasonable assistance to the Lead Regulatory Party in such filings, including preparation of the CMC portions of the Common Technical Document in English and supporting ancillary cGMP documents and analytical data as required to meet specific regulatory filing and approval requirements. Each Party shall promptly provide the other with copies of material written correspondence as reasonably necessary to permit each Party to comply with its relevant regulatory obligations described in the Agreement or as otherwise reasonably requested.

**8.2.6 Ownership of Regulatory Filings, Regulatory Approvals and Pricing and Reimbursement Approvals.** The Parties shall discuss through the JSC which Party shall apply for and hold the Regulatory Approvals directed to a Candidate or Product in each country in the Territory. Notwithstanding Section 6.5.2, if despite good faith efforts, the JSC is unable to reach unanimous agreement on which Party shall apply for and hold the MAA or Marketing Authorization Approvals directed to a Candidate or Product in any country in the Territory, then BioNTech shall have final decision making authority in that respect, *provided* that Pfizer shall not be required to apply for and hold any MAA or Marketing Authorization Approval in a country unless Pfizer and its Affiliates are already Commercializing a Pfizer vaccine product in such country and are permitted to hold an MAA or Marketing Authorization Approval for the Product in such country. The Parties acknowledge that, unless otherwise determined pursuant to this Section 8.2.6 or required under applicable Law, all Regulatory Approvals directed to a Candidate or Product in a country in the Territory and all applications therefor shall be made and/or held in the name of and owned by BioNTech or its Affiliate. For clarity, if under the applicable Law of any country BioNTech or its Affiliate is allowed to apply for a Regulatory Approval even though, at the time of such application, BioNTech or its Affiliate does not fulfil the requirements under applicable Law to hold such Regulatory Approval in such country, BioNTech or its Affiliate shall be allowed to file such application, *provided* that BioNTech reasonably believes that it will fulfill all such requirements within such time period as will not unreasonably delay approval of the applicable Regulatory Approval. In addition, the following principles shall apply:

**8.2.6.1** Where BioNTech or its Affiliate has applied for and/or holds in its own name any MAA or Marketing Authorization Approval directed to a Candidate or Product in a given country in the Territory, it may, upon giving reasonable notice to Pfizer, elect with Pfizer's agreement to transfer to Pfizer or any of its Affiliates such Regulatory Approval (or the relevant application therefor) in such country and Pfizer or its Affiliate will not withhold its agreement to such transfer if Pfizer or any of its Affiliates is already Commercializing a Pfizer vaccine product in such country and is permitted to hold such MAA or Marketing Authorization Approval in such country.

**8.2.6.2** Where an MAA or Marketing Authorization Approval directed to a Candidate or Product in a given country in the Territory is held by Pfizer or its Affiliate after it has been (i) applied for or obtained by Pfizer or its Affiliate or (ii) transferred to Pfizer or its Affiliate pursuant to Section 8.2.6.1 above, BioNTech, in its sole discretion, may at any time request in writing that Pfizer transfers or transfers back, as applicable, such Regulatory Approval (or application therefor) to BioNTech or its Affiliate and, upon such written request, the Parties will mutually agree on the date of the transfer or transfer back, as applicable, of such Regulatory Approval (or application therefor) to BioNTech or its Affiliate, *provided* that such date shall be no later than six (6) months after BioNTech's request and BioNTech has fulfilled all necessary requirements under applicable Law to

hold such Regulatory Approval (or application therefor) at the time of transfer or transfer back.

8.2.6.3 Recognizing that the transfer of the foregoing responsibilities or the responsibilities described in Sections 8.2.1 and 8.2.2 and Regulatory Approvals, as the case may be, requires time, coordination and effort, the Parties will agree a reasonable transition plan for each such transfer (including specifications for the transfer period) and during the transfer period BioNTech or Pfizer, as applicable, shall continue to use Commercially Reasonable Efforts to maintain the Regulatory Approvals in good standing and continue to perform its obligations as Lead Regulatory Party or owner of the Regulatory Approval (or application therefor), unless determined otherwise in the relevant transition plan.

8.2.6.4 A Party that is a Regulatory Approval holder under this Agreement shall procure that its Affiliates conduct all activities in connection with such Regulatory Approvals in accordance with this Agreement.

8.2.7 **Notice of Regulatory Investigation or Inquiry.** If any Regulatory Authority (i) contacts a Party with respect to the alleged improper Development, Manufacture, or Commercialization of a Candidate or Product in the Territory, (ii) conducts, or gives notice of its intent to conduct, an inspection at a Party's facilities used in the Development or Manufacturing of a Candidate or Product, or (iii) takes, or gives notice of its intent to take, any other regulatory action with respect to any activity of a Party that could reasonably be expected to adversely affect any Development, Manufacture or Commercialization Activities with respect to a Candidate or Product in the Territory, then such Party shall promptly notify the other Party of such contact, inspection or notice. The inspected Party shall provide such other Party with copies of all pertinent information and documentation issued by any such Regulatory Authority within [\*\*\*] of receipt, and, to the extent practicable, the JSC or appropriate subcommittee. Such other Party shall have the right to (a) be present at any such inspection where reasonably practicable, and (b) review and comment upon in advance any responses of the inspected Party that pertain to a Candidate or Product or a Party's activities hereunder.

### 8.3 Pharmacovigilance and Pharmacovigilance Agreement.

8.3.1 As soon as practicably possible following the Signing Date the Parties shall form a Joint Safety Committee to (a) review and approve each investigator's brochure for the clinical Development of Candidates and Products, (b) review and approve all aggregated data Drug Safety Update Reports, annual IND reports, and other period reports to Governmental Authorities information regarding patient safety (including adverse drug) experiences that are or may be associated with Candidates or Products, (c) review, discuss and agree the outputs of each Party's periodic Candidate and Product related benefit/risk analysis, and (d) such other patient safety-related activities as the Parties may delegate to it from time to time.

8.3.2 So long as BioNTech holds the necessary INDs/CTAs/Regulatory Approvals and is acting as sponsor in a country or region in the Territory, BioNTech may initiate clinical Development of the Candidates and Products in the EU prior to the Parties entering into a pharmacovigilance agreement. In such circumstances BioNTech shall be responsible for collecting, monitoring, evaluating, sharing and reporting to applicable Governmental Authorities in the EU information regarding patient safety (including adverse drug) experiences that are or may be

associated with Candidates or Products. BioNTech shall be responsible for maintaining a suitable safety database.

8.3.3 The Parties acknowledge and agree that they have entered into a pharmacovigilance agreement covering pharmacovigilance responsibility relating to Development Activities and shall update such agreement or enter into a new pharmacovigilance agreement with respect to Commercialization Activities (each a "Pharmacovigilance Agreement"), in each case reflecting the applicable terms set forth in Section 8.3.7 and Schedule 8.3.

8.3.4 Following the filing of the IND for Candidate(s) with FDA:

8.3.4.1 should BioNTech require Pfizer to take over certain activities in relation to collecting, monitoring, evaluating, sharing and reporting to applicable Governmental Authorities, but excluding Ethics Committees, information regarding patient safety (including adverse drug) experiences that are or may be associated with Candidates or Products in the EU, the Parties shall agree and execute an amendment to the Pharmacovigilance Agreement to (i) reflect the additional activities and responsibilities the Parties have agreed Pfizer will perform in the EU, and (ii) set out the procedures the Parties have agreed upon to allow for the reconciliation of BioNTech's safety database with Pfizer's safety database. The effectiveness of the amendment shall be conditional upon BioNTech delivering to Pfizer (x) confirmation from the relevant Governmental Authorities in the EU that they have accepted an amendment to the clinical trial protocol for any on-going clinical trial of Candidates or Product in the EU to reflect the necessary changes (as agreed with Pfizer) in responsibilities and contact information for collecting, monitoring, evaluating, sharing and reporting of information regarding patient safety (including adverse drug) experiences, and (y) written confirmation from BioNTech that it has amended the relevant clinical trial agreements to reflect the change in pharmacovigilance provider and trained the investigators on the new reporting procedures; and,

8.3.4.2 BioNTech through their agreement with Fosun shall ensure that Fosun, via BioNTech, deliver to Pfizer (x) a copy of a due diligence report on Fosun's safety data reporting system reasonably acceptable to Pfizer in terms of findings made, (y) a copy of the pharmacovigilance agreement between BioNTech and Fosun which, inter alia, provides for delivery to Pfizer of fully assessed, translated (into English) CIOMS forms for all SAEs: Death / life threatening SUSARs – 5 Business Days from Day 0 (Day 0 being receipt by Fosun from the clinical investigator), or 10 days for all other SAEs, [\*\*\*] and (z) details of the quality management system used with Fosun to ensure that if late inbound reports are received BioNTech can request root cause analysis and implementation of corrective and preventive actions by Fosun. The Parties agree that prior to Fosun's commencement of clinical activities by Fosun, BioNTech shall have entered into a written agreement with Fosun, reflecting the foregoing.

8.3.5 The Pharmacovigilance Agreement and each amendment to it from time to time shall set forth the responsibilities and procedures for (i) collecting, monitoring, evaluating, sharing and reporting to applicable Governmental Authorities information regarding patient safety (including adverse drug) experiences that are or may be associated with Candidates or Products in the countries covered by that agreement and (ii) providing regulatory information to and support

of the other Party with regard to regulatory obligations, provided, that, each such agreement shall include the following guiding principles: acting as BioNTech's delegate for regulatory interactions, Pfizer shall primarily control the regulatory process and regulatory interactions in the countries covered by that agreement, provided, however that the Parties shall work together collaboratively to further the purposes of the collaboration and the activities described in this Agreement. Subject to the proviso in the foregoing sentence, to the extent there is any conflict between the terms and conditions of the Pharmacovigilance Agreement (as amended from time to time) and this Agreement with respect to safety or regulatory matters, the Pharmacovigilance Agreement shall control.

8.3.6 **Audits.** Each Party shall have the right, at its sole cost and expense, to perform audits of the other Party's pharmacovigilance, regulatory, and environmental, health and safety activities concerning any Candidates or Products under this Agreement, including each Party's oversight of any Third Party contracted to perform pharmacovigilance, regulatory or environmental health and safety activities as outlined in this Agreement and in compliance with applicable Laws, which audit right is exercisable once per Calendar Year (or more frequently for material cause) during the Term, *provided, however*, that the auditing Party shall notify the other Party of the identity of any Third Party auditor, such other Party may require such Third Party auditor to sign a customary confidentiality agreement in form and substance reasonably acceptable to such other Party and the auditing Party shall not use such Third Party auditor without the prior consent of the other Party, such consent not to be unreasonably withheld, delayed or conditioned. Upon request, BioNTech shall provide Pfizer with a copy of its latest audit report on Fosun's pharmacovigilance activities.

8.3.7 **Global Safety Database and Safety Reporting.** Subject to the Pharmacovigilance Agreement entered into as described in Section 8.3.3 as amended from time, Pfizer shall maintain the global safety database for the Candidates and Products pursuant to this Agreement, *provided* that (a) BioNTech will hold a safety database to meet its sponsor responsibilities and regulatory responsibilities in the EU and any other countries or markets in the BioNTech Commercialization Territory and to hold safety data reports received from the Fosun Territory; (b) information shall be exchanged between Pfizer and BioNTech as described in the Pharmacovigilance Agreement to ensure alignment of information between the databases; and (c) BioNTech will delegate to Pfizer its responsibilities for the collection, processing, assessment and safety reporting to Regulatory Authorities for (i) all Clinical Trial(s) conducted pursuant to this Agreement and the Research and Development Plan thereunder in the Territory upon the approval of the IND for Candidate(s) with FDA and (ii) upon Regulatory Approval of the Marketing Authorization Applications or grant of Emergency Use Authorization, adverse event and other safety information relating to the Candidates or Products. Notwithstanding the foregoing, such responsibility can only be delegated to and Pfizer can only accept this responsibility if, with respect to safety information arising from clinical trials, the Clinical Trial sites for the Candidates and Products are reporting the safety data and, with respect to safety information from Commercialization Activities and Medical Activities, BioNTech and its Affiliates are reporting the safety data, in each case, including all individual Serious Adverse Events, translated into English, to Pfizer and for so long as Pfizer has access to all safety data, including all individual Serious Adverse Events, translated into English for any and all active Clinical Trials for the Candidates and Products, including products identical to Candidates or Products conducted under the terms and conditions of the Fosun Agreement (or subsequent agreements with other development partners) and for all Commercialization Activities and Medical

Activities conducted by or on behalf of BioNTech to allow Pfizer to meet its regulatory obligations as Lead Regulatory Party in the Territory.

8.3.8 **Procedures and Training.** Each Party will, at its sole cost and expense, put into place and cause its Affiliates to put into place, appropriate procedures, including the provision of adequate training to all applicable Representatives, to ensure full and timely compliance with its obligations under each of (a) this Section 8.3 and (b) the Pharmacovigilance Agreement.

8.4 **Product Complaints and Returns.** The Parties' rights and obligations with respect to non-conformance and returns of Products shall be governed by, as and to the extent applicable, Sections 9.3.1.2, 9.3.2.2, 9.10, 9.11, and Section 16 of this Agreement, and the applicable sections of the clinical supply agreement, the commercial supply agreement(s), any global quality agreement, any pharmacovigilance, in each case, where such agreement is related to the Product so affected. In addition, BioNTech may forward any product complaints received by it to Pfizer for further processing, reporting, closure and other related activities in the BioNTech Commercialization Territory to fulfill BioNTech's responsibilities for complaint handling on BioNTech's behalf in accordance with procedures that are agreed by the Parties.

8.5 **Clinical Trial Register.** BioNTech shall, in accordance with Law and its internal policies, register, and publish the summaries and results of, Clinical Trials relating to the Candidate or Product on a clinical trial register maintained by it (or an equivalent register), or as otherwise required by Law. If Pfizer is the Lead Development Party for a Clinical Trial, Pfizer shall prepare such summaries and results in accordance with its internal policies and in a timely manner so as to allow the summaries and results to be published within the mandatory time period, and provide such summaries and results to BioNTech for review and comment. Pfizer will give reasonable consideration to any such comments. BioNTech shall publish such summaries and results on a clinical trial register maintained by it (or an equivalent register), within the mandatory time period.

8.6 **Regulatory Exclusivity.** The JCC shall oversee the process of applying for and securing exclusivity rights that may be available under the applicable Law of countries in the Territory, including any data or market exclusivity periods such as those periods listed in the FDA's Orange Book or Purple Book (as applicable) or periods under national implementations of Article 10.1(a)(iii) of Directive 2001/EC/83 (including any pediatric exclusivity extensions or other forms of regulatory exclusivity that may be available), and all international equivalents.

8.7 **Liability.** Subject to Pfizer and its Affiliates compliance with (i) the obligations set forth in Sections 8.1.3.8 above, Pfizer and its Affiliates, employees, agents or representatives will not be liable to BioNTech or its Affiliates in respect of any act, omission, default or neglect on the part of Pfizer, its Affiliates, or their respective employees, agents or representatives in connection with the activities undertaken as a Lead Regulatory Party where such activities are undertaken in good faith, unless liability arises from Pfizer's or its Affiliates, employees, agents or representatives gross negligence or willful misconduct.

8.8 **Objection Right.** Notwithstanding any other provision of this Section 8, where a Party is the MA Holder, it shall have the right to object to or oppose any intended action of the other Party if such objecting Party reasonably and in good faith believes the other Party's intended action is contrary to applicable Law and carries a material risk that if such action is taken, it will result in a material negative impact on approvability of a Market Authorization Application or continued approval of a Marketing Authorization Approval for the Product or sanctions or fines from the relevant Governmental Authority. In

case of an objection or opposition by the MA Holder pursuant to the preceding sentence, the Parties shall promptly discuss the relevant issue in good faith and the objected or opposed intended action shall not be initiated or shall be put on hold until the Parties have reached an agreement on how to ensure compliance with applicable law.

8.9 Personal Data. The Parties agree that any processing of Personal Data pursuant to this Agreement will be in their capacity as independent controllers with respect to such Personal Data. To the extent the Parties shall be required to share Personal Data in connection with this Agreement, the Parties shall enter into a legally binding written agreement governing the Parties relationship and their processing activities as required by Applicable Data Protection Law.

## 9. COMMERCIALIZATION

### 9.1 Annual Plans.

9.1.1 **Preparation of Annual Plans.** The JCC shall prepare a Global Commercialization Plan (which will include a projected budget for Gross Profit for the applicable year set on a global and Major Market by Major Market basis) and will update such plan at least once per year. If the JCC agrees to establish one or more RCCs, each RCC shall prepare an Annual Regional Commercialization Plan which shall have regard to the Global Commercialization Plan's objectives and principles, and update such plan at least once per year for its respective Commercialization Region and submit the same to the JCC for review and approval solely in respect of those aspects where such local plans deviate from the Global Commercialization Plan. The Global Commercialization Plan (and updates made thereto) shall be prepared and reviewed in accordance with the timing for Pfizer's global operations planning process, which timing shall be communicated by Pfizer to BioNTech sufficiently in advance to enable the Parties to prepare and approve the Global Commercialization Plan and updates thereto in accordance with such timing. Each Annual Regional Commercialization Plan that is to be prepared or reviewed by a RCC shall be prepared and reviewed for such year in accordance with (a) the timing for Pfizer's operations planning process for the applicable Commercialization Region(s) within the Pfizer Commercialization Territory, which timing shall be communicated by Pfizer to BioNTech sufficiently in advance to enable the Parties to prepare and review such Annual Regional Commercialization Plan reasonably in advance of its implementation and (b) the timing for BioNTech's operations planning process for the applicable Commercialization Region(s) within the BioNTech Commercialization Territory, which timing shall be communicated by BioNTech to Pfizer sufficiently in advance to enable the Parties to prepare and review such Annual Regional Commercialization Plan reasonably in advance of its implementation.

9.1.2 **Content of Commercialization Plans.** The Global Commercialization Plan will include [\*\*\*]. It is expected that only certain aspects of the Global Commercialization Plan shall be updated each Calendar Year, to adjust the plan for annual variations including the forecasts for Units of Product to be sold during each Calendar Quarter of the applicable year.

9.2 Pfizer Commercialization Responsibilities. In the Pfizer Commercialization Territory, Pfizer, subject to Section 9.14 and at its own cost, shall (or shall cause its Affiliates, sublicensees or subcontractors to);

9.2.1 be responsible for commercial distribution of the Product and those other activities normally undertaken by the commercial distributor of a pharmaceutical product (in each case consistent with Commercially Reasonable Efforts), including, but not limited to:

9.2.1.1 rejecting or accepting and fulfilling Third Party orders for Products and selling Products;

9.2.1.2 subject to Section 9.6, applying for and negotiating for pricing and reimbursement of the Product;

9.2.1.3 conducting all customer contracting pertaining to the Product;

9.2.1.4 consulting with BioNTech whether to implement and, if so decided by Pfizer or BioNTech, as applicable in accordance with Section 9.11, implementing any recalls or market withdrawals of the Product; and

9.2.1.5 managing and responding to medical information requests;

9.2.2 manage and oversee product liability claims pertaining to Products distributed by it for use by its customers or patients in the Pfizer Commercialization Territory, and be responsible for the costs and Liabilities of all product liability claims solely to the extent that the injuries underlying such claims are caused by the breach or default, negligence or intentional misconduct of Pfizer, its Affiliates or any of its or their Representatives, and shall indemnify and hold harmless BioNTech and its Affiliates, Representatives from such costs;

9.2.3 be responsible for promoting and detailing the Product in each country or region, as applicable, of the Pfizer Commercialization Territory using Commercially Reasonable Efforts and in a manner not inconsistent with the strategy and Global Commercialization Plan established by the JCC and, if applicable, the Annual Regional Commercialization Plan established by any applicable RCC, provided, however, that in no event will Pfizer, its Affiliates or any of their respective sublicensees or subcontractors be required to conduct any such activity in a manner that is inconsistent with Pfizer's or its Affiliates' own promotion or its detailing practices, policies or procedures for Pfizer's or its Affiliates' other products, consistently applied;

9.2.4 subject to Sections 9.5 and 10.3, be responsible for training its medical and field sales personnel;

9.2.5 ensure that its sales, medical and other representatives comply with all applicable regulatory, professional and legal requirements governing Product marketing, promotion and detailing activity, including all Anti-Corruption Laws;

9.2.6 subject to Section 9.5.3, ensure that promotional materials developed by Pfizer are not inconsistent with the global messaging and global positioning platform approved by the JCC in the Global Commercialization Plan and in compliance with all Pfizer policies, the relevant Regulatory Approvals and applicable Laws;



- 9.2.7 comply with the standards and requirements set forth in Section 9.4.2;
- 9.2.8 subject to the Pharmacovigilance Agreement, be responsible for maintaining the global safety database and managing pharmacovigilance reporting in accordance with the Pharmacovigilance Agreement, in each case on the behalf of the MA Holder(s);
- 9.2.9 not actively solicit any orders for the Product from within the BioNTech Commercialization Territory;
- 9.2.10 sell the Products in its own name and on its own account, subject to the profit sharing mechanism set forth in Section 4.9 above;
- 9.2.11 invoice its customers and collect receivables in accordance with good industry practice, and
- 9.2.12 ensure through an active monitoring program that its personnel and other representatives fully comply with all applicable regulatory, professional and legal requirements governing Product Commercialization Activity.

Pfizer shall not be obliged to commence its detailing and promotional efforts in a country of the Pfizer Commercialization Territory until after the Product has received a Market Authorization Approval (as opposed to an Emergency Use Authorization) and recommendations from the applicable Vaccine Technical Committee in such country. For clarity, other Commercialization Activities and Medical Activities may be conducted by Pfizer, at its sole discretion, prior to Regulatory Approval of a Product to the extent permitted by applicable Law in order to prepare for promotion, marketing and sale of Products once such Regulatory Approval is obtained and Pfizer shall not be obligated to commence any detailing and promotional efforts in violation of applicable Law.

9.3 BioNTech Commercialization Responsibilities:

9.3.1 **General Responsibilities.** BioNTech, at its own cost, shall

9.3.1.1 in accordance with the Pharmacovigilance Agreement, promptly forward to Pfizer for handling all adverse event and associated safety information it or its representatives receive pertaining to the Product;

9.3.1.2 be responsible for and indemnify and hold harmless Pfizer and its Affiliates, representatives, personnel and subcontractors, against the costs and Liabilities of all product liability claims, except to the extent such costs and Liabilities are the responsibility of Pfizer pursuant to Section 9.2.2;

9.3.1.3 except to the extent Pfizer becomes the MA Holder for any country (including pursuant to Section 8.2.6 this Agreement), fulfill the obligations of the MA Holder and shall maintain the Regulatory Approvals for each Product and not diminish the label or indication for any Product without Pfizer's prior consent; and

9.3.1.4 ensure through an active monitoring program that its personnel and other representatives fully comply with all applicable regulatory, professional and legal requirements governing Product Commercialization Activity.

9.3.2 **BioNTech Commercialization Territory Responsibilities.** In the BioNTech Commercialization Territory, BioNTech, subject to Section 9.14 and at its own cost, shall (or shall cause its Affiliates, sublicensees or subcontractors to):

9.3.2.1 be responsible for commercial distribution of the Product and those other activities normally undertaken by the commercial distributor of a pharmaceutical product (in each case consistent with Commercially Reasonable Efforts), including, but not limited to

- (a) rejecting or accepting and fulfilling Third Party orders for Products and selling Products;
- (b) subject to Section 9.6, applying for and negotiating for pricing and reimbursement of the Product;
- (c) conducting all customer contracting pertaining to the Product;
- (d) consulting with Pfizer whether to implement and, if so decided by Pfizer or BioNTech, as applicable in accordance with Section 9.11, implementing any recalls or market withdrawals of the Product; and
- (e) managing and responding to medical information requests;

9.3.2.2 manage and oversee product liability claims pertaining to Products distributed by it for use by its customers or patients in the BioNTech Commercialization Territory, and be responsible for the costs of all product liability claims as set forth in Section 9.3.1.2;

9.3.2.3 be responsible for promoting and detailing the Product in each country or region, as applicable, of the BioNTech Commercialization Territory using Commercially Reasonable Efforts and in a manner not inconsistent with the strategy and Global Commercialization Plan established by the JCC and, if applicable, the Annual Regional Commercialization Plan established by any applicable RCC, provided, however, that in no event will BioNTech, its Affiliates or any of their respective sublicensees or subcontractors be required to conduct any such activity in a manner that is inconsistent with BioNTech's or its Affiliates' own promotion or its detailing practices, policies or procedures for BioNTech's or its Affiliates' other products, consistently applied, or if no such practices are established across multiple commercialized products, then in a manner compliant with applicable Law and consistent with established industry practices for promotion and detailing;

9.3.2.4 subject to Sections 9.5 and 10.3, be responsible for training its medical and field sales personnel;

9.3.2.5 ensure that its sales, medical and other representatives comply with all applicable regulatory, professional and legal requirements governing Product marketing, promotion and detailing activity, including all Anti-Corruption Laws;

9.3.2.6 subject to Section 9.5.3, ensure that promotional materials developed by BioNTech are not inconsistent with the global messaging and global positioning platform approved by the JCC in the Global Commercialization Plan and in compliance with all BioNTech policies, the relevant Regulatory Approvals and applicable Laws;

9.3.2.7 comply with the standards and requirements set forth in Section 9.4.2;

9.3.2.8 not actively solicit any orders for the Product from within the Pfizer Commercialization Territory;

9.3.2.9 sell the Products in its own name and on its own account, subject to the profit sharing mechanism set forth in Section 4.9 above;

9.3.2.10 invoice its customers and collect receivables in accordance with good industry practice, and

9.3.2.11 ensure through an active monitoring program that its personnel and other representatives fully comply with all applicable regulatory, professional and legal requirements governing Product Commercialization Activity.

BioNTech shall not be obliged to commence its detailing and promotional efforts in a country of the BioNTech Commercialization Territory until after the Product has received a Market Authorization Approval (as opposed to Emergency Use Authorization) and recommendations from the applicable Vaccine Technical Committee, if any, in or for such country. For clarity, other Commercialization Activities and Medical Activities may be conducted by BioNTech, at its sole discretion, prior to Regulatory Approval to the extent permitted by applicable Law of a Product in order to prepare for promotion, marketing and sale of Products once such Regulatory Approval is obtained and BioNTech shall not be obligated to commence any detailing and promotional efforts in violation of applicable Law.

#### 9.4 Sales Force.

9.4.1 **Maintenance of Sales Force.** Within its respective Commercialization Territory, in each Major Market Country, the applicable Commercializing Party will use Commercially Reasonable Efforts to provide and maintain, at its respective sole cost and expense (following Regulatory Approval of the Product in such country), (a) a well-trained internal or external sales force of PSRs sufficient to promote the Product in accordance with the applicable Annual Regional Commercialization Plan, if there is one or if not, in accordance with the Global Commercialization Plan and (b) an adequate number of well-trained internal or external Sales Managers to oversee all of such Commercializing Party's PSRs and other sales force Representatives.

9.4.2 **Pfizer Policies and Standards.** Pfizer will ensure that during the course of its promotion of the Product in the Pfizer Commercialization Territory, its respecting Sales Managers, PSRs and other sales and promotion representatives are governed by promotional standards and are subject to policies that (a) require them to limit the claims of efficacy and safety for the Product to those which are consistent with the Pfizer Promotional Materials approved by Pfizer and the Pfizer Training Materials; (b) require such individuals to use only the Pfizer Promotional Materials approved by Pfizer; (c) do not permit such individuals to add, delete or modify claims of efficacy

or safety contained in such Pfizer Promotional Materials or to make any other changes in any such Pfizer Promotional Materials; (d) include the manner in which employees and other representatives should handle unsolicited requests for information related to off-label uses of the Product; and (e) are designed to ensure compliance with applicable Laws. In addition, Pfizer will ensure that its marketing, promotion and detailing of the Product will be in adherence to all applicable Laws, Anti-Corruption Laws, Party Specific Regulations, Pfizer's Internal Compliance Codes, Professional Requirements and the applicable Annual Regional Commercialization Plan, if there is one, and any updates thereto, in each case to the extent applicable in such country. Pfizer shall provide BioNTech with access to copies of its global foundational headquarters level policies that have worldwide applicability to the promotion and Commercialization of the Product. [\*\*\*]

9.4.3 **BioNTech Policies and Standards.** BioNTech will ensure that during the course of its promotion of the Product in the BioNTech Commercialization Territory, its respecting Sales Managers, PSRs and other sales and promotion representatives are governed by promotional standards and are subject to policies that (a) require them to limit the claims of efficacy and safety for the Product to those which are consistent with the BioNTech Promotional Materials approved by BioNTech and the BioNTech Training Materials; (b) require such individuals to use only the BioNTech Promotional Materials approved by BioNTech; (c) do not permit such individuals to add, delete or modify claims of efficacy or safety contained in such BioNTech Promotional Materials or to make any other changes in any such BioNTech Promotional Materials; (d) include the manner in which employees and other representatives should handle unsolicited requests for information related to off-label uses of the Product; and (e) are designed to ensure compliance with applicable Laws. In addition, BioNTech will ensure that its marketing, promotion and detailing of the Product will be in adherence to all applicable Laws, Anti-Corruption Laws, Party Specific Regulations, BioNTech's Internal Compliance Codes, Professional Requirements and the applicable Annual Regional Commercialization Plan, if there is one, and any updates thereto, in each case to the extent applicable in such country. At least [\*\*\*] prior to Commercialization of the Product in the BioNTech Commercialization Territory, or such shorter period as may be agreed by the Compliance Committee, BioNTech shall provide Pfizer with BioNTech's policies in relation to promotion and Commercialization of the Product for Pfizer's review and compliance audit. Within [\*\*\*] after any change of such policies, BioNTech shall provide Pfizer with a copy of any changed compliance policies.

9.4.4 **Compliance of Personnel.** If information comes to a Party's attention that provides such Party with a reasonable basis to believe that any Sales Manager or PSR of the other Party or its Affiliates has (a) violated any applicable Law as it relates to promoting or detailing of the Product or (b) failed to comply with the terms of this Agreement in respect of its Commercialization Activities, then, with respect to either (a) or (b), such Party will have the right to (i) request that the other Party immediately assess the performance of such individual and (ii) exercise any other rights or remedies available to it under this Agreement, at law or in equity. The other Party will (A) promptly use Commercially Reasonable Efforts to evaluate and resolve such issue in accordance with its internal policies or as it may otherwise deem appropriate, (B) to the extent permitted by applicable Law, keep the first Party informed of the progress of, and information learned during, such evaluation and (C) within [\*\*\*] of the first Party bringing such information to the other Party's attention, provide the first Party, to the extent permitted by applicable Law, with a reasonably detailed written report summarizing any steps taken toward

resolution of the matter, unless such other Party has received an opinion from counsel that such disclosure would waive any applicable privilege attaching to information or written report.

9.5 Training Materials, Promotional Materials and Other Product Information.

9.5.1 **Pfizer's Training Obligations.** Pfizer or its Affiliates, at its cost and risk, will develop (as necessary or desirable to address local requirements or customs and market strategies and needs) and design training materials, for use by its PSRs and Sales Managers in particular countries within the Pfizer Commercialization Territory (the "Pfizer Training Materials"). The Pfizer Training Materials shall be in compliance with applicable Law, consistent with the applicable Regulatory Approvals for the Product and, except where necessary to comply with applicable Law, not be inconsistent with the global Commercialization strategy for the Product established by the JCC as reflected in the Global Commercialization Plan. Upon BioNTech's reasonable request, Pfizer shall provide BioNTech with access to the Pfizer Training Materials developed specifically for the Product for use in the Major Markets in the Pfizer Commercialization Territory for BioNTech to review, and Pfizer shall take into account any reasonable comments made by BioNTech in relation to such Pfizer Training Materials. Utilizing such Pfizer Training Materials, Pfizer will be responsible, at its own cost and risk, for preparing and delivering training to its PSRs and Sales Managers with respect to the Product and the detailing thereof. Such training shall occur (a) prior to the provision by such PSR or Sales Manager of any detailing or promotional activities with respect to the Product and (b) periodically thereafter in each country in the Pfizer Commercialization Territory as is consistent with Pfizer's practices for periodic training of its Sales Managers and PSRs or as may be otherwise needed to update such training based on new information. Pfizer shall share the Pfizer Training Materials with BioNTech for BioNTech's use, subject to Section 9.5.2 and at its sole risk, in the BioNTech Commercialization Territory; *provided, however*, that Pfizer shall not be liable to BioNTech for any inaccuracy or error in the Pfizer Training Materials.

9.5.2 **BioNTech's Training Obligations.** Utilizing the Pfizer Training Materials where applicable, BioNTech or its Affiliates, at its cost and risk, will adapt (as necessary or desirable to address local requirements or customs and market strategies and needs) and design training materials, for use in particular countries within the BioNTech Commercialization Territory (as so adapted and designed, the "BioNTech Training Materials"). BioNTech shall ensure that the BioNTech Training Materials shall be in compliance with applicable Law, consistent with the applicable Regulatory Approvals for the Product and, except where necessary to comply with applicable Law, not be inconsistent with the global Commercialization strategy for the Product established by the JCC as reflected in the Global Commercialization Plan. Utilizing such BioNTech Training Materials, BioNTech will be responsible, at its own cost and risk, for preparing and delivering training to its PSRs and Sales Managers with respect to the Product and the detailing thereof. Such training shall occur (a) prior to the provision by such PSR or Sales Manager of any detailing or promotional activities with respect to the Product and (b) periodically thereafter in each country in the BioNTech Commercialization Territory as is consistent with BioNTech's practices for periodic training of its Sales Managers and PSRs or as may be otherwise needed to update such training based on new information.

9.5.3 **Promotional Materials.** All written sales, promotion and advertising materials relating to the Product, and other media and materials used to promote the Product or educate the

public regarding the Product or any indication treated with the Product (collectively and including translations, "Promotional Materials") will be prepared by Pfizer for the Pfizer Commercialization Territory (the "Pfizer Promotional Materials") and by BioNTech for the BioNTech Commercialization Territory (the "BioNTech Promotional Materials") and, Pfizer or BioNTech, as applicable, will determine, in its discretion, but subject to the requirements set forth below in this Section 9.5.3 and in Section 9.12, the content, the quantity and the method of distribution of all such Promotional Materials within its respective Commercialization Territory. All such Promotional Materials prepared by a Party shall (a) be owned (as to Copyright) by such Party; (b) not be inconsistent with the global messaging platform approved by the JCC as reflected in the Global Commercialization Plan (c) be in compliance with the applicable Regulatory Approval(s) for the Product and applicable Law, and (d) be reviewed and approved for use in a manner consistent with such Party's normal procedures for reviewing and approving promotional materials for its other Products, consistently applied (or in the case of BioNTech in accordance with procedures consistent with applicable Laws and industry standards for review and approval of promotional materials for pharmaceutical and vaccine products), and in any event, in accordance with procedures to ensure that such Promotional Materials meet the requirements set forth in clauses (b) and (c) above. Pfizer and BioNTech shall coordinate to ensure there is consistency of approach by BioNTech of its Promotional Materials for Germany compared with Pfizer's Promotional Materials for the rest of the EU. In connection with the performance of its Commercialization Activities in each country of the Pfizer Commercialization Territory, Pfizer will and will cause its Affiliates and Representatives, including Pfizer's sales managers and PSRs, to use only the Pfizer Promotional Materials provided by Pfizer for use in such country and to not use such Pfizer Promotional Materials for any other purposes other than its Commercialization Activities under this Agreement. In connection with the performance of its Commercialization Activities in each country of the BioNTech Commercialization Territory, BioNTech will and will cause its Affiliates and Representatives, including BioNTech's sales managers and PSRs, to use only the BioNTech Promotional Materials provided by BioNTech for use in such country and to not use such Pfizer Promotional Materials for any other purposes other than its Commercialization Activities under this Agreement. On an item-by-item and country-by-country basis, and upon the written request of BioNTech and with Pfizer's prior written approval (such approval not to be unreasonably withheld or delayed), Pfizer hereby licenses BioNTech to use, reproduce, copy, modify, distribute and display such Pfizer Promotional Materials in accordance with this Agreement and compliance with applicable Law, *provided* that BioNTech will not use such Pfizer Promotional Materials for any other purposes other than its Commercialization Activities under this Agreement. For clarity, BioNTech may combine requests for Pfizer's approval for the use of several items in various countries in one written request.

9.6 Pricing, Reimbursement and Market Access.

9.6.1 **Guidelines.** The JCC shall establish a global pricing strategy, launch sequencing and a range of suggested prices and any discount strategies, rebates or managed entry strategies, which price ranges and strategies may differ by region or country, for each Product in the Territory (collectively, the "Pricing and Reimbursement Guidelines") which will be submitted by the JCC to each of the Parties as recommended but non-binding guidance. All sales of Product shall be made in accordance with the applicable Pricing and Reimbursement Guidelines [\*\*\*].

9.6.2 **Pricing Meetings, Submissions & Negotiations.** Subject to Section 8.2, the Commercializing Party having rights to Commercialize in a specific country or region of its Commercialization Territory will be solely responsible for conducting all meetings and negotiations with, and the preparation of all materials and submissions for, national and local Governmental Authorities, health insurance providers (e.g., managed care, sickness fund), retail and hospital pharmacies, other formulary segments (e.g., sub-national and local payors) and other Third Party payors relating to any pricing, tenders, direct procurement contracts, inclusion on formularies, coverage or reimbursement with respect to Products in each such country or region, and shall have the right to hold in its name and control all applications, registrations, licenses, authorizations, approvals required for such purposes. All such pricing meetings, submissions and negotiations shall be planned and conducted by each Party in compliance with applicable Law, Anti-Corruption Laws, applicable pharmaceutical industry guidelines, applicable Internal Compliance Codes and Party Specific Regulations.

9.7 **Purchase Agreements with Governmental Authorities.**

9.7.1 After the Amendment Signing Date, in negotiating any agreement with a Governmental Authority for such Government Authority to purchase the Product, [\*\*\*] such Party will notify and promptly meet to discuss with the other Party the results of such negotiation prior to concluding and entering into such agreement.

9.7.2 In any event, prior to entering into any agreement with any Government Authority in a Major Market Country after the Amendment Signing Date, for such Governmental Authority to purchase or have purchased from the Party negotiating such agreement or for such Party to otherwise supply Product to such Governmental Authority, to the extent permitted and provided the receiving Party has the necessary security and infrastructure in place as may be required by the Governmental Authority (provided that, where permitted, such security and infrastructure requirement shall be communicated to the receiving Party by the negotiating Party in writing reasonably in advance of any need for such security and infrastructure by the receiving Party), the applicable Party negotiating such agreement shall make a substantially negotiated draft version of such agreement available to the other Party for review and comment, and that other Party shall make available its comments (if any) to any such draft agreement to the Party negotiating such purchasing or supply agreement within [\*\*\*] of its receipt of such draft agreement. The Party negotiating such purchasing or supply agreement shall consider the other Party's comments in good faith when finalizing its negotiation of such purchasing or supply agreement with such Government Authority. In addition, each Party shall promptly submit to the other Party a copy of any such purchasing or supply agreement concluded with any Government Authority prior to the Amendment Signing Date to the extent permitted under such agreement (and, where required, shall use good faith efforts to obtain relevant consents of the Government Authority to allow such sharing of such agreement). Notwithstanding the provisions of Section 12.1, the Party receiving any agreements with Government Authorities that are provided pursuant to this Section 9.7, including any drafts provided hereunder, shall treat such agreements as the providing Party's Confidential Information and shall hold such agreements, including any drafts provided hereunder, strictly confidential in perpetuity and shall only disclose those aspects of such agreements to those Representatives of the receiving Party having a need to know.

9.8 Product Packaging Configurations. The Parties shall each provide to the JCC current information regarding their respective Product Shipping and Storage Costs associated with all current and proposed Packaging Configurations for which they are responsible. [\*\*\*]

9.9 Product Orders; Invoicing; Distribution and Sales. With respect to Product in each country of a Party's Commercialization Territory, the applicable Commercializing Party will have sole control and responsibility with respect to (a) receiving orders and order processing, including, rejection or acceptance and fulfillment of orders, (b) invoicing, (c) collection and receivables, (d) distribution and (e) effecting all sales of Product in the Commercialization Territory (provided that the foregoing shall not prevent or be breached by the unsolicited supply of Product by one Party from an EU country within its Commercialization Territory to an EU country outside of its Commercialization Territory in response to an unsolicited order).

9.10 Returns. With respect to Product in each country of a Party's Commercialization Territory, the applicable Commercializing Party will have sole control and, subject to Sections 9.2.2, 9.3.1.2 and 9.3.2.2, responsibility with respect to handling all returns of the Product and destruction of non-saleable or returned Product. Any and all costs associated with returns of Product, including accruals for returns of the Product sold during the Term will be included as a deduction from gross sales in the calculation of Net Sales pursuant to Section 4.9.2.

9.11 Recalls and Withdrawals. In the event that either Party believes that a recall or withdrawal of a Product is advisable in any country of the Territory, it shall promptly consult with the other Party with respect thereto. After such consultation, Pfizer will have the sole right and authority to make any decision to initiate a recall or withdrawal of the Product in any country of the Pfizer Commercialization Territory and BioNTech will have the sole right and authority to make any decision to initiate a recall or withdrawal of the Product in any country of the BioNTech Commercialization Territory, *provided, however*, that in each such case, with respect to (a) any lot or batch of Product manufactured by a Party, its Affiliates or any of their respective subcontractors, in the event that such Party, after consultation with the other Party, determines that such lot or batch of Product should be recalled in one or more countries of the other Party's Commercialization Territory, it shall so notify such other Party and such other Party shall promptly institute a recall of such lot or batch of such Product, and (b) if the Party that is the MA Holder in a country in the other Party's Commercialization Territory determines in good faith, after consultation with the other Party and its legal counsel, that a recall is required in such country by applicable Law, it shall so notify such other Party and such other Party shall promptly institute a recall. Subject to the foregoing and Sections 9.2.2, 9.3.1.2, 9.3.2.2 and 16.3, the Commercializing Party will have sole control, responsibility and discretion with respect to implementing any and all such recalls or withdrawals in each country of such Party's Commercialization Territory, *provided* that where the Recall Costs are to be borne by the other Party the Commercializing Party shall use Commercially Reasonable Efforts to mitigate any such Recall Costs. The Recall Costs of any such recall or withdrawal will be borne by BioNTech, except to the extent that the recall or withdrawal of Product is attributable to the (i) breach or default of Pfizer or its Affiliates or any of its or their Representatives under this Agreement or in its Manufacturing, handling or storing of the Product that is the subject of the recall or withdrawal, or (ii) negligence or willful misconduct of Pfizer, its Affiliates or any of its or their Representatives, in which event Pfizer will if such recall or withdrawal is in a country in the Pfizer Commercialization Territory, bear or, if such recall or withdrawal is in a country in the BioNTech Commercialization Territory, reimburse BioNTech and its Affiliates for such Recall Costs. If there is any



recall or withdrawal, then the Commercializing Party will implement any necessary action, and the other Party will provide any and all assistance as reasonably requested by the Commercializing Party.

9.12 Co-branding. As of the Amendment Signing Date, the Parties agree on the following co-branding provisions to govern the future use of the Pfizer House Mark and BioNTech House Mark:

Where permitted by applicable Law and consistent with the applicable Regulatory Approval, subject to Section 11.9.4, the Parties shall include on (a) Product Packaging and Labeling for the Product in the Territory, (b) all Promotional Materials to be distributed in the Territory by the Commercializing Party's Sales Managers and PSRs and (c) those Medical Education Materials related solely to the Product to be distributed in the Territory by the Commercializing Party's MSLs (the materials described in each of (a), (b) and (c), the "Commercialization Materials"), both the Pfizer House Mark and the BioNTech House Mark, with both House Marks being clearly visible to the customer and having equal prominence; *provided that*:

9.12.1 with respect to Commercialization Materials distributed in connection with the Product Commercialized under an Emergency Use Authorization issued by the FDA or by a Regulatory Authority in reference to the Emergency Use Authorization issued by the FDA, then on a country by country basis:

(a) [\*\*\*]; and

(b) [\*\*\*];

9.12.2 [\*\*\*]

9.12.3 [\*\*\*].

[\*\*\*]

9.13 Vaccine Technical Committees. Pfizer shall have the right to seek all recommendations for use of the Product from the applicable Vaccine Technical Committees throughout the Pfizer Commercialization Territory and BioNTech shall have the sole right to seek all recommendations for use of the Product from the applicable Vaccine Technical Committees throughout the BioNTech Commercialization Territory.

9.14 Diligence and Performance Standards. Each Party's obligations to Commercialize the Product in its respective Commercialization Territory (and to undertake any Medical Activities in its respective Commercialization Territory) [\*\*\*]. For clarity, [\*\*\*], provided that a Party's Commercialization Activities or Medical Activities in such country shall remain subject to this Article 9 and Article 10, including compliance with all applicable Laws, including Anti-Corruption Laws and provided further that if one Party does not actively Commercialize the Product in any such country which is part of its Commercialization Territory, the other Party may, through written notice to such Party, notify such Party that it desires to discuss taking over Commercialization in such country and, in such event, the Parties shall discuss in good faith whether such country shall be added to the Commercialization Territory of the other Party; *provided that* the Party that is entitled to Commercialize in such Commercialization Territory shall have no obligation to agree to add such country to the Commercialization Territory of the

other Party. Notwithstanding the foregoing, the Parties acknowledge the provisions of Section 4.15 and that neither Party guarantees the success of the Product.

9.15 **Management of Representatives.** Each Party will have sole authority and responsibility for recruiting, hiring, managing, compensating (including paying for all benefits, wages, special incentives, workers' compensation and employment taxes), disciplining, terminating the employment of and otherwise controlling the Representatives provided or engaged by or on behalf of such Party or its Affiliates for performance of its Commercialization Activities and other obligations under this Agreement; *provided that* all such Representatives will be, to the extent relevant to the activities to be performed by such Representatives, subject to written obligations of confidentiality and invention assignment substantially consistent with the relevant provisions of this Agreement prior to, and as a condition of, such Representatives performing any such Commercialization Activities, *provided, further*, that to the extent that ownership of all relevant inventions of such Representative vests in such Party or its Affiliates, no such written obligation of invention assignment are required. Each Party will respectively provide for the day-to-day management of its or its Affiliates' Sales Managers, PSRs, MSLs and other Representatives involved in any Commercialization Activities, including furnishing administrative support, financial resources, equipment and supplies.

## 10. **MEDICAL AFFAIRS**

10.1 **Global Medical Activities.** The Parties shall, but only using Commercially Reasonable Efforts in accordance with its obligations pursuant to Section 9.14, undertake their respective global medical activities [\*\*\*] ("Global Medical Activities"). The medical affairs section of the Global Commercialization plan will address medical strategies and guidelines; *provided, however*, that each Party will have final say on its own Global Medical Activities. A copy of any article or abstract that relates directly to the Product which has been published in a scientific, medical, academic or industry publication by either Party under its Medical Activities for its respective Commercialization Territory shall be provided to the respective other Party after its publication. All such Global Medical Activities shall be planned and conducted by each Party in compliance with applicable Law, applicable pharmaceutical industry guidelines, applicable Internal Compliance Codes and Party Specific Regulations. Each Party will bear its own internal costs associated with planning, conducting and attending any such Global Medical Activities.

### 10.2 **Medical Science Liaisons.**

10.2.1 **BioNTech Medical Science Liaisons.** In each country of the BioNTech Commercialization Territory where BioNTech determines the use of MSLs are appropriate in connection with the Product, BioNTech shall, at its sole cost and using its Commercially Reasonable Efforts, provide and maintain MSLs to engage in MSL Activities pertaining to the Product in such country, each in accordance with the medical portion of the applicable Global Commercialization Plan and the applicable Annual Regional Commercialization Plan, if any, for such Commercialization Region. Each such BioNTech MSL may be either a full-time or a part-time employee of BioNTech or its Affiliates or an employee of a Third Party company or agency that provides temporary employees to BioNTech or its Affiliates pursuant to a contract between BioNTech or its Affiliate and such Third Party company or agency and in each case, such BioNTech MSL will remain exclusively under the authority of BioNTech or its Affiliate and be subject to all required training and Compliance requirements.

10.2.2 **Pfizer Medical Science Liaisons.** In each country of the Pfizer Commercialization Territory where Pfizer determines the use of MSLs are appropriate in connection with the Product, Pfizer shall, at its sole cost, but only using Commercially Reasonable Efforts in accordance with its obligations pursuant to Section 9.14, provide and maintain MSLs to engage in MSL Activities pertaining to the Product in such country, each in a manner not inconsistent with the medical portion of the applicable Global Commercialization Plan and the applicable Annual Regional Commercialization Plan, if any, for such country. Each such Pfizer MSL may be either a full-time or a part-time employee of Pfizer or its Affiliates or an employee of a Third Party company or agency that provides temporary employees to Pfizer or its Affiliates pursuant to a contract between Pfizer or its Affiliate and such Third Party company or agency and in each case, such Pfizer MSL will remain exclusively under the authority of Pfizer or its Affiliate and be subject to all required training and Compliance requirements.

10.2.3 **MSL Activities.** Each Party will, and will cause its respective Affiliates to, ensure that, in each country within its Commercialization Territory, the activities of such Commercializing Party's MSLs are (i) aligned with guidelines established by the applicable Commercializing Party across its product portfolio, consistently applied (*e.g.*, related to internal and external interactions), or if the Party does not have such guidelines, then consistent with industry standards for such governing MSL Activities, and (ii) not inconsistent with the global medical strategy for the Product as set forth in the medical portion of the applicable Global Commercialization Plan or the medical strategy for the Product in such country as set forth in the applicable Annual Regional Commercialization Plan. Each Party will, and will cause its Affiliates to, ensure that, in each country within its Commercialization Territory, its MSLs only use Medical Education Materials approved by the applicable Commercializing Party for use in such country.

10.3 **Training and Medical Education Materials.**

10.3.1 **Pfizer's Training Obligations.** Pfizer or its Affiliates, at its cost and risk, will develop training materials for its MSLs, for use in particular countries within the Pfizer Commercialization Territory (the "Pfizer Medical Training Materials"). The Pfizer Medical Training Materials shall be in compliance with applicable Law, consistent with the applicable Regulatory Approvals for the Product and, except where necessary to comply with applicable Law, not be inconsistent with the global medical strategy for the Product established by the JCC as reflected in the medical affairs section of the Global Commercialization Plan. Utilizing such Pfizer Medical Training Materials, Pfizer will be responsible, at its own cost and risk, for preparing and delivering training to its MSLs with respect to the Product. Such training shall occur (a) prior to the provision by such MSL of any MSL Activities with respect to the Product and (b) periodically thereafter in each country in the Pfizer Commercialization Territory as is consistent with Pfizer's practices for periodic training of its MSLs or as may be otherwise needed to update such training based on new information. Pfizer will share, at BioNTech's risk, such Pfizer Medical Training Materials (to the extent such materials are solely related to the Product) for BioNTech's use, subject to Section 10.3.2, in the BioNTech Commercialization Territory; *provided, however*, that Pfizer shall not be liable to BioNTech for any inaccuracy or error in the Pfizer Medical Training Materials.

10.3.2 **BioNTech's Training Obligations.** BioNTech or its Affiliates, at its cost and risk, will develop (as necessary or desirable to address local requirements or customs and medical strategies and needs) and design training materials, for use in particular countries within the

BioNTech Commercialization Territory, including by adapting and modifying the Pfizer Medical Training Material (the "BioNTech Medical Training Materials"). BioNTech shall ensure that the BioNTech Medical Training Materials shall be in compliance with applicable Law, consistent with the applicable Regulatory Approvals for the Product and, except where necessary to comply with applicable Law, not be inconsistent with the global medical strategy for the Product established by the JCC as reflected in the medical affairs section of the Global Commercialization Plan. Utilizing such BioNTech Medical Training Materials, BioNTech will be responsible, at its own cost and risk, for preparing and delivering training to its MSLs with respect to the Product. Such training shall occur (a) prior to the provision by such MSL of any MSL Activities with respect to the Product and (b) periodically thereafter in each country in the BioNTech Commercialization Territory as is consistent with BioNTech's practices for periodic training of its MSLs or as may be otherwise needed to update such training based on new information.

10.3.3 **Communication with MSLs.** Subject to this Section 10.3, each Party will, directly or through its Affiliates, have full and sole responsibility for the dissemination of all information regarding the Product to its MSLs.

10.3.4 **Medical Education Materials.** All written medical educational materials to be provided to healthcare professionals relating to any condition treated with the Product, and other media and materials used to educate the public regarding the Product or any indication treated with the Product (collectively and including translations, "Medical Education Materials") will be prepared by Pfizer for use in the Pfizer Commercialization Territory and by BioNTech for use in the BioNTech Commercialization Territory. Subject to applicable Law, Pfizer will determine the content, quantity and method of distribution of all such Medical Education Materials and other Pfizer Commercial Materials for use in the Pfizer Commercialization Territory in its sole discretion and BioNTech will determine the content, quantity and method of distribution of all such Medical Education Materials and other BioNTech Commercial Materials for use in the BioNTech Commercialization Territory in its sole discretion, provided that, in each case, all such Medical Education Materials and Pfizer Commercial Materials or BioNTech Commercial Materials, as applicable, will be in compliance with applicable Law. Pfizer and BioNTech each will provide the other copies of the Medical Education Materials it prepares, and the other Party shall be free to utilize all or part of such Medical Education Materials in the design of the Medical Education Materials it will prepare solely for use in and distribute solely by its or its Affiliates' MSLs and other employees, as permitted by applicable Law and such Party's Internal Compliance Codes, in its Commercialization Territory. Each of Pfizer and BioNTech will, and will cause its respective Affiliates and its and their respective Representatives, including each MSL and other Representative to, as applicable, (a) use all Pfizer Commercial Materials solely in connection with Pfizer's MSL Activities under this Agreement, (b) use all BioNTech Commercial Materials solely in connection with BioNTech's MSL Activities under this Agreement, (c) not create or modify, distribute or use sales, promotion or any other material relating to the Product other than the Medical Education Materials or other approved materials per each respective Party's Compliance policies, and requirements under local labeling, Regulatory Approval and applicable Law.

10.4 **Unsolicited Medical Requests.** Pfizer will have the exclusive right to respond to all Unsolicited Medical Requests received from HCPs, patients, payors or other customers in the Pfizer Commercialization Territory and BioNTech will have the exclusive right to respond to all Unsolicited Medical Requests received from HCPs, patients, payors or other customers in the BioNTech

Commercialization Territory. In the event a Commercializing Party or its Representatives receives an UMR from an individual within and concerning a country in the other Commercializing Party's Commercialization Territory, such Commercializing Party (i) will log all Unsolicited Medical Requests it or any of its Representatives receives in accordance with its respective policies and procedures in effect in each country within its Commercialization Territory, (ii) will, and will use Commercially Reasonable Efforts to cause its respective Affiliates and their respective Representatives to, communicate promptly to the other Party all UMRs so received concerning that other Party's Commercialization Territory, by contacting the other Party's medical information function in the applicable country, and (iii) to the extent practicable, shall refer the individual making such Unsolicited Medical Request to the other Party for response in accordance with referral instructions that such other Party has previously provided and that are then in effect. The applicable RCC for each such country or if there is no RCC for such country, the Party in whose Commercialization Territory such country is located, will be responsible for reviewing such policies and procedures related to logging UMRs as well as determining the manner by which a Party will communicate UMRs to the other Party as provided above, including points of contact for each such country. If any gaps or significant differences between the applicable policies and procedures of BioNTech and Pfizer related to the logging of UMRs in a given country are identified, then each Party will promptly consult with applicable internal personnel and each other to determine how such policies and procedures are to be reconciled. Each party will share analytics such as inquiry volumes and topics on a monthly basis or other mutually agreed upon timeframe.

10.5 **Medical Information Content.** Pfizer shall be responsible for preparing all medical information standard response documents, content and frequently asked questions (FAQs) documents to be used in the context of the Commercialization of the Product or Product Materials in the Territory (such medical information individually or collectively, "Medical Information Content") and shall make such Medical Information Content available to BioNTech within [\*\*\*], [\*\*\*].

10.6 **Medical Affairs Studies.** Either Party shall have the right, at its own expense, to plan, design, recruit, monitor and conduct studies (other than Clinical Trials) relating to the Product, including surveillance studies, epidemiological studies, or other non-interventional studies where the effectiveness of the Product is not an endpoint nor are such studies used to support Regulatory Approval of the Product or expansion of the Product label ("Medical Affairs Studies"), *provided* that (i) such study shall be conducted in compliance with applicable Law and all applicable Professional Requirements and (ii) solely to the extent that data arising from any such study is of application exclusively to the Product, such data shall be owned by BioNTech, and Pfizer shall make such data available to BioNTech upon completion of the relevant study, and Pfizer shall be free to use and sublicense (through multiple tiers) such data (on a royalty free and irrevocable basis) for any purpose. The Party conducting such studies shall keep the other Party reasonably informed regarding the results of all such studies. In the event that the other Party desires to use the data from any such study in the Commercialization of the Product in its Commercialization Territory, the Parties shall discuss in good faith a cost-sharing arrangement with respect to costs of such studies in consideration for a license to use such data from such study.

## 11. **INTELLECTUAL PROPERTY**

11.1 **Patent Committee.** Within the first [\*\*\*] following the Effective Date, or as otherwise agreed by the Parties, the Parties will establish a patent committee (the "Patent Committee"), comprised of at least [\*\*\*] of BioNTech and at least [\*\*\*] of Pfizer (which [\*\*\*] may be replaced by either Party at any time through written notice to the other Party). The Patent Committee shall coordinate all activities in

relation to Patent Rights applicable to the terms of this Agreement. In particular, the Patent Committee shall:

- 11.1.1 coordinate all activities in relation to the filing and prosecution of Patent Rights relating to this Agreement pursuant to Sections 11.2.1 and 11.3.1 of this Agreement,
- 11.1.2 discuss any actual, potential or suspected infringement of such Patent Rights pursuant to Section 11.4.1,
- 11.1.3 regularly review which BioNTech Patent Rights may be relevant to Candidates and Products; and
- 11.1.4 discuss and consider any potential Future License, including in meetings where relevant attorneys and business personnel of the Parties are invited to participate in such discussions and considerations, *provided* that the decision for any agreement to become a Future License shall only be made on mutual agreement by the Parties.

11.1.5 The Patent Committee shall meet (either in-person or by audio or video conference) as often as determined by the Patent Committee as well as upon the reasonable request of either Party. It is acknowledged that particularly in the case of any Enforcement Action the Patent Committee may need to meet at very short notice and be required to expedite and make decisions very quickly and the Parties shall procure that the Patent Committee shall meet urgently as quickly as reasonably required in connection with any Enforcement Action. The Patent Committee will be chaired by a Patent Committee member chosen by mutual agreement. The Patent Committee shall operate in good faith and acting reasonably. Sections 6.3.2 and 6.3.3, unless otherwise mutually agreed between the Parties, shall apply *mutatis mutandis*. The Patent Committee will use good faith efforts to reach agreement on all matters properly brought before it. If, despite such good faith efforts, the Patent Committee is unable to reach unanimous agreement on a particular matter, such matter shall be escalated to the JSC for final resolution and decisions of the JSC in this regard must be made by unanimous consent.

11.2 Ownership of Intellectual Property.

- 11.2.1 **Ownership of Product Technology.** [\*\*\*]
- 11.2.2 **Ownership of BioNTech Improvements and Pfizer Improvements.** As between the Parties, (a) BioNTech will own all BioNTech Improvements and (b) Pfizer will own all Pfizer Improvements.
- 11.2.3 **Ownership of other Research and Development Program Technology.** Except for BioNTech Improvements, Pfizer Improvements and [\*\*\*], the ownership of other Research and Development Program Technology, will be allocated based on inventorship as defined under the Laws of the United States. Notwithstanding the foregoing, during the Term, and without prejudice to Section 11.3 the Parties (through the Patent Committee) shall cooperate and discuss in good faith with respect to the timing, scope and filing of any Patent Rights claiming or disclosing any Research and Development Program Technology.
- 11.2.4 **Ownership of Joint Technology.** Subject to Section 11.2.1, 11.2.2 and 11.2.3, the Parties will jointly own any Joint Technology. Subject to (a) the grant of licenses or sublicenses

under Section 3, (b) BioNTech's representations, warranties and covenants under Section 13 and (c) the Parties' other rights and obligations under this Agreement (including Section 3.11), each Party will be free to exploit, either itself or through the grant of licenses to Third Parties (which Third Party licenses may be further sublicensed), Joint Technology throughout the world without restriction, without the need to obtain further consent from or provide notice to the other Party, and without any duty to account or otherwise make any payment of any compensation to the other Party.

11.2.5 **Ownership of Other Intellectual Property.** Except as set forth in Sections 11.2.1, 11.2.2, 11.2.3 and 11.2.4, each Party will own all right, title and interest in and to any and all Know-How, Patent Rights or other Intellectual Property Rights that such Party owns as of the Effective Date or otherwise develops, creates or acquires pursuant to activities under this Agreement during the Term. For the purposes of determining ownership under this Agreement, as applicable, inventorship will be determined in accordance with United States patent laws.

11.3 **Patent Rights.**

11.3.1 Filing, Prosecution and Maintenance of Patent Rights.

11.3.1.1 *Prosecution by BioNTech.* BioNTech will have the first right, and a Commercially Reasonable Efforts obligation, to file, Prosecute and Maintain the BioNTech Patent Rights owned by BioNTech or its Affiliates and any Product Patent Rights, and Patent Rights claiming BioNTech Improvements (together the "BioNTech Prosecution Patent Rights") at BioNTech's sole expense using counsel of its own choice reasonably acceptable to Pfizer in Australia, Canada, the member states of the European Patent Convention including the Major EU Market Countries, Japan, the United States, Brazil, Russia, India, Mexico and South Korea ("Key Patent Jurisdictions"). Upon request of Pfizer, BioNTech shall file one or more BioNTech Prosecution Patent Rights in one or more jurisdictions other than the Key Patent Jurisdictions ("Additional Patent Jurisdictions"), and BioNTech will have the first right, and a Commercially Reasonable Efforts obligation, to file, Prosecute and Maintain such BioNTech Prosecution Patent Rights in such Additional Patent Jurisdictions at Pfizer's sole expense (until such time as Pfizer elects not to maintain such Patent Rights in such Additional Patent Jurisdictions whereupon BioNTech can elect to abandon or surrender the same or to continue the Prosecution and Maintenance of such Patent Rights at its own expense) using counsel of its own choice reasonably acceptable to Pfizer. BioNTech will keep Pfizer advised on the status of the preparation, filing, prosecution, and maintenance of the Patent Rights included within BioNTech Prosecution Patent Rights in all the jurisdictions where filed. Further, in respect of any jurisdiction, BioNTech will (a) allow Pfizer a reasonable opportunity and reasonable time to review and provide comments to BioNTech's patent counsel regarding relevant substantive communications to BioNTech and drafts of any responses or other proposed substantive filings by BioNTech before any applicable filings are submitted to any relevant patent office (or Governmental Authority) with respect to any BioNTech Prosecution Patent Rights and (b) reflect any reasonable and timely comments offered by Pfizer in any final filings submitted by BioNTech to any relevant patent office (or Governmental Authority) with respect to any BioNTech Prosecution Patent Rights. If BioNTech elects not to file a Patent Right included in the BioNTech Prosecution Patent

Rights in any Key Patent Jurisdiction or Additional Patent Jurisdiction or elects to cease the prosecution or maintenance of one or more Patent Rights included in the BioNTech Prosecution Patent Rights in any Key Patent Jurisdiction or Additional Patent Jurisdiction and, as relevant, no Third Party has agreed to continue the prosecution or maintenance of such Patent Rights under agreements concluded before the Effective Date, BioNTech will provide Pfizer with written notice of its decision not to file, not to Prosecute and Maintain not less than [\*\*\*] before any action is required to avoid abandonment or lapse. In the event of any such notice, if Pfizer elects to file or continue such prosecution or maintenance in the name of BioNTech at Pfizer's sole expense, (x) Pfizer shall be entitled to do so and take all steps in such Prosecution and Maintenance at its sole discretion; (y) BioNTech will reasonably cooperate to promptly transfer the necessary files and execute the necessary forms regarding such transfer and (z) Pfizer will keep BioNTech advised on the status of such filing, Prosecution and Maintenance and will reasonably consider any comments made by BioNTech in connection therewith. If Pfizer elects not to file or continue such prosecution or maintenance, then BioNTech may immediately abandon, allow to lapse, or omit to prosecute such Patent Right, as the case may be. BioNTech will promptly, and no later than [\*\*\*] after written request by Pfizer, by written notice to Pfizer update Schedule 13.3.4 to identify all BioNTech Patent Rights to be added thereto.

11.3.1.2 *Other Patent Rights.* Except as provided in Section 11.3.1.1, each Party will have the sole right, but not the obligation, to file, Prosecute and Maintain the Research and Development Program Patent Rights or other Patent Rights that it solely owns under this Agreement or to which it otherwise has control of prosecution rights in its sole discretion, provided that at a Party's reasonable request, the other Party will provide status or other requested information for any Research and Development Program Patent Right and will consider in good faith any recommendations made by such Party in regard to the filing, prosecution or maintenance of any such Patent Right.

11.3.1.3 *Reference of Research and Development Program Know-How.* If a Party chooses to file, and thereafter Prosecute and Maintain, Patent Rights after the expiration of the Term, including any extension to the Term, that Party may use or incorporate Research and Development Program Know-How in the filing or prosecution of such Patent Rights filed after the Term, if it determines in its sole discretion that it is necessary or useful to use or incorporate such Research and Development Program Know-How.

11.3.2 **Joint Patent Rights.** In the event the Parties make any Joint Know-How, the Parties will promptly meet to discuss and determine, based on mutual consent, whether to seek patent protection thereon. Neither Party will file any Joint Patent Right without mutual consent. Unless otherwise agreed between the Parties, if the Parties decide to seek patent protection for any Joint Know-How: (a) BioNTech will have the first right, but not the obligation, to prepare, file, Prosecute and Maintain any Joint Patent Right predominantly relating to the RNA Technology or RNA Process Technology throughout the world, and (b) Pfizer will have the first right, but not the obligation, to prepare, file, Prosecute and Maintain any other Joint Patent Right throughout the world, in each case of (a) and (b) with the respective provisions of Section 11.3.1.1 to apply *mutatis mutandis* except as provided in this Section 11.3.2. The non-filing Party will reimburse the filing Party for 50% of the costs reasonably incurred by the filing Party in preparing, filing, prosecuting and maintaining such Joint Patent Rights, which reimbursement will be made pursuant to, and



within 75 days of, invoices (including supporting documentation) submitted by the filing Party to the non-filing Party no more often than once per Pfizer Quarter. The non-prosecuting Party will cooperate with the prosecuting Party in taking reasonable measures to control costs and non-prosecuting Party shall be responsible for 100% of (x) any fees or costs related to any correspondence of outside counsel with or instructions to outside counsel by such Party (or any of such Party's Representatives) which is independent of joint prosecution efforts, or (y) any patent office fees, and associated counsel/agent fees and costs, for extensions which are not incurred at the request of, and not due to the actions of, the prosecuting Party. If, once the Parties have agreed to prepare and file an application of Joint Patent Rights, either Party (the "Declining Party") at any time thereafter declines to participate in the preparation, filing, prosecution or maintenance of any Joint Patent Right or share in the costs of filing, prosecuting and maintaining any Joint Patent Right, on a country-by-country basis, the Declining Party will provide the other Party (the "Continuing Party") with 30 days prior written notice to such effect, in which event, the Declining Party will (A) have no responsibility with respect to the filing, prosecution or maintenance of the applicable Joint Patent Right after the end of such 30 day period, (B) have no responsibility for any expenses incurred in connection with such Joint Patent Right after the end of such 30 day period and (C) if the Continuing Party elects to continue filing, prosecution or maintenance, the Declining Party, upon the Continuing Party's request, will execute such documents and perform such acts, at the Continuing Party's expense, as may be reasonably necessary (1) to assign to the Continuing Party all of the Declining Party's right, title and interest in and to such Joint Patent Right and (2) to permit the Continuing Party to file, Prosecute and Maintain such Joint Patent Right at its sole expense. Where such Joint Patent Right is assigned to Pfizer as the Continuing Party, BioNTech will retain a non-exclusive, sublicensable, perpetual, irrevocable, royalty-free, fully paid-up worldwide right and license to practice and exploit such Patent Right for any and all purposes excluding, during the Term, in the Field; and where such Joint Patent Right is assigned to BioNTech as the Continuing Party, it will be excluded from the definition of BioNTech Patent Rights, and Pfizer will retain a non-exclusive, sublicensable, perpetual, irrevocable, royalty-free, fully paid-up worldwide right and license to practice and exploit such Joint Patent Right for any and all purposes.

11.3.3 **Prosecution by Third Party Licensors.** Except in the ordinary course of filing continuation applications, BioNTech shall not decline to pay for or participate in the filing, prosecution or maintenance of any Patent Right under any BioNTech Third Party Agreement in any Key Patent Jurisdiction (or other country to the extent doing so may result in BioNTech's loss of license to such Patent Right in such country), to the extent BioNTech is obligated to pay for, or has the right to participate in, such filing, prosecution or maintenance, that is included in the BioNTech Patent Rights and that, in Pfizer's reasonable opinion, covers any Candidate, Product or [\*\*\*] in the Field in the Territory, and the loss of which would result in loss of right to or would materially diminish the overall protection of such Candidate or Product, without Pfizer's prior written consent, not to be unreasonably withheld or delayed.

11.3.4 **Patent Term Restoration and Extension.** Upon the request of either Party, the Parties will (through the Patent Committee) reasonably discuss patent term extension and supplemental protection certificate strategies in relation to Patent Rights Covering Candidates or Products at any time. Notwithstanding the above, within the time period specified by applicable Law upon receiving Regulatory Approval for a Product in any country in the Territory, [\*\*\*].

11.3.5 **Clarifications.** For clarity, prosecution under this Section 11.3 includes opposition, revocation and post-grant review proceedings before the granting patent office or other patent office proceedings ("Prosecution Proceeding"). If such Prosecution Proceedings are concurrent with Third Party litigation under Section 11.4 and are applicable to or part of a coordinated enforcement of such rights, the prosecuting Party and the enforcing Party shall work together and closely align their prosecution and enforcement strategy in accordance with Section 11.5 (including the right for one Party to have final control as stipulated in Section 11.5).

11.3.6 **Liability.** To the extent that a Party is obtaining, Prosecuting or Maintaining a Patent Right or otherwise exercising its rights under this Section 11.3, such Party, and its Representatives, will not be liable to the other Party in respect of any act, omission, default or neglect on the part of any such Party, or its Representatives, in connection with such activities undertaken in good faith.

11.3.7 **Recording.** If either Party deems it necessary or useful to register or record this Agreement or evidence of this Agreement with any patent office or other appropriate Governmental Authority(ies) in one or more jurisdictions, the other Party will reasonably cooperate to execute and deliver to such Party any documents accurately reflecting or evidencing this Agreement that are necessary or useful, in such Party's reasonable judgment, to complete such registration or recordation.

11.3.8 **Joint Research Agreement.** This Agreement shall be understood to be a joint research agreement under 35 U.S.C. § 103(c)(3) for pre-AIA Patent Rights and 35 U.S.C. § 100(h) for post-AIA Patent Rights entered into for the purpose of researching, identifying and Developing Candidates and Products.

#### 11.4 Enforcement of Patent Rights.

11.4.1 **Notification of Infringement and Decision about Enforcement Actions.** Each Party will promptly notify the other (through the Patent Committee) in the event of any actual, potential or suspected infringement of a patent under the BioNTech Patent Rights or Research and Development Program Patent Rights by any Third Party. In the event of any such notification, the Parties will (through the Patent Committee) discuss in good faith the relevant actual, potential and suspected infringement and the risks and chances of success as well as chances of settlement connected with the institution of any litigation or other step to remedy infringement (any such steps, or threat of or assertion or enforcement of a Patent Right being an "Enforcement Action") taking into account the possible uses of the relevant Patent Rights by each Party, its respective Affiliates or its or their licensees and the revenues relating to or impacted by such Patent Rights, with the goal to agree on whether or not any Enforcement Action should be taken and, if yes, to closely coordinate so far as reasonably possible their respective efforts and strategies. The Parties acknowledge that time shall be of the essence in connection with any Enforcement Action and each shall move urgently and expeditiously to discuss and seek agreement on any actual or proposed Enforcement Action.

11.4.2 **Enforcement of BioNTech Patent Rights and Product Patent Rights.** Subject to Section 11.4.1, and unless otherwise agreed between the Parties on a case-by-case basis, as between Pfizer and BioNTech, BioNTech shall have the first right, but not the obligation, to institute any Enforcement Action in connection with the BioNTech Patent Rights [\*\*\*] in the Field

in the Territory (the "BioNTech Enforcement Patent Rights"), and any such Enforcement Action will be at BioNTech's expense including BioNTech indemnifying and holding harmless Pfizer and its Affiliates from and against any adverse cost award, where Pfizer or its Affiliates consent to join any such Enforcement Action upon BioNTech's request, or where required by Law or where Pfizer or its Affiliates are enjoined by the counterparty. BioNTech shall not name as a party Pfizer or its Affiliates in any Enforcement Action without Pfizer's prior written consent. In any event, BioNTech will not, without the prior written consent of Pfizer, enter into any compromise or settlement relating to such litigation that (a) admits the invalidity or unenforceability of any BioNTech Enforcement Patent Right or (b) requires BioNTech to abandon any BioNTech Enforcement Patent Right. Upon the request of BioNTech, Pfizer shall have the sole discretion to decide whether or not to join as a party in any such Enforcement Action, and where it elects to do so it shall, at BioNTech's expense, join and cooperate with BioNTech in such Enforcement Action. Pfizer will have the right to consult with, and provide comments to, BioNTech about such Enforcement Action (irrespective of Pfizer or its Affiliate being a party to such Enforcement Action), and to participate in and be represented by independent counsel in such Enforcement Action at Pfizer's own expense, and BioNTech shall take into account any reasonable comments provided by Pfizer in such Enforcement Action. Neither Party will incur any liability to the other Party (other than that related to a Party's indemnification obligation pursuant to Section 16) as a consequence of any Enforcement Action initiated or pursued pursuant to this Section 11.4 or any unfavorable decision resulting therefrom, including any decision holding any BioNTech Enforcement Patent Rights invalid or unenforceable. Any infringement recoveries resulting from such litigation or steps relating to a claim of Third Party infringement, after deducting BioNTech's out of pocket expenses (including counsel fees and expenses including any adverse cost award) in pursuing such claim, will be treated as Gross Profits for the purposes of this Agreement.

11.4.3 **Pfizer's Enforcement Rights.** In respect of an infringement of any BioNTech Enforcement Patent Right in the Field in the Territory in connection with a Competitive Product ("Competitive Product Infringement"), if, following (a) discussion of any potential Enforcement Action pursuant to Section 11.4.1 and (b) a subsequent written request by Pfizer to initiate any Enforcement Action in connection with such Competitive Product Infringement, BioNTech does not initiate any Enforcement Action in connection with such Competitive Product Infringement within thirty (30) days following receipt of such notices, or as soon as possible and in any event no later than ten (10) Business Days if preliminary injunction proceedings are a potential or likely recourse to remedy the infringement), or ten (10) days before the time limit, if any, set forth in the applicable Laws for the filing of such actions, Pfizer shall have the right, but not the obligation, in place of BioNTech to institute any Enforcement Action in connection with such Competitive Product Infringement and any such Enforcement Action will be at Pfizer's expense and the provisions set forth in the first paragraph of this Section 11.4.2 shall apply *mutatis mutandis*. Pfizer's rights with respect to an Enforcement Action for BioNTech Enforcement Patent Rights other than Product Patent Rights shall be limited to (i) Major Market Countries; (ii) Enforcement Actions in countries in which a Competitive Product (or part thereof) reasonably believed to be designated for any Major Market Country is Manufactured; and (iii) Enforcement Actions in Belgium, Ireland or the Netherlands that are in parallel with Enforcement Actions in any of the Major EU Market Countries. [\*\*\*]

11.4.4 **BioNTech Enforcement outside the Field and/or outside the Territory.** Subject to Section 11.4.1 and unless otherwise agreed between the Parties on a case-by-case basis, as

between Pfizer and BioNTech, BioNTech shall have the sole right, but not the obligation, to institute any Enforcement Action outside the Field and/or outside the Territory in connection with any BioNTech Enforcement Patent Rights), and any such Enforcement Action will be at BioNTech's expense including BioNTech indemnifying and holding harmless Pfizer and its Affiliates from and against any adverse cost award, where Pfizer or its Affiliates consent to join any such Enforcement Action upon BioNTech's request, where required by Law or where Pfizer or its Affiliates are enjoined by the counterparty. BioNTech shall not name as a party Pfizer or its Affiliates in any Enforcement Action without Pfizer's prior written consent. In any event, BioNTech will not, without the prior written consent of Pfizer, enter into any compromise or settlement relating to such Enforcement Action that (i) admits the invalidity or unenforceability of any BioNTech Enforcement Patent Rights or (ii) requires BioNTech to abandon any BioNTech Enforcement Patent Rights. Upon the request of BioNTech, Pfizer shall have the sole discretion to decide whether or not to join as a party in any such Enforcement Action, and where it elects to do so it shall, at BioNTech's expense, join and cooperate with BioNTech in such Enforcement Action. Pfizer will have the right to consult with, and provide comments to, BioNTech about such Enforcement Action (irrespective of Pfizer or its Affiliate being a party to such Enforcement Action), and to participate in and be represented by independent counsel in such Enforcement Action at Pfizer's own expense, and BioNTech shall take into account any reasonable comments provided by Pfizer in such Enforcement Action. Neither Party will incur any liability to the other Party (other than that related to a Party's indemnification obligation pursuant to Section 16 or otherwise in this sub-section) as a consequence of any Enforcement Action initiated or pursued pursuant to this Section 11.4.3 or any unfavorable decision resulting therefrom, including any decision holding any BioNTech Enforcement Patent Rights invalid or unenforceable.

11.4.5 **Pfizer Patent Rights.** Pfizer shall have the sole right, but not the obligation, to institute litigation or take other steps to remedy infringement in connection with any field in respect of any Patent Rights that it solely owns including any Pfizer Patent Right. In the event that any such Patent Rights are based on inventions made or created solely or jointly by BioNTech, its Affiliates or its Representatives acting on BioNTech's behalf, BioNTech shall provide reasonable assistance to Pfizer at Pfizer's expense in connection with such litigation.

11.4.6 Biosimilar Notices.

11.4.6.1 *BioNTech Cooperation.* Upon Pfizer's request, BioNTech and Pfizer will use Commercially Reasonable Efforts to assist and cooperate with each other in (A) establishing a strategy for responding to requests for information from Regulatory Authorities and Third Party requestors and (B) preparing submissions responsive to any Biosimilar Notices received by Pfizer or BioNTech; *provided that* BioNTech will make the final decisions with respect to such strategy and any such responses.

11.4.6.2 *Compliance with Biosimilar Notices.* The MA Holder will have the sole right in its discretion to comply with the applicable provisions of 42 U.S.C. § 262(l) (or any amendment or successor statute thereto), any similar statutory or regulatory requirement enacted in the future regarding biologic products in the United States, or any similar statutory or regulatory requirement in any non-U.S. country or other regulatory jurisdiction, in each case, with respect to any Biosimilar Notice received from any Third Party regarding any Product that is being Commercialized in the Field in the Territory in

the applicable jurisdiction, and the exchange of information between any Third Party and such MA Holder pursuant to such requirements; *provided that*, prior to any submission of information by MA Holder to a Third Party, the other Party will have the right to review the patent information included in such proposed submission, and to make suggestions as to any changes to such patent information that Pfizer reasonably believes to be necessary; *provided further* that MA Holder will determine the final content of any such submission. In the case of a Product approved in the United States under the PHS Act (or, in the case of a country in the Territory other than the United States, any similar Law), to the extent permitted by applicable Law, the MA Holder, as the sponsor of the application for the Product, will be the "reference product sponsor" under the PHS Act. The MA Holder will give written notice to the other Party of receipt of a Biosimilar Notice received by MA Holder with respect to a Product, and MA Holder will consult with the other Party with respect to the selection of any Patent Rights to be submitted pursuant to 42 U.S.C. § 262(l) (or any similar law in any country of the Territory outside the United States); *provided* that the MA Holder will have final say on such selection of Patent Rights. Such other Party agrees to be bound and will cause its Affiliates and use Commercially Reasonable Efforts to cause all Third Party Licensors to be bound by the confidentiality provisions of 42 U.S.C. § 262(l)(1)(B)(iii). In connection with any action brought by such other Party under this Section 11.4.6, such other Party, upon the MA Holder's request, will reasonably cooperate and will cause its Affiliates and use Commercially Reasonable Efforts to cause all Third Party Licensors to reasonably cooperate with MA Holder in any such action, including timely commencing or joining in any action brought by MA Holder under this Section 11.4.6.

11.4.7 **Unified Patent Court.** In respect of BioNTech Enforcement Patent Rights, for each and every such Patent Right having effect anywhere within any member state that was or is, from time to time, a signatory to the UPC Agreement, BioNTech shall have the sole discretion to decide whether to (a) opt in or opt out (and to opt in again), pursuant to Article 83 of the UPC Agreement, of the Unified Patent Court system; and (b) elect if such Patent Rights should, during their prosecution, be designated as a Unitary Patent or a European Patent. The other Party shall promptly do all things necessary and execute all documents and make all necessary elections required to give effect to such decision(s) or election(s).

11.4.8 **Settlement Cross-Licensing.** If pursuant to a bona fide settlement of any Enforcement Action or Infringement Claim controlled by Pfizer, Pfizer, with BioNTech's prior written consent, which shall not be unreasonably withheld, conditioned or delayed, grants to a Third Party (that was a party to the Enforcement Action or Infringement Claim) any sublicense to any of the Patent Rights licensed to Pfizer under this Agreement in respect of that Third Party's Competitive Product, then Pfizer shall pay to BioNTech (a) at a minimum, if such sublicense includes any of the rights granted to Pfizer under a Current License or future BioNTech Third Party Agreement (subject to Section 3), all royalties due by BioNTech to the relevant Third Party for such sublicense under any Current License and Future BioNTech Third Party Agreement in respect of licensed sales of such Third Party Competitive Product and (b) all other royalties received by Pfizer shall be deemed Gross Profits. For the avoidance of doubt, should the Third Party as part of the same agreement grant any cross-license to Pfizer (sublicensable to BioNTech for the purposes of this Agreement) for any Candidates or Products, such cross-license shall not be deemed "non-cash" consideration for the purpose of the Net Sales definition.

11.5 **Other Actions by Third Parties.** Separate from Prosecution Proceedings, each Party will promptly notify the other Party in the event of any legal action by any Third Party involving any BioNTech Enforcement Patent Rights of which it becomes aware, including any nullity, revocation, declaratory judgment, interference, *inter partes* reexamination, reexamination or compulsory license proceeding. The right to defend against any such action shall be with the Party controlling the filing, Prosecution and Maintenance of the affected Patent Right (as determined in accordance with Section 11.3.1), and the provisions of Section 11.3.1 shall apply *mutatis mutandis* in respect of such defense. If any such action has been instituted by any Third Party in response to, or in connection with, any Enforcement Action pursuant to Section 11.4, or any Enforcement Action is to be pursued as a consequence of such action being instituted by any Third Party, the Party controlling the Enforcement Action and the Party controlling the defense shall work together and closely align their enforcement and defense strategy, which may include the (joint) appointment of the same patent counsel for all concurrent Third Party litigation and patent office proceedings taking into account the impact on enforcement and potential for revenues relating to such Patent Rights, and in the absence of agreement, the enforcing Party shall have the final say over the Prosecution Proceedings in so far as the Prosecution Proceeding will adversely impact the ongoing enforcement of such right, subject to having given good faith consideration to the comments and suggestions of the prosecuting Party. Further details of such joint proceeding may be agreed between the Parties from time to time.

11.6 **Purple Book Listings.** To the extent of any BioNTech Enforcement Patent Rights, the Parties shall cooperate with each other to enable BioNTech to make filings with Regulatory Authorities, as required or allowed in connection with (a) in the United States, the FDA's Purple Book and the Biologics Price Competition and Innovation Act and (b) outside the United States, under the national implementations of Article 10.1(a)(iii) of Directive 2001/EC/83 or other international equivalents thereof within the Territory. Pfizer shall consider BioNTech's reasonable requests in connection therewith, including meeting any submission deadlines, in each case, to the extent required or permitted by applicable Law.

11.7 **Allegations of Infringement and Right to Seek Third Party Licenses.**

11.7.1 **Notice.** If either Party becomes aware that the Development, Manufacture, Commercialization or use of any Candidate or Product, the practice of any BioNTech Technology or Research and Development Program Technology in the Field, or the exercise of any other right granted by BioNTech to Pfizer or any of its Affiliates or Sublicensees hereunder (collectively, the "**Licensed Activities**") is alleged by a Third Party to infringe, misappropriate or otherwise violate such Third Party's Patent Rights or other Intellectual Property Rights or either Party otherwise identifies any Third Party Patent Rights or other Intellectual Property Rights that may be relevant to such Licensed Activities (collectively, an "**FTO Action**"), such Party will, as soon as reasonably practicable, notify the other Party in writing and the Parties will discuss the FTO Action in good faith to determine and agree upon a resolution of the same.

11.7.2 **Option to Negotiate.** If the Parties determine that to resolve the FTO Action it is necessary or useful to obtain a license under one or more Patent Rights or other Intellectual Property Rights Controlled by a Third Party, then [\*\*\*] will negotiate and enter into a license or other agreement with such Third Party in close coordination with the other Party. If the Parties do not agree that a license from a Third Party is necessary or useful to resolve the FTO Action, the Party who considers a license is necessary or useful to resolve the FTO Action shall be entitled to

negotiate and enter into a license or other agreement with such Third Party, but shall do so keeping the other Party reasonably informed. [\*\*\*].

11.7.3 **Option to Challenge.** Other than in response to an Infringement Claim, if a Party determines that to anticipate, mitigate or resolve an FTO Action, it is useful or advisable to pre-emptively challenge one or more Patent Rights or other Intellectual Property Rights Controlled by a Third Party by filing suit or bringing an action, including any nullity, revocation, declaratory judgment, interference, *inter partes* reexamination, reexamination or compulsory license proceeding, then either (a) BioNTech, where the FTO Action predominantly impacts use of BioNTech Technology; or (b) Pfizer, where the FTO Action predominantly impacts use of Pfizer Technology, will, as applicable, have the first right (but not the obligation) to control such suit or action, and any such suit or action shall be at the controlling Party's expense and if that Party does not commence such suit or action the other Party may (but shall not be obliged) to do so. The controlling Party shall, however, be entitled to consider its own contractual obligations to Third Parties that would be impacted when challenging any Patent Rights or other Intellectual Property Rights pursuant to this Section 11.7.3, and if it elects not to pursue any such action then the other Party shall be entitled (but not obliged) to do so. The foregoing shall not preclude or impede a Party from taking any such pre-emptive action in connection with a different product.

11.8 **Third Party Infringement Suits.** Each of the Parties will promptly notify the other in the event that any Third Party files any suit or brings any other action alleging patent infringement by Pfizer or BioNTech or any of their respective Affiliates or Sublicensees with respect to the Development, Manufacture, Commercialization or use of any Candidate or Product or the practice of any BioNTech Technology or Research and Development Program Technology (any such suit or other action referred to herein as an "Infringement Claim"). In the case of any Infringement Claim against Pfizer (including its Affiliates or Sublicensees) alone, or against both Pfizer and BioNTech (including their respective Affiliates), Pfizer will have the right, but not the obligation, to control the defense of such Infringement Claim, including control over any related litigation, settlement, appeal or other disposition arising in connection therewith. BioNTech, upon request of Pfizer, agrees to cooperate with Pfizer at Pfizer's expense. BioNTech will have the right to consult with Pfizer concerning any Infringement Claim and to participate in and be represented by independent counsel in any associated litigation in which BioNTech is a party at BioNTech's own expense. If Pfizer elects to control the defense of any Infringement Claim and BioNTech is obligated under Section 16.3 to indemnify Pfizer (including any Pfizer Indemnified Party) with respect to such Infringement Claim, then (a) Pfizer will bear 100% of its own attorneys' fees incurred in investigating, preparing or defending such Infringement Claim notwithstanding the provisions of Section 16.3 and (b) BioNTech will otherwise indemnify Pfizer and any applicable Pfizer Indemnified Parties to the full extent provided for under Section 16.3, provided that Pfizer shall not enter into any compromise or settlement with the Third Party in respect of such Infringement Claim without BioNTech's prior written consent (such consent not to be unreasonably withheld, conditioned or delayed) where such compromise or settlement requires the payment of monetary penalty or damages that are indemnified by BioNTech under this Agreement. In the case of any Infringement Claim against BioNTech alone, Pfizer will have the right to consult with BioNTech concerning such Infringement Claim and Pfizer, upon request of BioNTech, will reasonably cooperate with BioNTech at BioNTech's expense. Neither Party will enter into any compromise or settlement in respect of an Infringement Claim admitting or implying that the Development, Manufacture, Commercialization or use of any Candidate or Product or the practice of any

BioNTech Technology or Research and Development Program Technology infringes Third Party patents without the other Party's written consent.

11.9 Product Trademarks.

11.9.1 **Trademark Selection, Clearance and Registration.** The Parties shall collaborate to develop a list of potential Trademarks to be used to identify the Products in the Territory. Such list shall be submitted to the JCC for review and the JCC shall, by mutual agreement, select one or more of such potential Trademarks as the Product Trademark for use in identifying the Products in the Territory, *provided* that no such Product Trademark shall be confusingly similar to any Trademark that either Party or any of its Affiliates then use or have filed or registered in any country in or outside of the Territory (except as permitted by such Party). BioNTech, in consultation with Pfizer, shall be responsible for the creation, filing, registration, and Prosecution and Maintenance of the Product Trademarks, *provided* that all out-of-pocket costs and expenses associated therewith (including law firm and service provider costs) as well as costs of any Third Party claims arising from said filing, registration, Prosecution and Maintenance or use of the Product Trademarks shall be shared equally between the Parties (but not as Shared Development Costs). Pfizer, in consultation with BioNTech, shall undertake the searching and clearance of all potential Product Trademarks, *provided* that all out-of-pocket costs and expenses associated therewith (including law firm and service provider costs) shall be shared equally between the Parties (but not as Shared Development Costs) and Pfizer and its Affiliates, employees, agents or representatives will not be liable to BioNTech, its Affiliates or licensees in respect of any act, omission, default or neglect on the part of Pfizer, its Affiliates, or their respective employees, agents or representatives in connection with such searching and clearance activities. BioNTech and Pfizer will each perform such actions at the same level of quality as would be performed for their own Trademarks, respectively. BioNTech shall select a reputable law firm (subject to the approval of Pfizer, such approval not to be unreasonably withheld) to instruct, manage and interact with local Trademark agents throughout the Territory and to act as a single point of contact for BioNTech and Pfizer with respect to the filing and Prosecution and Maintenance of applications for and the registration and maintenance of the Product Trademarks in each country of the Territory. BioNTech shall keep Pfizer reasonably informed of the status of the actual and prospective Trademarks filings, prosecution and registration status and any office actions, oppositions or objections received. BioNTech shall not withdraw, surrender, allow to lapse or otherwise permit any Trademark application or registration to cease to have effect in respect of the Product Trademark anywhere in the Territory without Pfizer's consent (which shall not be unreasonably withheld or delayed). Furthermore, with respect to any office actions, oppositions or other objections received, BioNTech shall consult and cooperate with Pfizer, and take Pfizer's comments reasonably into account, regarding the strategic approach and costs to handling such matters.

11.9.2 **Title.** Unless otherwise decided by the JCC by mutual agreement, BioNTech will own all right, title and interest in and to the Product Trademarks in the Territory. If the JCC decides to adopt one of the Pfizer pre-existing Trademarks (if offered by Pfizer) as a Product Trademark, then BioNTech shall be responsible for preparing and recording all Trademark assignments necessary to transfer ownership of such Product Trademark to BioNTech, and BioNTech shall bear all costs related thereto including legalization costs, and such Trademark shall be deemed a Product Trademark according to the provisions of this Agreement (including with respect to BioNTech's responsibility for the same). The Product Trademarks will not use, be comprised of, or incorporate



all or any part of either Party's House Marks without such Party's prior written consent, which may be provided or withheld in such Party's sole discretion. Neither Party will, nor will cause its Affiliates to: (a) challenge any application for a Product Trademark approved by the JCC or the registration thereof in any country in the Territory; (b) file, register or maintain any registrations for any trademarks or trade names that are identical to or confusingly similar to any Product Trademark, in any country without the express prior written consent of the other Party; or (c) authorize or assist any Third Party to do any of the foregoing. Each Party shall own all right, title and interest in any Patient or HCP Support Program Trademarks developed and/or used by or on behalf of such Party in such Party's Commercialization Territory.

11.9.3 **Domain Names.** The Parties shall also collaborate on the selection and registration of domain names incorporating the Product Trademarks. Unless otherwise determined by the JCC by mutual agreement, BioNTech will register, maintain and manage such domain names and will own all right, title and interest in and to such domain names and similar electronic media references. BioNTech shall ensure that all such domain names are timely registered and renewed as necessary to support websites in the Territory related to the Product Trademarks, or for defensive purposes, regardless of which Party operates such websites. All costs in connection with the registration and maintenance of such domains shall be shared equally between the Parties (but not as Shared Development Costs).

11.9.4 **Required Use and Compliance.** Each Party will not and will cause its Affiliates to not use Product Trademarks or the other Party's House Marks in a way that might materially prejudice their distinctiveness or validity or the goodwill of the other Party therein. Each Party will not and will cause its Affiliates not to use any trademarks or trade names so resembling any of the Product Trademarks as to be likely to cause confusion or deception. Each Party will and will cause its Affiliates (a) to include, where possible, the trademark registration symbol ® or ™, as appropriate, in connection with the use of any Product Trademark or (as requested) the other Party's House Marks; and (b) not to use any Trademarks or trade names so resembling any of the other Party's House Marks as to be likely to cause confusion or deception.

11.9.5 Trademark Licenses.

11.9.5.1 *To Pfizer.* Subject to the terms and conditions of this Agreement, for the Term BioNTech hereby grants to Pfizer and its Affiliates (i) a non-exclusive, royalty-free license to use the BioNTech House Marks in the Pfizer Commercialization Territory solely as set forth in Section 9.12 and (ii) an exclusive (even as to BioNTech), royalty-free, fully paid-up, non-assignable and sublicensable license to use the Product Trademarks in the Pfizer Commercialization Territory, in each case, solely in connection with the exercise by Pfizer or its Affiliates of Pfizer's rights or obligations under this Agreement or the performance by Pfizer or its Affiliates of Pfizer's Commercialization Activities.

11.9.5.2 *To BioNTech.* Subject to the terms and conditions of this Agreement, Pfizer hereby grants to BioNTech and its Affiliates a non-exclusive, royalty-free license to use the Pfizer House Marks in the BioNTech Commercialization Territory solely as set forth in Section 9.12 in connection with the exercise by BioNTech or its Affiliates of BioNTech's rights or obligations under this Agreement. In addition, to the extent the JCC decides in accordance with Section 11.9.2 that Product Trademarks shall be owned by Pfizer, Pfizer hereby grant to BioNTech and its Affiliates for the Term an exclusive (even

as to Pfizer), royalty-free, fully paid-up, non-assignable and sublicensable license to use the Product Trademarks in the BioNTech Commercialization Territory solely in connection with the exercise by BioNTech or its Affiliates of BioNTech's rights or obligations under this Agreement or the performance by BioNTech or its Affiliates of BioNTech's Commercialization Activities.

11.9.6 **Respect of Trademarks.** Pfizer will not have, assert or acquire any right, title or interest in or to any BioNTech House Marks or Product Trademarks (unless ownership is otherwise decided by the JCC in accordance with Section 11.9.2), or the goodwill pertaining thereto, and BioNTech will not have, assert or acquire any right, title or interest in or to any Pfizer House Marks or the goodwill pertaining thereto, except in each case for the limited licenses explicitly provided in this Agreement. Pfizer will maintain necessary quality standards with respect to Pfizer's use under license of Product Trademarks and each Party will maintain necessary quality standards with respect to the use by such Party of the other Party's House Marks pursuant to the licenses granted under Section 11.9.5, as applicable. Each Party recognizes and agrees that no ownership rights are vested or created by the limited licenses granted pursuant to Section 11.9.5 and that all goodwill arising by virtue of the use of (i) the Pfizer House Marks including use by any sublicensee will inure to the exclusive benefit of Pfizer; and (ii) the BioNTech House Marks and the Product Trademarks including use by any sublicensee (unless ownership is otherwise decided by the JCC in accordance with Section 11.9.2) inures to the exclusive benefit of BioNTech.

11.9.7 **Infringement.**

11.9.7.1 **Monitoring and Infringements.** Each Party will monitor the Product Trademarks and House Marks against infringing uses in the Territory relating to the Product (including (i) with respect to domain names, unauthorized online activities and other digital handles and (ii) with respect to the Product Trademarks and with respect to either Party's House Marks as used on the Product or Product Packaging and Labeling, unauthorized uses amounting to counterfeiting or unlawful product diversion) (collectively, "Infringements") and will promptly notify the other Party of any infringement or threatened infringement thereof of which it becomes aware. BioNTech will use Third Party watch services, as necessary, to monitor filings for Third Party Trademarks that may be similar to the Product Trademarks, and will, in consultation with Pfizer, defend the Product Trademarks against oppositions, cancellations, nullity or other legal actions filed by Third Parties and will promptly, in consultation with Pfizer, undertake to oppose, cancel, nullify or take other appropriate action, where reasonable, against confusingly similar or identical Third Party Trademarks filed for products or services related to those claimed by the Product Trademarks, or where the Third Party use would be dilutive of the Product Trademarks. BioNTech will have the right to determine what action, if any, to take in response to any such Infringement or threatened infringement of any Product Trademark in the BioNTech Commercialization Territory, and Pfizer will have the right to determine what action, if any, that BioNTech should take in response to any such Infringement or threatened Infringement of any Product Trademark in the Pfizer Commercialization Territory, recognizing that in all cases such actions legally may need to be filed or brought in the name of the trademark owner (BioNTech). The Parties will cooperate in good faith to formulate an agreed-upon process for such actions. Each Party shall keep the other Party reasonably informed of the status of such oppositions,

cancellations, Infringements, threatened Infringements and other actions. Each Party shall not withdraw, surrender, allow to lapse or otherwise permit any Trademark application or registration to cease to have effect in respect of the Product Trademark without the consent of the other Party (which shall not be unreasonably withheld or delayed). All costs in connection with any activities under this Section 11.9.7.1 (including law firm and service provider costs) shall be shared equally between the Parties (but not as Shared Development Costs). Each Party shall be exclusively responsible for and have the exclusive right (at its sole discretion) to take or not take any action with respect to its House Mark.

11.9.7.2 *Responsibility for Protection.* Unless otherwise agreed between the Parties, the Parties will mutually agree upon the protection and maintenance of the Product Trademarks, including all enforcement against Infringements or threatened Infringements and defense thereof. The Parties recognize that anti-counterfeiting activity may involve law enforcement actions or customs authority seizures based on the Product Trademarks and/or based on either or both Party's House Marks as they appear on the Product or Product Packaging and Labeling, and the Parties will cooperate in good faith to create anti-counterfeiting strategies and processes -- as well as anti-diversion strategies and processes -- for the Products throughout the Territory. The Parties will also cooperate to formulate an agreed-upon process to handle and support such anti-counterfeiting actions brought by law enforcement authorities including but not limited to customs seizures and criminal actions. Each Party will provide all assistance reasonably requested by the other Party in connection with the maintenance, enforcement and defense of the Product Trademarks in the Territory. The foregoing obligations shall apply to all trademark uses including with respect to domain names, online activities and use of other digital handles. All costs and expenses (including law firm and service provider costs) in connection with any activities under this Section 11.9.7.1 and 11.9.7.2 anywhere in the Territory shall be shared equally between the Parties (but not as Shared Development Costs).

11.9.7.3 *House Marks.* Each Party will have sole control and discretion with respect to protecting and maintaining its respective House Marks, including all enforcement and defense thereof. To the extent that anti-counterfeiting or anti-diversion activity for the Product must be based on a Party's House Marks, the Parties will cooperate in good faith on decisions relating to control of such actions, and costs of same shall constitute the sole cost of the applicable Party whose House Mark is in issue.

11.10 Packaging and Labeling Rights and Licenses. Subject to the terms and conditions of this Agreement, for the Term each Party hereby grants to the other Party and its Affiliates a non-exclusive, royalty-free license under any Intellectual Property Rights it Controls in the Packaging and Labeling selected for the Product solely for use in connection with (i) Commercializing the Product in the Territory; and (ii) Commercializing a product identical to the Product in the Fosun Territory.

11.11 No Implied Licenses. No right or license under any Pfizer Technology, BioNTech Technology, BioNTech House Mark, Pfizer House Mark, Product Trademark, or any other Intellectual Property Right or Trademark of a Party is granted or will be granted by implication as a result of the

respective rights of the Parties under this Agreement. All such rights or licenses are or will be granted only as expressly provided in this Agreement.

## 12. CONFIDENTIALITY, PUBLICATIONS AND PRESS RELEASES

12.1 **Confidentiality.** Except to the extent expressly authorized by this Agreement, the Parties agree that, during the Term and for [\*\*\*] years thereafter (except to the extent a longer period is required by a Current License applicable for such Confidential Information disclosed pursuant to that Current License), each Party (the "**Receiving Party**") receiving any Confidential Information of the other Party (the "**Disclosing Party**") hereunder will: (a) keep the Disclosing Party's Confidential Information confidential; (b) not disclose, or permit the disclosure of, the Disclosing Party's Confidential Information; and (c) not use, or permit to be used, the Disclosing Party's Confidential Information for any purpose other than as expressly permitted under the terms of this Agreement (including under any license or right of use granted hereunder).

### 12.2 Authorized Disclosure.

12.2.1 **Disclosure to Party Representatives.** Notwithstanding the foregoing provisions of Section 12.1, the Receiving Party may disclose Confidential Information belonging to the Disclosing Party to the Receiving Party's Representatives who (a) have a need to know such Confidential Information in connection with the performance of the Receiving Party's obligations or the exercise of the Receiving Party's rights under this Agreement and (b) have agreed in writing to non-disclosure and non-use provisions with respect to such Confidential Information that are at least as restrictive as those set forth in this Section 12.

12.2.2 **Disclosure to Third Parties.** Notwithstanding the foregoing provisions of Section 12.1, each Party may disclose Confidential Information belonging to the other Party to the extent such disclosure is reasonably necessary:

12.2.2.1 in conducting the activities contemplated, or exercising rights under this Agreement;

12.2.2.2 to Governmental Authorities to the extent useful, to (a) obtain or maintain Regulatory Approvals (including fulfilling post-approval regulatory obligations) for any Product within the Territory; or (b) obtain or maintain any Regulatory Approvals for a product comprising a Candidate in the Field outside of the Territory; (c) to ministries of health, Vaccine Technical Committees or similar public health or scientific bodies for purposes of securing vaccine recommendations, tenders, direct procurement contracts or responding to relevant requests for information; (d) complying with applicable governmental regulations with respect to performance under this Agreement or (e) in order to respond to inquiries, requests or investigations (i) relating to Candidates or Products or this Agreement within the Territory; or (ii) relating to any product comprising a Candidate in the Field outside of the Territory; *provided, however*, that BioNTech may not disclose any Pfizer Confidential Information to Fosun or its Affiliates without the prior written consent of Pfizer, other than to the extent necessary for Fosun or its Affiliates (or such other collaboration partner in or for the Fosun Territory) to undertake fill/finish of a product identical to any Product in the Fosun Territory or to comply with information requirements of the China National Medical Products Administration (or equivalent), relating to such

product required under applicable Law, in each case so far as such use is licensed under Sections 3.4.2(b) or 3.4.4(b);

12.2.2.3 to outside consultants (including any professional advisor), potential acquisition partners (including any potential successors in interest), private investors or financing sources, contractors, advisory boards, managed care organizations, and non-clinical and clinical investigators, in each case to the extent useful to develop, register or market any Candidate or Product within the Territory; *provided* that the Receiving Party will obtain the same confidentiality obligations from such Third Parties as it obtains with respect to its own similar types of confidential information;

12.2.2.4 in connection with filing or prosecuting Research and Development Program Patent Rights, Product Patent Rights or Trademark rights as permitted by this Agreement;

12.2.2.5 in connection with any prosecution or litigation actions or defenses undertaken pursuant to Section 11 or any other litigation directly related to a Candidate or Product in the Field in the Territory;

12.2.2.6 subject to the provisions of Section 12.5.2, in connection with or included in scientific presentations and publications relating to Candidates or Products, including abstracts, posters, journal articles and the like, and posting results of and other information about clinical trials to clinicaltrials.gov or PhRMA websites;

12.2.2.7 by either Party in respect of Confidential Information belonging to the other Party (including the terms of the Agreement) to any bona fide or potential subcontractor under this Agreement in connection with the Development, Manufacture or Commercialization of the Candidate or Product in the Territory, in each case who has agreed in writing to non-disclosure and non-use provisions with respect to such Confidential Information that are at least as restrictive as those set forth in this Section 11.1; and

12.2.2.8 to the extent necessary or useful in order to enforce its rights under this Agreement.

12.2.2.9 to the extent otherwise required by applicable Law or agreements with Governmental Authorities; *provided that* if a Party is so required by applicable Law to make any such disclosure of the other Party's Confidential Information it will, except where impracticable for necessary disclosures (for example, in the event of medical emergency), give reasonable advance notice to the other Party of such disclosure requirement and will use its reasonable efforts to secure confidential treatment of such Confidential Information required to be disclosed; or

12.2.2.10 to the extent mutually agreed to by the Parties.

Notwithstanding anything herein to the contrary, each Party acknowledges and agrees that the use by a Party of the other Party's Confidential Information disclosed under the Related Agreements or the Flu Collaboration License in the performance of this Agreement is not a breach of the

confidentiality obligations under this Agreement, the Related Agreements or the Flu Collaboration License, and vice versa.

12.3 Confidential Treatment of the Terms and Conditions, SEC Filings and Other Disclosures. The Parties agree that the terms and conditions of this Agreement will be Confidential Information of each Party, and such material terms and conditions will not be disclosed, except (a) as otherwise permitted under Section 12.2. Notwithstanding the foregoing, either Party may disclose the terms of this Agreement and make any other public written disclosure regarding the existence of, or performance under, this Agreement, to the extent required, in the reasonable opinion of such Party's legal counsel, to comply with (a) applicable Law, including the rules and regulations promulgated by the United States Securities and Exchange Commission or (b) any equivalent Governmental Authority, securities exchange or securities regulator in any country. Before disclosing this Agreement or any of the terms hereof pursuant to this Section 12.3, the Parties will consult with one another on the terms of this Agreement to be redacted in making any such disclosure, with the Party disclosing pursuant to this Section 12.3 providing as much advance notice as is feasible under the circumstances, and giving consideration to the comments of the other Party. Further, if a Party discloses this Agreement or any of the terms hereof in accordance with this Section 12.3, such Party will, at its own expense, seek such confidential treatment of confidential portions of this Agreement and such other terms, as may be reasonably requested by the other Party and limit its disclosure of such Confidential Information to only that required to comply with applicable Law.

12.4 Residual Knowledge Exception. Notwithstanding any provision of this Agreement to the contrary, Residual Knowledge will not be considered Confidential Information for purposes of this Section 11.1; provided that, for clarity, a Party's rights to Residual Knowledge hereunder shall not include the right to practice any Patent Right owned or Controlled by the other Party that claims such Residual Knowledge unless otherwise expressly granted in another provision of this Agreement or in another agreement between the Parties.

12.5 Public Announcements; Publications.

12.5.1 **Announcements.** Except as may be expressly permitted under Section 12.3, neither Party will (i) make any public announcement about this Agreement without the prior written approval of the other Party (such approval not to be unreasonably withheld, conditioned or delayed); or (ii) make any public announcement which otherwise relates to the performance or subject matter of this Agreement or to the Product without having given to the other Party prior notice of such public announcement (including its wording and reasonably relevant information) and a reasonable time period to comment on such public announcement, taking into account the circumstances surrounding such public announcement. As a general rule, a Party shall provide an initial draft for the other Party's review and comments, and the other Party shall have two (2) Business Days to review and provide comments to such initial draft and the Parties shall work promptly and collaboratively in preparation for release of the public announcement, reasonably taking into account the other Party's comments. In the event of an urgent announcement that relates to an unknown or unplanned event, such that the review period referenced above is not practicable, a Party shall endeavor to provide the other Party with as much notice as reasonably possible and the Parties shall work promptly and collaboratively in preparation for release of the public announcement, reasonably taking account the other Party's comments. Unless the Parties mutually agree otherwise in writing, every public announcement made by either Party shall include a statement that is substantially identical to the statement set forth on Schedule 12.5.1. Nothing in this Section shall prevent a Party from advertising for promotional purposes the Product in its

respective Commercialization Territory and such advertising does not require review and approval as set forth in this Section 12.5.1, *provided* that such advertising is in compliance with other terms and provisions of this Agreement and applicable Law and that a statement substantially identical to the statement set forth in Schedule 12.5.1 shall be included, to the extent permitted under Applicable Law, also into all advertisements issued pursuant to this sentence.

12.5.2 **Publications.** During the Term, each Party will submit to the other Party for review and approval (such approval not to be unreasonably withheld, delayed or conditioned) any proposed publication or public presentation proposed by a Party or its Affiliates or any of their respective Representatives that relates to the activities conducted under this Agreement, including the Research and Development Plan; *provided* that notwithstanding the requirement for approval (a) neither Party shall be prevented from submitting any publication or making a presentation in respect of a Clinical Trial for which the Party is either the IND holder or the Lead Development Party to the extent such publication or presentation is required under applicable Law or such Party's internal publication policies, but such publishing Party shall not disclose the other Party's confidential information in respect of its technology and Intellectual Property Rights, and shall take on board and reasonably consider any reasonable requests of the other Party with respect to such proposed publication or presentation; (b) the Party whose approval is sought shall not unreasonably withhold or condition such approval; (c) nothing shall prohibit a Party from making any press release or statement where required pursuant to applicable Law or stock exchange rule, subject to such publishing Party shall take on board and reasonably consider any reasonable requests of the other Party with respect to such proposed publication or presentation and (d) neither Party is required to obtain the prior consent of the other Party with respect to presentations made to any Vaccine Technical Committee, nor shall the Party making such presentation be required to submit the presentation to the other Party prior to making such presentation to any Vaccine Technical Committee. Each Party's review and approval will be conducted only for the purposes of identifying if confidential information should be modified or deleted so as to preserve the value of the technology owned by such Party or its Affiliates and the rights granted to each Party hereunder. Written copies of such proposed publication or presentation required to be submitted hereunder will be submitted as soon as practically possible before submission for publication or presentation (the "Review Period"). The reviewing Party will provide its comments with respect to such publications and presentations within [\*\*\*] of its receipt of such written copy. The Review Period may be extended for an additional [\*\*\*] in the event a Party can, within [\*\*\*] of receipt of the written copy, demonstrate reasonable need for such extension including for the preparation and filing of patent applications. Each Party will comply with standard academic practice regarding authorship of scientific publications and recognition of contribution of other parties in any publication governed by this Section 12.5.2, including International Committee of Medical Journal Editors standards regarding authorship and contributions.

12.6 Non-Disclosure in the Fosun Territory. For the avoidance of doubt, nothing in this Agreement authorizes or permits BioNTech to disclose to Fosun, its Affiliates or any other collaboration partner in or for the Fosun Territory any Pfizer Confidential Information without the prior written consent of Pfizer other than to the extent necessary for Fosun or its Affiliates (or such other collaboration partner in or for the Fosun Territory) to undertake fill/finish of a product identical to any Product in the Fosun Territory or to comply with information obligations required by the China National Medical Products

Administration or equivalent, relating to such product in accordance with applicable Law, in each case so far as such use is licensed under Sections 3.4.2(b) or 3.4.4(b).

12.7 Obligations in Connection with Change of Control. If a Party is subject to a Change of Control or if a Party or any of its Affiliates acquires or merges with a Third Party during the Term ("Change of Control Party"), such Change of Control Party will, and it will cause its Representatives to, ensure that no Confidential Information of the other Party is released to (a) any Affiliate of the Change of Control Party that becomes an Affiliate of the Change of Control Party as a result of the Change of Control or (b) any other Representatives of the Change of Control Party (or of the relevant surviving entity of such Change of Control) who become Representatives of the Change of Control Party as a result of the Change of Control, unless such Affiliate or other Representatives, as applicable, have signed individual confidentiality agreements which include equivalent obligations to those set out in this Section 12. Upon occurrence of a Change of Control, the Change of Control Party will promptly notify the other Party, share with the other Party the policies, procedures and technical and organizational measures it plans to implement in order to protect the confidentiality of the other Party's Confidential Information prior to such implementation and make any adjustments to such policies and procedures that are reasonably requested by the other Party.

### 13. REPRESENTATIONS AND WARRANTIES

13.1 Mutual Representations and Warranties. Each of BioNTech and Pfizer hereby represents and warrants as of the Amendment Signing Date to the other Party that:

13.1.1 it is duly organized, validly existing and in good standing under the laws of the jurisdiction of its organization;

13.1.2 the execution, delivery and performance of this Agreement by such Party has been duly authorized by all requisite action under the provisions of its charter, bylaws and other organizational documents, and does not require any action or approval by any of its shareholders or other holders of its voting securities or voting interests;

13.1.3 it has the power and authority to execute and deliver this Agreement and to perform its obligations hereunder;

13.1.4 this Agreement has been duly executed and is a legal, valid and binding obligation on each Party, enforceable against such Party in accordance with its terms; and

13.1.5 the execution, delivery and performance by such Party of this Agreement and its compliance with the terms and provisions hereof does not and will not conflict with or result in a breach of or default under any Binding Obligation existing as of the Effective Date.

13.2 Mutual Covenants. In addition to the covenants made by the Parties elsewhere in this Agreement, each of BioNTech and Pfizer hereby covenants to the other Party that, from the Effective Date until expiration or termination of this Agreement it will perform its obligations under this Agreement in compliance with applicable Laws.

13.3 Representations and Warranties of BioNTech. As of the Signing Date, BioNTech hereby represents and warrants to Pfizer that, unless otherwise disclosed in Schedule 13.3 (or otherwise as accepted to have been disclosed between BioNTech's external counsel and Pfizer's external counsel other than in writing), and provided that those provisions of the Current Licenses set forth in Schedule 1.45 shall be



deemed disclosed against the representations and warranties given by BioNTech at sections 13.3.1, 13.3.2, 13.3.4, 13.3.10 and 13.3.11 of this Agreement and provided further that all disclosures made under the Flu Collaboration License shall be deemed disclosed also under this Agreement:

13.3.1 as of the Signing Date, except with respect to BioNTech Technology Controlled by BioNTech pursuant to a Current License, BioNTech or its Affiliates are the sole and exclusive owner of the BioNTech Technology, and all BioNTech Technology is free and clear of any claims, liens, charges or encumbrances;

13.3.2 as of the Signing Date, BioNTech has, and to its knowledge will have, the full right, power and authority to (a) grant all of the right, title and interest in the licenses and other rights granted or to be granted to Pfizer, Pfizer's Affiliates or Pfizer's Sublicensees under this Agreement and (b) perform its obligations under this Agreement;

13.3.3 Schedule 1.21 sets forth a true and complete list of all Candidates relevant to the Field discovered, developed or Controlled by BioNTech or its Affiliates on or prior to the Signing Date;

13.3.4 as of the Signing Date, (a) Schedule 13.3.4 sets forth a true and complete list of all Patent Rights (i) owned or otherwise Controlled by BioNTech or its Affiliates or (ii) to which BioNTech or its Affiliates have been granted or otherwise transferred any right to practice under, in each case of (i) and (ii), that relate to the Candidates, the Products, the BioNTech Technology, or the Parties' activities in the Research and Development Program, (b) each such Patent Right is in full force and effect and, so far as BioNTech is aware, valid and enforceable, (c) BioNTech or its Affiliates have timely paid, or caused the appropriate Third Parties to pay, all filing and renewal fees payable with respect to such Patent Rights; (d) BioNTech Controls all Patent Rights listed in Schedule 13.3.4; and (e) other than those licensed hereunder, there are no other Patent Rights owned or Controlled by BioNTech that Candidates or Products would infringe;

13.3.5 as of the Signing Date, BioNTech is not aware of any material adverse event, or medical or scientific concern or doubt regarding the safety, contraindications or effectiveness of the use of the BioNTech Technology or the Candidates that have not previously been disclosed in writing to Pfizer;

13.3.6 to BioNTech's knowledge as of the Signing Date, (a) no Third Party (i) is infringing any BioNTech Patent Right or (ii) has challenged or threatened in writing to challenge the ownership, scope, validity or enforceability of, or BioNTech's or any Current Licensor's rights in or to, any BioNTech Patent Right (including, by way of example, through the institution or written threat of institution of interference, nullity or similar invalidity proceedings before the United States Patent and Trademark Office or any analogous foreign Governmental Authority);

13.3.7 as of the Signing Date, BioNTech has independently developed all BioNTech Know-How and BioNTech Materials or otherwise has a valid right to use, and to permit Pfizer, Pfizer's Affiliates and Pfizer's Sublicensees to use, the BioNTech Know-How and BioNTech Materials for all permitted purposes under this Agreement;

13.3.8 except with respect to BioNTech Technology Controlled by BioNTech pursuant to a Current License, BioNTech or its Affiliates have obtained from all inventors of BioNTech Technology existing as of the Signing Date, valid and enforceable agreements assigning to

BioNTech or its Affiliates each such inventor's entire right, title and interest in and to all such BioNTech Technology (except to the extent applicable Law provides that all right, title and interest in and to such BioNTech Technology automatically vests in BioNTech or its Affiliates by operation of law);

13.3.9 in respect of BioNTech Technology solely or jointly owned by BioNTech existing as of the Signing Date, neither BioNTech nor its Affiliates are subject to any funding agreement with any government or Governmental Authority;

13.3.10 as of the Effective Date (a) there are no BioNTech Third Party Agreements other than the Current Licenses set forth in Schedule 1.45, (b) true and complete copies of each Current License (other than the Fosun Agreement) have been provided to Pfizer, (c) except as provided in the Current Licenses, no Third Party has any right, title or interest in or to, or any license under, any BioNTech Technology in the Field, (d) no rights granted by or to BioNTech or its Affiliates under any Current License conflict with any right or license granted to Pfizer or its Affiliates hereunder and (e) BioNTech and its Affiliates are in compliance in all material respects with all Current Licenses;

13.3.11 as of the Signing Date, to BioNTech's knowledge, the use by BioNTech or Pfizer (or their respective Affiliates or Sublicensees) of the BioNTech Technology in accordance with this Agreement, and the Development, Manufacture or Commercialization of those Candidates listed in Schedule 1.21 or Products incorporating such Candidates in accordance with this Agreement (a) does not and will not infringe any Patent Right of any Third Party or (b) will not infringe the claims of any published Third Party pending Patent Right when and if such claims issue;

13.3.12 as of the Effective Date, there is no (a) written claim, demand, suit, proceeding, arbitration, inquiry, investigation or other legal action of any nature, civil, criminal, regulatory or otherwise, pending or, to BioNTech's knowledge, made or threatened (irrespective of whether or not in writing) against BioNTech or any of its Affiliates or (b) judgment or settlement against or owed by BioNTech or any of its Affiliates, in each case in connection with the BioNTech Technology, the Current Licenses, any Candidate or Product or relating to the transactions contemplated by this Agreement;

13.3.13 as of the Signing Date, BioNTech and its Affiliates (a) have claimed and remunerated all employee inventions of their respective employees comprised within the GEIA Technology in accordance with the provisions of the GEIA; and (b) are entitled to unrestrictedly claim all rights to employee inventions of their employees comprised within the GEIA Technology;

13.3.14 as of the Signing Date, BioNTech has obtained all necessary assignment documents for the BioNTech Technology inventions in its files and maintains written track records of the proper claiming of any inventions made by employees of BioNTech, its Affiliates or Third Parties included in BioNTech Technology or Research and Development Program Technology by the employer and/or the proper assignment of the inventors of their rights in the invention, including the right to claim priority to said invention, to the employer;

13.3.15 as of the Signing Date, BioNTech has no knowledge of (a) any inequitable conduct or fraud on any patent office with respect to any of the BioNTech Patent Rights or (b) any Person

(other than Persons identified in the applicable patent applications or patents, as inventors of inventions disclosed in the BioNTech Patent Rights) who claims to be an inventor of an invention disclosed in the BioNTech Patent Rights;

13.3.16 as of the Signing Date, BioNTech and its Affiliates are not, and to BioNTech's knowledge, no Current Licensor or Representative of BioNTech (in each case, as applicable) is, debarred by any Regulatory Authority or the subject of debarment proceedings by any Regulatory Authority and, in the course of the discovery or pre-clinical development of any Candidate or Product, BioNTech and its Affiliates have not and, to the knowledge of BioNTech, no Current Licensor or Representative of BioNTech (in each case, as applicable) have used any employee or consultant that is debarred by any Regulatory Authority or, to the knowledge of BioNTech, is the subject of debarment proceedings by any Regulatory Authority;

13.3.17 BioNTech, its Affiliates, and to BioNTech's knowledge, all third parties and Representatives acting on BioNTech's behalf, have and will comply in all material respects with all applicable Law and accepted pharmaceutical industry business practices in connection with this Agreement, including, to the extent applicable, the FD&C Act (21 U.S.C. § 301, et seq.), the Anti-Kickback Statute (42 U.S.C. § 1320a-7b), Civil Monetary Penalty Statute (42 U.S.C. § 1320a-7a), the False Claims Act (31 U.S.C. § 3729 et seq.), comparable state statutes, the regulations promulgated under all such statutes, and the regulations issued by the FDA, consistent with the 'Compliance Program Guidance for Pharmaceutical Manufacturers' published by the Office of Inspector General, U.S. Department of Health and Human Services;

13.3.18 with respect to any Candidates, Products, or payments or services provided under this Agreement, BioNTech, its Affiliates, and to its knowledge all third parties and Representatives acting on BioNTech's behalf, have not taken and will not during the Term take any action directly or indirectly to offer, promise or pay, or authorize the offer or payment of, any money or anything of value in order to improperly or corruptly seek to influence any Government Official or any other person in order to gain an improper advantage, and has not accepted, and will not accept in the future such payment;

13.3.19 BioNTech, its Affiliates, and to its knowledge all third parties and Representatives acting on BioNTech's behalf, have and will continue to comply with the laws and regulations of the countries where it operates, including Anti-Corruption Laws, accounting and record keeping laws, and laws relating to interactions with HCPs, Governments and Government Officials;

13.3.20 BioNTech has implemented a compliance and ethics program containing adequate systems, policies, and procedures for the detection, investigation, documentation, and remediation of any allegations, reports, or findings related to a potential violation of Applicable Law with respect to the Products, payments, and Services under this Agreement. Such policies and procedures should set out rules governing interactions with HCPs and Government Officials, the engagement of third parties, and where appropriate, conducting due diligence, and the investigation, documentation, and remediation of any allegations, reports, or findings related to a potential violation of Applicable Law;

13.3.21 BioNTech has implemented policies and procedures, including but not limited to anti-corruption policies and procedures, commensurate with its current risk profile, and shall review said policies from time to time setting out rules governing interactions with HCPs and

Government Officials, engagement of Third Parties, including, where appropriate, due diligence (“Policies”), and its Policies will mandate a robust set of internal controls, including accounting controls designed to ensure the making and keeping of fair and accurate books, records and accounts, on its operations around the world and apply worldwide to all its employees, subsidiaries, and Third Parties acting on its behalf to provide reasonable assurance that BioNTech, its subsidiaries and such Third Parties will comply with Laws, including but not limited to Anti-Corruption Laws to the extent required by such Laws. BioNTech will reasonably monitor and audit its operations and the operations of its Affiliates with the purpose of ensuring compliance with its Policies and the effectiveness of its Policies at the reasonable assurance level and make necessary changes from time to time and in response to identified issues, in particular as its business activities expand;

13.3.22 the Impf Group does not own or Control any Intellectual Property Rights used by BioNTech or that BioNTech may reasonably require or be useful to exploitation of any of the RNA Technology.

13.3.23 BioNTech has been provided with a copy of Pfizer’s International Anti-Bribery and Anti-Corruption Principles and has communicated such principles to all persons acting on its behalf in connection with this Agreement, including its employees, agents, contractors, or subcontractors.

13.4 Accuracy of Representations and Warranties.

13.4.1 BioNTech will take no action which would render any representation or warranty made by BioNTech and contained in Section 13.1 or Section 13.2 inaccurate or untrue; provided that such covenant shall not apply to representations and warranties expressly given as of the Effective Date;

13.4.2 BioNTech will promptly notify Pfizer of any lawsuits, claims, administrative actions, regulatory inquiries or investigations, or other proceedings asserted or commenced against BioNTech or its Representatives involving in any material way the ability of BioNTech to deliver the rights, licenses and sublicenses granted herein;

13.4.3 BioNTech will promptly notify Pfizer in writing of any facts or circumstances which come to its attention and which cause, or through the passage of time may cause, any of the representations and warranties contained in Section 13.1, Section 13.2, Section 17.10 or otherwise in this Agreement to be untrue or misleading in any material respect at any time during the Term; and in addition to the foregoing, with regard to any of the representations under Section 17.10, BioNTech will suspend all affected activities (including making any related payments) under this Agreement, unless and until Pfizer determines that such activities may be resumed; provided that such covenant shall not apply to representations and warranties expressly given as of the Effective Date; and

13.4.4 BioNTech undertakes to inform Pfizer if it becomes aware that a Government or Government Official has become an owner of at least one (1) percent of BioNTech’s shares or has come into a position of authority or control within the structure of BioNTech that includes influence over decisions with respect to any Products, payments, or services provided under this Agreement.

13.5 BioNTech Covenants. In addition to the covenants made by BioNTech elsewhere in this Agreement, BioNTech hereby covenants to Pfizer that, from the Effective Date until expiration or termination of this Agreement:

13.5.1 BioNTech will, at all times during the term of this Agreement, maintain its licenses, consents, authorizations or registrations to do business and continue to make any notifications as may be necessary or required by local Laws, regulations, policies, or administrative requirements in order to provide the Products or Services encompassed within this Agreement, and will ensure that providing such Products or Services will not be inconsistent with any other obligation of BioNTech;

13.5.2 BioNTech will not, and will cause its Affiliates not to (a) license, sell or assign (other than in a connection with a permitted assignment of this Agreement by BioNTech pursuant to Section 17.1) or otherwise transfer to any Person (other than Pfizer or its Affiliates or Sublicensees pursuant to the terms of this Agreement) any BioNTech Technology or Research and Development Program Technology (or agree to do any of the foregoing) or (b) incur or permit to exist, with respect to any BioNTech Technology or Research and Development Program Technology, any lien, encumbrance, charge, security interest, mortgage, liability, assignment, grant of license or other Binding Obligation, in each case of (a) and (b) that is inconsistent with the licenses and other rights granted (or that may be granted) to Pfizer or its Affiliates under this Agreement;

13.5.3 Except as explicitly permitted under this Agreement, BioNTech will not (a) take, or omit to take, any action that diminishes the rights under the BioNTech Technology or Research and Development Program Technology granted (or that may be granted) to Pfizer or Pfizer's Affiliates under this Agreement or (b) take, or omit to take, any action that is reasonably necessary to avoid diminishing the rights under the BioNTech Technology or Research and Development Program Technology granted (or that may be granted) to Pfizer or Pfizer's Affiliates under this Agreement (for the avoidance of doubt, BioNTech shall not be in breach of the covenants set forth in this Section 13.5.3 due to any reasonable act or position taken in connection with the filing, prosecution, maintenance, defense or enforcement of BioNTech Technology or Research and Development Program Technology as permitted in Section 11);

13.5.4 BioNTech will (a) not enter into any BioNTech Third Party Agreement that adversely affects (i) the rights granted (or that may be granted) to Pfizer, Pfizer's Affiliates or Sublicensees hereunder or (ii) BioNTech's ability to fully perform its obligations hereunder; (b) not amend or otherwise modify any BioNTech Third Party Agreement (including any Current License) or consent or waive rights with respect thereto in any manner that (A) adversely affects the rights granted (or that may be granted) to Pfizer or Pfizer's Affiliates or Sublicensees hereunder or (B) BioNTech's ability to fully perform its obligations hereunder; (c) promptly furnish Pfizer with true and complete copies of all (1) amendments to the Current Licenses and (2) BioNTech Third Party Agreements and related amendments executed following the Effective Date (in each case with redactions only in respect of sensitive information which is not relevant for the purposes of this Agreement); (d) remain, and cause its Affiliates to remain, in compliance in all material respects with all BioNTech Third Party Agreements; and (e) furnish Pfizer with copies of all notices received by BioNTech or its Representatives relating to any alleged breach or default by BioNTech or its Representatives under any BioNTech Third Party Agreement within ten (10) Business Days

after receipt thereof (in each case with redactions only in respect of sensitive information which is not relevant for the purposes of this Agreement); and

13.5.5 BioNTech will not enter into or otherwise allow itself or its Representatives to be subject to any agreement or arrangement, other than the Current Licenses, which limits the ownership or licensed rights of Pfizer or its Affiliates with respect to, or limits the ability of Pfizer or its Affiliates to grant a license, sublicense or access, or provide or provide access or other rights in, to or under, any Intellectual Property Right or material (including any Patent Right, Know-How or other data or information), in each case, that would, but for such agreement or arrangement, be included in the rights licensed or assigned (or that may be licensed or assigned) to Pfizer or its Affiliates pursuant to this Agreement

13.5.6 BioNTech and its Affiliates will maintain or obtain valid and enforceable agreements with or from all inventors of BioNTech Technology or Research and Development Program Technology who are employed by or otherwise acting on behalf of BioNTech or its Affiliates assigning to BioNTech or its Affiliates each such inventor's entire right, title and interest in and to all such BioNTech Technology or Research and Development Program Technology (except to the extent applicable Law provides that all right, title and interest in and to such BioNTech Technology or Research and Development Program Technology automatically vests in BioNTech or its Affiliates by operation of law).

13.5.7 BioNTech will unrestrictedly claim and remunerate (and procure that its Affiliates will unrestrictedly claim and remunerate) all employee inventions of their respective employees comprised within the GEIA Technology in accordance with the provisions of the GEIA.

13.5.8 In respect of GEIA Technology created after the Effective Date to which Pfizer shall obtain a license hereunder, BioNTech will use Commercially Reasonable Efforts (and will procure that its Affiliates use Commercially Reasonable Efforts) to conclude agreements with BioNTech employee inventors regarding the respective inventions by which the respective inventors: (a) waive the employer's obligation to release the employee invention and to enable the employee inventor upon request to apply for foreign Intellectual Property Rights for such foreign countries in which it does not intend to apply for Intellectual Property Rights (Sec. 14 GEIA); and (b) waive the employer's obligation to notify the employee inventor and to transfer the right in the invention to the employee inventor at the latter's request and expense, if it does not intend to pursue the application for the grant on an Intellectual Property Right for the invention any further or if it does not want to maintain the Intellectual Property Right granted for the job-related invention (Sec. 16 GEIA); and (c) waive the employer's obligation to acknowledge protectability of the invention in case the employer decides not to file a registration, but to keep the invention secret (Sec. 17 GEIA);

13.5.9 To the extent BioNTech Technology or Research and Development Program Technology is created after the Effective Date by inventors employed by or acting on behalf of BioNTech's or its Affiliates' Third Party subcontractors, BioNTech will (a) use Commercially Reasonable Efforts (and will procure that its Affiliates use Commercially Reasonable Efforts) to obtain valid and enforceable agreements with their respective Third Party subcontractors imposing on their Third Party subcontractors the obligation to claim the rights in the invention in accordance with applicable Law and to conclude agreements with its employee inventors assigning to the respective Third Party subcontractor each such inventor's entire right, title and interest in and to all

such BioNTech Technology or Research and Development Program Technology (except to the extent applicable Law provides that all right, title and interest in and to such BioNTech Technology or Research and Development Program Technology automatically vests in the Third Party subcontractor by operation of law) and, (b) to the extent GEIA applies to such BioNTech Technology or Research and Development Program Technology, use Commercially Reasonable Efforts to obtain a waiver of inventor in his rights in Sec. 14, 16 and 17 GEIA;

13.5.10 with respect to any BioNTech Technology or Research and Development Program Technology to which Pfizer shall obtain a license hereunder that is made after the Effective Date in the jurisdiction of the GEIA by an inventor on behalf of BioNTech or its Affiliates who is employed by a university pursuant to Sec. 42 GEIA (e.g. university professors, research assistants), BioNTech will use Commercially Reasonable Efforts (and will procure that its Affiliates use Commercially Reasonable Efforts) to obtain valid and enforceable trifold agreements with such inventor and the respective university by which the university (a) waives its entire right, title and interest in and to that BioNTech Technology or Research and Development Program Technology made by the inventor, (b) the inventor assigns its rights, title and interest in and to that BioNTech Technology or Research and Development Program Technology to BioNTech or its Affiliates, (c) the inventor waives its rights pursuant to Sec. 14, 16 and 17 GEIA as well as (d) waives its negative publication right (Sec. 42 Nr. 2 GEIA) vis-a-vis BioNTech or its Affiliates;

13.5.11 with respect to animals used in conducting activities under this Agreement, BioNTech will, and will cause its Affiliates and permitted subcontractors to, comply with its policies on animal care and use which shall be no less strict than Pfizer's Corporate Policy regarding Animal Care and Use, attached hereto as Exhibit C (except where in conflict with applicable Law);

13.5.12 with respect to Human Material used, including collection or transfer, by BioNTech, its Affiliates or permitted subcontractors in conducting activities under this Agreement, (a) such use shall be in accordance with the binding part of the Research and Development Plan and shall be within the scope of and consistent with its ethical approval policies, (b) BioNTech will, and will cause its Affiliates or permitted subcontractors to, handle and use the Human Material in accordance with all applicable Laws and the ICF, which shall permit Pfizer to use the Human Material for the research purposes contemplated by this Agreement, (c) BioNTech will provide the ICF to Pfizer upon request by Pfizer, (d) the Human Material will be used for research purposes only and not be used for treatment of or administration to humans and (e) if BioNTech procures any Human Material from a Third Party such as a sample bank, it will ensure that the collection and transfer of the Human Material and the use of the Human Material for purposes of the Research and Development Plan is in accordance with all applicable Laws and recognized international standards for the protection of human research subjects;

13.5.13 BioNTech shall, at all times, maintain and enforce a compliance and ethics program containing adequate systems, policies and procedures for the detection, investigation, documentation, and remediation of any allegations, reports or findings related to a potential violation of applicable Law, including Anti-Corruption Laws, with respect to the Candidates, Products, payments and services under this Agreement, which policies shall be not less strict than Pfizer's Anti-Bribery and Anti-Corruption Principles attached hereto as Exhibit B. Such policies and procedures should set out rules governing interactions with HCPs, Government Officials, the engagement of Third Parties, and where appropriate, conducting due diligence, and the

investigation, documentation and remediation of any allegations, reports or findings related to a potential violation of applicable Laws, and BioNTech shall, upon Pfizer's request, require any persons acting on behalf of BioNTech in connection with this Agreement to complete anti-corruption compliance training provided by Pfizer, and will notify Pfizer of any persons that require or may require such training during the Term;

13.5.14 if BioNTech finds, following an investigation, credible evidence of a violation of any applicable policies and procedures that are designed to ensure compliance with any applicable Laws, including any criminal, civil or administrative laws or regulations, or violations of policies or procedures related to scientific misconduct or data integrity, BioNTech shall promptly inform Pfizer of the occurrence and the steps taken by BioNTech to remediate the occurrence;

13.5.15 in it undertaking, sponsoring, or having regulatory oversight over any Clinical Trials, BioNTech shall ensure and procure that all documentation for such Clinical Trials shall comply with, and take advantage of, any applicable Laws that serve to limit product liability claims and losses having regard to the pandemic status of COVID-19, including any requirements under any declarations pursuant to the Public Readiness and Emergency Preparedness (PREP) Act in the USA or any equivalent, similar or comparable legislation in the Territory;

13.5.16 In connection with its activities under this Agreement, BioNTech agrees to comply with all Applicable Laws, including all applicable Anti-Corruption Laws; and BioNTech has not taken, and will not during the term of this Agreement, take any action directly or indirectly to (i) offer, promise, provide, or authorize the offer or provision of money or anything of value, in order to improperly or corruptly seek to influence any Government Official or any other person in order to obtain or retain business or any other improper business advantage; (ii) request or accept any such improper payment; or (iii) cause a violation of any applicable Anti-Corruption Law. For example, this includes providing any inducement for such Government Official or person to approve, reimburse, prescribe, or purchase a Product, to influence the outcome of a clinical trial, or otherwise to benefit BioNTech's business activities improperly;

13.5.17 BioNTech agrees, at all times during the term of this Agreement, to: (i) maintain truthful and complete documentation supporting, in reasonable detail, the work and services performed and any expenses incurred in connection with this Agreement; and (ii) maintain financial books and records that timely, fairly, accurately, and completely reflect all financial transactions, in accordance with all Applicable Laws, including applicable Anti-Corruption Laws (for example, invoices, reports, statements, books, and other records), and shall maintain such books and records during the term of this Agreement and for five years after final payment has been made under this Agreement;

13.5.18 In connection with any audit or any investigation regarding any potential violations of Applicable Laws related to this Agreement, including all applicable Anti-Corruption Laws, BioNTech agrees to permit, during the term of this Agreement and for five years after final payment has been made under this Agreement, Pfizer's external auditors access to any non-privileged relevant books, documents, papers, and records of BioNTech involving transactions related to the Products, payments, or services provided under this Agreement; and

13.5.19 BioNTech agrees, from the beginning of the Commercialization Activities onwards until the end of the Term, to maintain and enforce adequate policies and procedures



describing the materials and information that may be distributed or discussed by BioNTech's employees, contractors, subcontractors, or agents related to the Products, and the manner in which such persons should handle unsolicited requests for information related to off-label uses of the Products. Such policies and procedures should be designed to ensure compliance with applicable Laws and regulations.

13.6 Pfizer Covenants. In addition to the covenants made by Pfizer elsewhere in this Agreement, Pfizer hereby covenants to BioNTech that, from the Effective Date until expiration or termination of this Agreement,

13.6.1 In connection with its activities under this Agreement, Pfizer will, at all times during the term of this Agreement, maintain its licenses, consents, authorizations or registrations to do business and continue to make any notifications as may be necessary or required by local Laws, regulations, policies, or administrative requirements in order to provide the Products or Services encompassed within this Agreement, and will ensure that providing such Products or Services will not be inconsistent with any other obligation of Pfizer;

13.6.2 Pfizer and its Affiliates maintain or will obtain valid and enforceable agreements with or from all inventors of Pfizer Improvements or Research and Development Program Technology who are employed by or otherwise acting on behalf of Pfizer or its Affiliates valid and enforceable agreements assigning to Pfizer or its Affiliates each such inventor's entire right, title and interest in and to all such Pfizer Improvements or Research and Development Program Technology (except to the extent applicable Law provides that all right, title and interest in and to such Pfizer Improvements or Research and Development Program Technology automatically vests in Pfizer or its Affiliates by operation of law), and Pfizer and its Affiliates have made or will make any payments owing to any such inventors in respect of any Pfizer Improvements or Research and Development Program Technology or any other Person that is required in connection with the creation or exploitation of or transfer of rights to such Pfizer Improvements or Research and Development Program Technology;

13.6.3 with respect to Human Material used, including collection or transfer, by Pfizer, its Affiliates or permitted subcontractors in conducting activities under this Agreement, (a) such use shall be within the scope of and consistent with its ethical approval policies, (b) Pfizer will, and will cause its Affiliates or permitted subcontractors to, handle and use the Human Material in accordance with all applicable Laws and the ICF, (c) Pfizer will provide the ICF to BioNTech upon request by BioNTech, (d) the Human Material will be used for research purposes only and not be used for treatment of or administration to humans and (e) if Pfizer procures any Human Material from a Third Party such as a sample bank, it will ensure that the collection and transfer of the Human Material and the use of the Human Material for purposes of the Research and Development Plan is in accordance with all applicable Laws and recognized international standards for the protection of human research subjects; and

13.6.4 Pfizer will comply with the provisions of the Current Licenses set forth in Schedule 1.45 in respect of BioNTech Technology sublicensed to Pfizer under the respective Current Licenses insofar as Pfizer is using such BioNTech Technology;

13.6.5 Pfizer shall comply with its Anti-Bribery and Anti-Corruption Principles attached hereto as Exhibit B and its Corporate Policy regarding Animal Care and Use, attached hereto as Exhibit C; and

13.6.6 in it undertaking, sponsoring, or having regulatory oversight over any Clinical Trials, Pfizer shall ensure and procure that all documentation for such Clinical Trials shall comply with, and take advantage of, any applicable Laws that serve to limit product liability claims and losses having regard to the pandemic status of COVID-19, including any requirements under any declarations pursuant to the Public Readiness and Emergency Preparedness (PREP) Act in the USA or any equivalent, similar or comparable legislation in the Territory.

13.6.7 In connection with its activities under this Agreement, Pfizer agrees to comply with all applicable Laws, including all applicable Anti-Corruption Laws; and Pfizer has not taken, and will not during the term of this Agreement, take any action directly or indirectly to (i) offer, promise, provide, or authorize the offer or provision of money or anything of value, in order to improperly or corruptly seek to influence any Government Official or any other person in order to obtain or retain business or any other improper business advantage; (ii) request or accept any such improper payment; or (iii) cause a violation of any applicable Anti-Corruption Law. For example, this includes providing any inducement for such Government Official or person to approve, reimburse, prescribe, or purchase a Product, to influence the outcome of a clinical trial, or otherwise to benefit Pfizer's business activities improperly;

13.6.8 Pfizer agrees, at all times during the term of this Agreement, to: (i) maintain truthful and complete documentation supporting, in reasonable detail, the work and services performed and any expenses incurred in connection with this Agreement; and (ii) maintain financial books and records that timely, fairly, accurately, and completely reflect all financial transactions, in accordance with all applicable Laws, including applicable Anti-Corruption Laws (for example, invoices, reports, statements, books, and other records), and shall maintain such books and records during the term of this Agreement and for five years after final payment has been made under this Agreement;

13.6.9 In connection with any audit or any investigation regarding any potential violations of applicable Laws related to this Agreement, including all applicable Anti-Corruption Laws, Pfizer agrees to permit, during the term of this Agreement and for five years after final payment has been made under this Agreement, BioNTech's external auditors access to any non-privileged relevant books, documents, papers, and records of Pfizer involving transactions related to the Products, payments, or services provided under this Agreement; and

13.6.10 Pfizer agrees, from the beginning of the Commercialization Activities onwards until the end of the Term, to maintain and enforce adequate policies and procedures describing the materials and information that may be distributed or discussed by Pfizer's employees, contractors, subcontractors, or agents related to the Products, and the manner in which such persons should handle unsolicited requests for information related to off-label uses of the Products. Such policies and procedures should be designed to ensure compliance with applicable Laws and regulations;

13.7 Notifications. During the Term:

13.7.1 BioNTech will promptly notify Pfizer in writing or orally in the event that it learns of:

13.7.1.1 any prior art or other facts that BioNTech believes would result in the invalidity or unenforceability of any of the claims included in any of the BioNTech Patent Rights or Research and Development Program Patent Rights; or

13.7.1.2 any inequitable conduct or fraud on the patent office with respect to any of the BioNTech Patent Rights or Research and Development Program Patent Rights; or

13.7.1.3 any Person (other than Persons identified as inventors of inventions disclosed in the BioNTech Patent Rights or Research and Development Program Patent Rights) who claims to be an inventor of an invention disclosed in the BioNTech Patent Rights or Research and Development Program Patent Rights; and

13.7.1.4 any material lawsuits, claims, administrative actions, government inquiries or investigations, or other proceedings related to the activities contemplated under this Agreement or under any Related Agreement to the extent such notification is permitted under applicable Law, except to the extent that BioNTech's counsel reasonably believes that such disclosure to Pfizer could violate applicable privacy laws or have a significant adverse impact on BioNTech's legal position or defense (including the loss of attorney-client privilege) with respect to any such lawsuit, claim, administrative action, government inquiry or investigation, or other proceeding. In the event that BioNTech determines that disclosure could violate applicable privacy laws or have a significant adverse impact on its legal position or defense, BioNTech shall promptly notify Pfizer that it is exercising its right not to disclose.

13.7.2 Pfizer will promptly notify BioNTech in writing or orally in the event that it learns of any material lawsuits, claims, administrative actions, government inquiries or investigations, or other proceedings related to the activities contemplated under this Agreement or under any Related Agreement to the extent such notification is permitted under applicable Law, except to the extent that Pfizer's counsel reasonably believes that such disclosure to BioNTech could violate applicable privacy laws or have a significant adverse impact on Pfizer's legal position or defense (including the loss of attorney-client privilege) with respect to any such lawsuit, claim, administrative action, government inquiry or investigation, or other proceeding. In the event that Pfizer determines that disclosure could violate applicable privacy laws or have a significant adverse impact on its legal position or defense, Pfizer shall promptly notify BioNTech that it is exercising its right not to disclose.

13.8 Representation by Legal Counsel. Each Party hereto represents that it has been represented by legal counsel in connection with this Agreement and acknowledges that it has participated in the drafting

hereof. In interpreting and applying the terms and provisions of this Agreement, the Parties agree that no presumption will exist or be implied against the Party which drafted such terms and provisions.

13.9 BioNTech's Knowledge. All references in this Section 13 to BioNTech's knowledge (or equivalent) shall refer to the actual knowledge after reasonable internal inquiry of BioNTech's management comprising those individuals set forth in Schedule 13.9.

13.10 Disclaimer. THE FOREGOING REPRESENTATIONS AND WARRANTIES OF EACH PARTY ARE IN LIEU OF ANY OTHER REPRESENTATIONS AND WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR ANY IMPLIED WARRANTIES OF FITNESS FOR A PARTICULAR PURPOSE, ALL OF WHICH ARE HEREBY SPECIFICALLY EXCLUDED AND DISCLAIMED.

13.11 Compliance Certificates. Each Party agrees to complete and submit to the other, on an annual basis for the Term, a certification in the form set out in Schedule 13.11 (an ABAC Compliance Certification).

#### 14. GOVERNMENT APPROVALS; TERM AND TERMINATION

14.1 Government Approvals. Each of BioNTech and Pfizer will cooperate with the other Party and to make all registrations, filings and applications, to give all notices and to obtain as soon as practicable all governmental or other consents, transfers, approvals, orders, qualifications authorizations, permits and waivers, if any, and to do all other things necessary or useful for the consummation of the transactions as contemplated hereby including the collection of Human Material.

14.2 Term. The term of this Agreement (the "Term") will commence on the Effective Date and shall continue, unless terminated earlier in accordance with this Section 14, for so long as either at least one Candidate or Product is being Developed for use in the Territory or a Product Commercialized anywhere in the Territory.

14.3 Termination for Cause by a Party. Either Party may terminate this Agreement for cause, at any time during the Term, by giving written notice to the other Party in the event that such other Party commits a material breach of its obligations under this Agreement which, taking into account the breached obligation and the effect of the breach, has a material detrimental effect on the overall total value and fundamental purpose of this Agreement, and such material breach remains uncured for at least one hundred and [\*\*\*], in each case measured from the date written notice of such material breach is given to the other Party; *provided, however*, that if any breach is not reasonably curable within [\*\*\*] and if the Party accused of breach is making a bona fide effort to cure such breach, such termination will be delayed for a time period either to be agreed by both Parties (which non-breaching Party's consent shall not be unreasonably withheld or conditioned) or in the absence of agreement for such reasonable additional period required to cure the breach (having regard to the nature of the breach and steps required to cure it) in order to permit the Party accused of a breach a reasonable period of time to cure such breach. If the alleged material breach relates to the non-payment of any amount due under this Agreement, the cure period will be tolled pending resolution of any bona fide dispute between the Parties as to whether such payment is due. For the avoidance of doubt, a Party's failure to use Commercially Reasonable Efforts to Commercialize the Product in its

Commercialization Territory may constitute a material breach of this Agreement if such failure is a material default that has materially diminishes the overall total value and fundamental purpose of this Agreement.

14.4 Termination by Pfizer for Convenience. [\*\*\*], Pfizer may terminate this Agreement, on a country-by-country basis or in its entirety for convenience upon [\*\*\*] prior written notice [\*\*\*] (which notice period may be shortened by BioNTech in BioNTech's sole discretion through written notice to Pfizer at any time after BioNTech's receipt of such termination notice) without any liability to BioNTech.

14.5 Termination by Pfizer for [\*\*\*]. [\*\*\*].

14.6 Termination Following Certain Violations.

14.6.1 **Cause for Termination following Certain Violations.** Subject to Section 14.8, this Agreement may be terminated at any time during the Term by either Party immediately upon written notice to the other Party (the "Violating Party") if:

14.6.1.1 the Violating Party is convicted of violating any Anti-Corruption Law in connection with the performance of its obligations under this Agreement and such violation materially adversely affects the ability of either Party to perform its Commercialization Activities or Medical Activities;

14.6.1.2 the Violating Party enters into a settlement or other resolution that includes an admission of liability under any such Anti-Corruption Law in connection with this Agreement and such admission of liability materially adversely affects the ability of either Party to perform its Commercialization Activities or Medical Activities;

14.6.1.3 the Violating Party materially breaches any of its covenants, contained in Section 13.5.14, 13.5.16, 13.5.17 or 13.5.18, or violates any Anti-Corruption Law in connection with its Commercialization Activities or Medical Activities and such violation materially adversely affects the ability of either Party to perform its Commercialization Activities or Medical Activities (provided that the term "material" shall be interpreted taking into account each Party's responsibilities under the Agreement);

provided that in each case, that the Violating Party has not cured (such cure to be pursuant to Section 14.6.2, as applicable) such material breach or violation within ninety (90) days after written notice delivered by the non-Violating Party to the alleged Violating Party requesting cure of the breach.

14.6.2 **Cure of Violations of Anti-Corruption Laws.** With respect to any breach resulting in a right of termination under Section 14.6.1, such breach may be cured by taking all of the following actions to the extent relevant to such breach:

14.6.2.1 diligent investigation of the facts relating to such breach or violation by the Violating Party and, to the extent not covered by any opinion from the Violating Party's counsel that such disclosure would waive any applicable privilege attaching to such findings, the sharing of the investigation's findings with the other Party;

14.6.2.2 appropriate disciplinary action by the Violating Party (which may include termination) with respect to any of its directors, officers or employees who the Violating

Party believes was responsible for or involved in the breach or violation, or any related violation of the Violating Party's compliance and ethics program;

14.6.2.3 appropriate remedial action by the Violating Party, which may include termination of any contractor, agent, sub-contractor, customer, other Person or vendor that the Violating Party believes was responsible for or involved in the breach or violation or termination of any business or relationship that the Violating Party believes was obtained through bribery; and

14.6.2.4 presentation to the other Party of the Violating Party's plan for resolution or remediation of the breach or violation and informing the other Party that the Violating Party has initiated activities under such plan (e.g., through the applicable Committee(s) or other applicable mechanism under this Agreement) unless the Violating Party has received an opinion from counsel that such disclosure would waive any applicable privilege attaching to such plan.

14.7 Exclusion of termination rights. Save for the rights expressly set out in this Agreement, neither Party may terminate this Agreement prior to expiry of the term under any common law right or other remedy.

14.8 Effects of Expiration or Termination.

14.8.1 **General.** Upon the expiration or termination of this Agreement, with regard to the Product in the countries that are the subject of such expiration or termination, the Parties acknowledge and agree that, except as otherwise expressly set forth in this Agreement and subject to Section 14.8.8, each Party's rights and obligations under this Agreement will terminate in their entirety (including all rights and licenses and sublicenses granted by either Party to the other Party hereunder, and all sublicenses granted to Affiliates or Third Parties under the rights granted hereunder) with respect to the Terminated Territory from and after the Termination Effective Date.

14.8.2 **Termination for Cause by a Party.** In the event that a Party terminates this Agreement for cause pursuant to Section 14.3 or upon its expiration, all rights and obligations of each Party hereunder will cease (including all rights and licenses and sublicenses granted by either Party to the other Party hereunder, and all sublicenses granted to Affiliates or Third Parties under the rights granted hereunder), except as otherwise expressly provided herein.

14.8.3 **Termination for Pfizer's Convenience.** Upon Pfizer's termination of the Agreement as a whole pursuant to Section 14.4, (a) Pfizer shall pay for all Shared Development Costs (i) incurred by either Party in accordance with the binding portions of the Research and Development Plan, Manufacturing Plan and Development Budget up to the date notice is served to terminate by Pfizer; and (ii) that are irrevocably committed to by a Party prior to the date notice is served to terminate by Pfizer in accordance with the binding portions of the Research and Development Plan, Manufacturing Plan and Development Budget, and which costs cannot be refunded, reduced or otherwise allocated to another project; and (b) Pfizer shall pay for all future Development costs that are irrevocably committed to by BioNTech in accordance with the binding portions of the Research and Development Plan, Manufacturing Plan and Development Budget prior to the date notice is served to terminate by Pfizer, and which costs cannot be refunded, reduced or otherwise allocated to another project.

14.8.4 **No Effect on Related Agreements.** Unless explicitly agreed otherwise, termination or expiration of this Agreement shall not affect any other agreements concluded hereunder, including the Manufacturing agreements pursuant to Section 7.

14.8.5 **Termination-specific Definitions.** Solely for purposes of this Section 14:

14.8.5.1 **“Termination Effective Date”** means the effective date of expiration or termination with respect to the Product in the applicable Terminated Territory.

14.8.5.2 **“Terminated Territory”** means (i) in the event of termination pursuant to Section 14.4, those countries regarding which such termination has occurred (to the extent this Agreement is not terminated with respect to the entire Territory pursuant to Section 14.4) or (ii) in the event of expiration or any other termination, the entire Territory.

14.8.6 **Return of Rights and Materials.** BioNTech will have the sole right, as between the Parties, to Develop, Manufacture, Commercialize and otherwise exploit the Product in and for the Terminated Territory. Accordingly, upon the Termination Effective Date for such Product, or such earlier time as is indicated in this Section 14.8.6, the Parties will undertake the activities set forth below; *provided* that in the event that BioNTech terminates this Commercialization Agreement pursuant to Section 14.3, the remedies provided for in this Section 14.8.6 shall be taken into account to reduce any damages calculation awarded in any action relating to Pfizer’s alleged material breach of this Agreement:

14.8.6.1 **Cessation of Activities.** Pfizer will, except as required under this Section 14.8 or as required by applicable Law, immediately cease all of its Commercialization Activities in or for the Terminated Territory as of the Termination Effective Date, and (x) if BioNTech terminates this Agreement pursuant to Section 14.3 or Pfizer terminates this Agreement pursuant to Section 14.4, BioNTech shall be entitled to request from Pfizer to purchase, or re-purchase, as applicable, any or all of the inventory of Product then owned by Pfizer that is of appropriate quality for sale or resale by BioNTech (provided that if Pfizer is obligated to supply Product pursuant to Section 14.8.6.5, BioNTech shall be obligated to first purchase, or re-purchase, as applicable all such inventory of Product then owned by Pfizer of such saleable quality prior to Pfizer manufacturing or having manufactured for it Product pursuant to Section 14.8.6.5) and (y) if Pfizer terminated this Agreement pursuant to Section 14.3, then Pfizer shall be entitled to require BioNTech to purchase, or re-purchase, as applicable, any or all such inventory of Product then owned by Pfizer of such saleable quality, and in each case of (x) or (y) with the understanding that (i) the Party having such option may exercise such option by providing written notice thereof to the other Party within [\*\*\*] after the Termination Effective Date, and upon exercise of such option, (ii) Pfizer shall promptly ship such inventory of Product to BioNTech or its designee, and (iii) BioNTech shall pay Pfizer the Transfer Price (or cancel any outstanding unpaid invoices) for such inventory of Product, including all shipping costs.

14.8.6.2 **Product Data.** Pfizer, upon BioNTech’s written request and subject to any applicable obligations to Third Parties, will promptly transfer to BioNTech copies of all data, reports, records, and other Know-How specified in such request that (i) solely relate to the Product, (ii) was generated by or on behalf of Pfizer or its Affiliates under this

Agreement, (iii) is reasonably necessary for BioNTech's continued Commercialization of the Product in the Terminated Territory, and (iv) is at the time of such request in Pfizer's or its Affiliates' possession and Control ("Terminated Product Data"), provided that Pfizer shall not be obligated to provide to BioNTech any such Terminated Product Data where Pfizer or its Affiliates are restricted from doing so by Applicable Law or the terms and conditions of any agreement between Pfizer or any of its Affiliates and a Third Party. The Terminated Product Data will be provided in the form in which Pfizer or its Affiliates has maintained such Terminated Product Data; *provided that* Pfizer will not unreasonably withhold its consent and cooperation, if necessary, in connection with BioNTech's (or its designee's) further Commercialization of the Product in the Terminated Territory to obtain original hardcopies or duplicate copies thereof. BioNTech shall not disclose the Terminated Product Data to any Third Party, except to the extent necessary for BioNTech, after the Termination Effective Date, to Commercialize the Product in the Terminated Territory and, for clarity, BioNTech shall have no right to use or to permit any Affiliate or Third Party to use any or the Terminated Product Data outside of the Territory (except in accordance with the licenses granted under this Agreement).

14.8.6.3 *Transfer or Destruction of Confidential Information.* Pfizer will promptly transfer to BioNTech, or destroy upon BioNTech's request (and certify such destruction to BioNTech), all Confidential Information of BioNTech, except to the extent that Pfizer (i) must retain such Confidential Information in order to perform its obligations under this Section 14 or to comply with applicable Laws, (ii) is permitted to retain such Confidential Information pursuant to the terms and conditions of this Agreement or (iii) has received such Confidential Information pursuant to the Flu Collaboration License or (iv) has a need to retain or use such Confidential Information for purposes of exercising its rights or performing its obligations under the Flu Collaboration License. BioNTech will promptly transfer to Pfizer, or destroy upon Pfizer's request (and certify such destruction to Pfizer), all Confidential Information of Pfizer, except to the extent that BioNTech (i) must retain such Confidential Information in order to perform its obligations under this Section 14 or to comply with applicable Laws, (ii) is permitted to retain such Confidential Information pursuant to the terms and conditions of this Agreement or (iii) has received such Confidential Information pursuant to the Flu Collaboration License or (iv) has a need to retain or use such Confidential Information for purposes of performing its obligations under the Flu Collaboration License.

14.8.6.4 *Use of the Pfizer House Mark.* Following the Termination Effective Date, BioNTech will not use the Pfizer House Mark in connection with the Commercialization of the Product, including on any Packaging and Labeling, Promotional Materials or Medical Education Materials; *provided that* BioNTech may use any and all then-existing inventory of Packaging and Labeling, Promotional Materials and Medical Education Materials bearing the Pfizer House Mark for such time, if any, in a country within the Territory as may be required to receive any required Regulatory Approvals in such country in the Territory in connection with the removal of the Pfizer House Mark from such Packaging and Labeling, Promotional Materials or Medical Education Materials and a reasonable sell-off period thereafter (not to exceed [\*\*\*]), in each case, if permitted by applicable Law; *provided, further,* that, promptly following the Termination Effective Date, BioNTech promptly will seek such Regulatory Approval in each applicable country



in the Territory for the removal of the Pfizer House Mark from any existing supplies of such Packaging and Labeling, Promotional Materials and Medical Education Materials bearing the Pfizer House Mark, and BioNTech will implement the same within [\*\*\*] following its receipt of such approvals.

14.8.6.5 *Continuation of Pfizer Licenses.* Except in the event of Pfizer's termination of this Agreement pursuant to Section 14.3 or 14.9.1, (a) [\*\*\*], (b) [\*\*\*], (c) [\*\*\*], and (d) [\*\*\*].

14.8.6.6 *Exclusivity.* In the event of Pfizer's termination pursuant to Section 14.3 or 14.9, the Parties' obligations pursuant to Section 3.11.3 shall survive the termination or expiration of this Agreement for a period of [\*\*\*] years provided that BioNTech shall not be prevented from using the Product within the Field. In the event of Pfizer's termination pursuant to Section 14.4 or 14.5, [\*\*\*].

14.8.6.7 *Transition Plan.* In the event of any termination of this Agreement, the Parties shall prepare and agree upon a written transition plan setting forth the responsibilities of each Party and the timeline for the transition to BioNTech of the responsibilities for distribution, Commercialization and promotion of the Product in the Pfizer Commercialization Territory. Such transition plan will provide for a transition as quickly as is practicable, provided that transition planning and activities may begin prior to the Termination Effective Date and such transition shall be completed within twelve (12) months after the Termination Effective Date. Such transition plan shall not be inconsistent with this Section 14.8.6. Each Party (i) will use its Commercially Reasonable Efforts to complete the activities required of it under such transition plan in a timely manner, and (ii) bear its own costs in undertaking such activities.

14.8.7 **Accrued Rights.** Subject to Section 14.8.6, Expiration or termination of this Agreement for any reason will be without prejudice to any right which will have accrued to the benefit of either Party prior to such expiration or termination or are attributable to activities prior to such termination or expiration, including damages arising from any breach under this Agreement. Expiration or termination of this Agreement will not relieve either Party from any obligation which is expressly indicated to survive such expiration or termination.

14.8.8 **Survival Period.** The following sections, together with any sections that expressly survive or are intended to survive after expiration or termination, will survive expiration or termination of this Agreement for any reason: Sections 1 (Definitions), 3.5 (additional licenses), 3.7 (Sublicenses) (only to the extent the relevant licenses survive), 4.9 (Gross Profit Sharing) and 4.10 (Third Party License Payments), but only in relation to any Pfizer Quarter in which sales have occurred prior to the termination or expiration, 4.11 (Taxes), 4.12 (Currency, Source of Payments), 4.13 (Method of Payment), 4.14 (Record Keeping and Audits), 4.17 (Late Payment), 4.18 (No Double Counting), 5.4.2 (Title to Materials), 5.4.4 (Return of Proprietary Materials), 8.2.6.2 (Transfer of Regulatory Filings by Pfizer), 8.7 (Liability), 9.2.2, 9.3.1.2 and 9.3.2.2 (Product Liability), 9.10 (Returns) and 9.11 (Recalls), but, in each case of 9.2.2, 9.3.1.2, 9.3.2.2, 9.10 and 9.11, only in relation to sales of Product that occurred prior to termination, 11.2 (Ownership of Intellectual Property), 11.3.1.2 and 11.3.1.3 (Filing, Prosecution and Maintenance of Patent Rights), 11.3.2 (Joint Patent Rights), 11.3.6 (Liability), 12 (Confidentiality), 14.8 (Effects of Termination), 14.9 (Provision for Insolvency), 16.1 (No Consequential Damages), 16.2

(Indemnification by Pfizer), 16.3 (Indemnification by BioNTech), 16.4 (Procedure), 17 (Miscellaneous) and, to the extent an Enforcement Action or Infringement Claim is active, live or pending at the time of expiry or termination, Sections 11.4 or 11.8, as applicable.

14.9 Provision for Insolvency.

14.9.1 **Termination Right.** BioNTech will be deemed a “Debtor” under this Agreement if, at any time during the Term (a) a case is commenced by or against BioNTech under the Bankruptcy Code, (b) BioNTech files for or is subject to the institution of bankruptcy, reorganization, liquidation or receivership proceedings (other than a case under the Bankruptcy Code), (c) BioNTech assigns all or a substantial portion of its assets for the benefit of creditors, (d) a receiver or custodian is appointed for BioNTech’s business or (e) a substantial portion of BioNTech’s business is subject to attachment or similar process; *provided, however*, that in the case of any involuntary case under the Bankruptcy Code, BioNTech will not be deemed a Debtor if the case is dismissed within 60 days after the commencement thereof. If BioNTech is deemed a Debtor, then Pfizer may terminate this Agreement by providing written notice to BioNTech. If Pfizer terminates this Agreement pursuant to this Section 14.9.1, then: (i) all licenses granted to Pfizer under this Agreement will become irrevocable and perpetual, and Pfizer will have no further obligations to BioNTech under this Agreement other than (A) those obligations that expressly survive termination in accordance with Section 14.8.8 and (B) an obligation to pay royalties with respect to Net Sales of Products in an amount equal to 100% of the amount that would otherwise have been payable under this Agreement, such amount to be paid in accordance with and subject to the other terms of this Agreement governing the payment of royalties; (ii) such termination will not be construed to limit BioNTech’s right to receive payments that accrued before the effective date of such termination; (iii) Pfizer will have the right to offset, against any payment owing to BioNTech as provided for under clause (i), above, any damages found or agreed by the Parties to be owed by BioNTech to Pfizer; and (iv) nothing in this Section 14.9.1 will limit any other remedy Pfizer may have for any breach by BioNTech of this Agreement.

14.9.2 **Rights to Intellectual Property.** All rights and licenses now or hereafter granted by BioNTech to Pfizer under or pursuant to any Section of this Agreement, including Sections 3.1.1, 3.2.1, 3.3, 3.4.1, 3.5.1 and Section 9 hereof, are rights to “intellectual property” (as defined in the Bankruptcy Code). The Parties hereto acknowledge and agree that the payments provided for under Sections 4 and all other payments by Pfizer to BioNTech hereunder or under this Agreement do not constitute royalties within the meaning of Section 365(n) of the Bankruptcy Code or relate to licenses of intellectual property hereunder. If (a) a case under the Bankruptcy Code is commenced by or against BioNTech, (b) this Agreement is rejected as provided in the Bankruptcy Code and (c) Pfizer elects to retain its rights hereunder as provided in Section 365(n) of the Bankruptcy Code, then BioNTech (in any capacity, including debtor-in-possession) and its successors and assigns (including any trustee) will provide to Pfizer all Intellectual Property Rights licensed hereunder, and agrees to grant and hereby grants to Pfizer and its Affiliates a right to access and to obtain possession of and to benefit from and, in the case of any chemical or biological material or other tangible item of which there is a fixed or limited quantity, to obtain a pro rata portion of, each of the following to the extent related to any Candidate or Product, or otherwise related to any right or license granted under or pursuant to this Agreement: (i) copies of pre-clinical and clinical research data and results; (ii) all of the following (to the extent that any of the following are so related): BioNTech Materials, cell lines, antibodies, assays, reagents and other biological

materials; (iii) samples or Candidates and Products; (iv) BioNTech Technology, Product Technology, and RNA Technology, (v) laboratory notes and notebooks; (vi) Candidate and Product data or filings, and (vii) rights of reference in respect of filings for and Regulatory Approvals, all of which constitute "embodiments" of intellectual property pursuant to Section 365(n) of the Bankruptcy Code, and (viii) all other embodiments of such intellectual property, whether any of the foregoing are in BioNTech's possession or control or in the possession and control of any Third Party but which BioNTech has the right to access or benefit from and to make available to Pfizer. BioNTech will not interfere with the exercise by Pfizer or its Affiliates of rights and licenses to Intellectual Property Rights licensed hereunder and embodiments thereof in accordance with this Agreement and agrees to use Commercially Reasonable Efforts to assist Pfizer and its Affiliates to obtain such Intellectual Property Rights and embodiments thereof in the possession or control of Third Parties as reasonably necessary or useful for Pfizer or its Affiliates or Sublicensees to exercise such rights and licenses in accordance with this Agreement.

14.9.3 **No Limitation of Rights.** All rights, powers and remedies of Pfizer provided in this Section 14.9 are in addition to and not in substitution for any and all other rights, powers and remedies now or hereafter existing at Law or in equity (including the Bankruptcy Code) in the event of the commencement of a case under the Bankruptcy Code involving BioNTech. To the extent equivalent rights exist under the Bankruptcy Code existing from time to time in the jurisdiction where BioNTech is established the foregoing provisions shall be interpreted in accordance with such equivalent rights, and where such equivalent rights do not exist Pfizer shall be entitled to avail of itself all remedies and rights available to it as a creditor and licensee of Intellectual Property Rights under such local Bankruptcy Code.

## 15. CHANGE OF CONTROL

15.1 Change of Control. If a Change of Control occurs with respect to a Party and a Third Party during the Term, or if a Party or any of its Affiliates acquires or merges with a Third Party during the Term, (in either case such Party being the "Affected Party"):

15.1.1 if such Third Party is, at the time of such Change of Control or acquisition or merger, conducting activities that would cause the Affected Party or one of its Affiliates to violate Section 3.11.1 (such activities, a "Acquisition Program"), then such Affected Party or such Third Party shall be permitted to continue such Acquisition Program and such continuation will not constitute a violation of Section 3.11.1;

15.1.2 the provisions of Section 12.7 shall apply and no Confidential Information of the other Party or its Affiliates may be disclosed to the Third Party and shall not be used in any Acquisition Program (if any) and the Affected Party shall implement and maintain, in accordance with such Affected Party's internal commercially reasonable practices, an information and personnel barrier between the working teams involved in the day to day conduct of such Affected Party's internal program of Development and Manufacture of Candidates and Products under this Agreement, and any activities of the Third Party, including under any Acquisition Program; and

15.1.3 if BioNTech is the Affected Party, then [\*\*\*].

15.2 Effects of Change of Control. In the event of a Change of Control of BioNTech by during the Term, the following provisions of this Section 15 shall also apply:

15.2.1 **BioNTech Intellectual Property**. All BioNTech Technology and Research and Development Program Technology, Controlled by BioNTech immediately prior to such BioNTech Change of Control shall continue to be BioNTech Technology and Research and Development Program Technology licensed to Pfizer for purposes of this Agreement.

15.2.2 **Existing Acquirer Intellectual Property**. Patent Rights and Know-How that were Controlled by the entity acquiring BioNTech or such entity's Affiliates that were not Affiliates of BioNTech prior to such BioNTech Change of Control (collectively, the "Acquirer") shall not be included within the licenses granted to Pfizer hereunder.

15.2.3 **Independent Intellectual Property**. Patent Rights and Know-How that, following such BioNTech Change of Control, are developed, made or otherwise acquired or Controlled by the Acquirer outside of the Research and Development Plan, or the Manufacturing Plan or outside of conducting Commercialization or regulatory activities pursuant to this Agreement and without use of Pfizer's Technology, Pfizer's Confidential Information, Research and Development Program Technology, BioNTech Improvements or BioNTech Technology shall not be included within the Research and Development Program Technology or BioNTech Technology or BioNTech Third Party Agreements (it being understood, however, for the avoidance of doubt, that all BioNTech Technology, Research and Development Program Technology, and Intellectual Property Rights developed by BioNTech or the Acquirer in the course of, or used by BioNTech or the Acquirer under the Research and Development Plan, used in the Manufacture of the Candidates or Products by BioNTech, or used by BioNTech in its Commercialization or regulatory activities, shall be licensed to Pfizer pursuant to the licenses set forth in this Agreement).

15.2.4 **Research and Development Program Technology**. No Research and Development Program Technology Controlled by Pfizer including Pfizer Improvements shall be licensed or sub-licensable to the Acquirer, and no Confidential Information of Pfizer or its Representatives shall be disclosed to the Acquirer, in each case without the prior written consent of Pfizer.

15.2.5 **Effect on Certain Agreement Provisions**. From and after the effective date of a BioNTech Change of Control by a Specified Person, the Acquirer shall not be considered an "Affiliate" for the purposes of this Agreement, provided that the Acquirer does not engage in any activities otherwise restricted under Section 3.11 using any Research and Development Program Technology, Pfizer Technology, Pfizer Improvements or Confidential Information of Pfizer.

## 16. LIMITATION OF LIABILITY, INDEMNIFICATION AND INSURANCE

16.1 No Consequential Damages. Except with respect to liability arising from a breach of Sections 11 or 12, from any willful misconduct or intentionally wrongful act, or to the extent such Party may be required to indemnify the other Party under this Section 16, in no event will either Party or its Representatives be liable under this Agreement for any special (only as related to indirect, incidental or consequential damages), indirect, incidental, consequential or punitive damages, whether in contract, warranty, tort, negligence, strict liability or otherwise, including loss of indirect profits or revenue suffered by the other Party or any of its Representatives. Without limiting the generality of the foregoing,

“consequential damages” will be deemed to include, and neither Party will be liable to the other Party or any of such other Party’s Representatives or stockholders for any damages based on or measured by loss of projected or speculative future sales of the Products, any development, regulatory, launch or sales threshold milestone payments due or any other unearned, speculative or otherwise contingent payments provided for in this Agreement.

16.2 **Indemnification by Pfizer.** Pfizer will indemnify, defend and hold harmless BioNTech, each of its Affiliates, and each of its and its Affiliates’ employees, officers, directors and agents (each, a “**BioNTech Indemnified Party**”) from and against any and all claims, causes, or allegations (whether threatened or pending), judgments, expenses, damages, liabilities, obligations, fees (including the reasonable fees of attorneys and other consulting or testifying professionals), costs and losses (collectively, “**Liabilities**”) that the BioNTech Indemnified Party may be required to pay to one or more Third Parties resulting from or arising out of (a) use of the Pfizer Technology, Pfizer Materials, and/or Pfizer Know-How disclosed by or on behalf of Pfizer in accordance with the rights licensed under this Agreement infringing a Third Party Patent Right or misappropriating a Third Party trade secret, (b) use of the Pfizer House Marks in accordance with the rights licensed under this Agreement or (c) the material breach by Pfizer of any of its representations, warranties or covenants set forth in Section 5.4.1, Section 13.1 or Section 13.2 or Section 13.6; except, in each case, to the extent caused by the negligence, recklessness or intentional misconduct of BioNTech or any BioNTech Indemnified Party or to the extent BioNTech indemnifies Pfizer under this Agreement.

16.3 **Indemnification by BioNTech.** BioNTech will indemnify, defend and hold harmless Pfizer, its Affiliates, Sublicensees, contractors, distributors and each of its and their respective employees, officers, directors and agents (each, a “**Pfizer Indemnified Party**”) from and against any and all Liabilities that the Pfizer Indemnified Party may be required to pay to one or more Third Parties resulting from or arising out of (a) use of the BioNTech Technology [\*\*\*], BioNTech Materials, and/or BioNTech Know-How disclosed by or on behalf of BioNTech in accordance with the rights licensed under this Agreement infringing a Third Party Patent Right or misappropriating a Third Party trade secret, (b) the Candidates or Products in accordance with the rights licensed under this Agreement, save to the extent the Liabilities are in respect of (i) the exploitation of Pfizer Technology, Pfizer Materials, and/or Pfizer Know-How in accordance with the rights licensed under this Agreement infringing a Third Party Patent Right or misappropriating a Third Party trade secret or (ii) [\*\*\*]; (c) use of the BioNTech House Marks in accordance with the rights licensed under this Agreement, (d) rights or obligations under the GEIA relating to inventions made by employees of BioNTech or its Affiliates or Third Party Licensors in relation to BioNTech Technology or Research and Development Program Technology used in any Candidate or Product; or (e) the material breach by BioNTech or any of its Representatives of any of its representations, warranties or covenants set forth in Section 8, Section 13.1, Section 13.2, Section 13.3, or Section 13.5; except, in each case, to the extent caused by the negligence, recklessness or intentional misconduct of Pfizer or any Pfizer Indemnified Party or to the extent Pfizer indemnifies BioNTech under this Agreement.

16.4 **Procedure.**

16.4.1 **Notice.** Each Party will notify the other Party in writing in the event it becomes aware of a claim for which indemnification may be sought hereunder. In the event that any Third Party asserts a claim or other proceeding (including any governmental investigation) with respect to any matter for which a Party (the “**Indemnified Party**”) is entitled to indemnification hereunder (a “**Third Party Claim**”), then the Indemnified Party will promptly notify the Party obligated to

indemnify the Indemnified Party (the "Indemnifying Party") thereof; *provided, however*, that no delay on the part of the Indemnified Party in notifying the Indemnifying Party will relieve the Indemnifying Party from any obligation hereunder unless (and then only to the extent that) the Indemnifying Party is prejudiced thereby.

16.4.2 **Control.** Subject to either Party's right to control any actions described in Section 9 (even where the other Party is the Indemnifying Party), the Indemnifying Party will have the right, exercisable by notice to the Indemnified Party within [\*\*\*] after receipt of notice from the Indemnified Party of the commencement of or assertion of any Third Party Claim, to assume direction and control of the defense, litigation, settlement, appeal or other disposition of the Third Party Claim (including the right to settle the claim solely for monetary consideration) with counsel selected by the Indemnifying Party and reasonably acceptable to the Indemnified Party; provided that (a) the Indemnifying Party has sufficient financial resources, in the reasonable judgment of the Indemnified Party, to satisfy the amount of any adverse monetary judgment that is sought, (b) the Third Party Claim seeks solely monetary damages and (c) the Indemnifying Party expressly agrees in writing that as between the Indemnifying Party and the Indemnified Party, the Indemnifying Party will be solely obligated to satisfy and discharge the Third Party Claim in full (the conditions set forth in clauses (a), (b) and (c) above are collectively referred to as the "Litigation Conditions"). [\*\*\*] after the Indemnifying Party has given notice to the Indemnified Party of its exercise of its right to defend a Third Party Claim, the Indemnified Party will give notice to the Indemnifying Party of any objection thereto based upon the Litigation Conditions. If the Indemnified Party reasonably so objects, the Indemnified Party will continue to defend the Third Party Claim, at the expense of the Indemnifying Party, until such time as such objection is withdrawn. If no such notice is given, or if any such objection is withdrawn, the Indemnifying Party will be entitled, at its sole cost and expense, to assume direction and control of such defense, with counsel selected by the Indemnifying Party and reasonably acceptable to the Indemnified Party. During such time as the Indemnifying Party is controlling the defense of such Third Party Claim, the Indemnified Party will cooperate, and will cause its Affiliates and agents to cooperate upon request of the Indemnifying Party, in the defense or prosecution of the Third Party Claim, including by furnishing such records, information and testimony and attending such conferences, discovery proceedings, hearings, trials or appeals as may reasonably be requested by the Indemnifying Party. In the event that the Indemnifying Party does not satisfy the Litigation Conditions or does not notify the Indemnified Party of the Indemnifying Party's intent to defend any Third Party Claim within [\*\*\*] after notice thereof, the Indemnified Party may (without further notice to the Indemnifying Party) undertake the defense thereof with counsel of its choice and at the Indemnifying Party's expense (including reasonable, out-of-pocket attorneys' fees and costs and expenses of enforcement or defense). The Indemnifying Party or the Indemnified Party, as the case may be, will have the right to join in (including the right to conduct discovery, interview and examine witnesses and participate in all settlement conferences), but not control, at its own expense, the defense of any Third Party Claim that the other party is defending as provided in this Agreement.

16.4.3 **Settlement.** The Indemnifying Party will not, without the prior written consent of the Indemnified Party, enter into any compromise or settlement that commits the Indemnified Party to take, or to forbear to take, any action. The Indemnified Party will have the sole and exclusive right to settle any Third Party Claim, on such terms and conditions as it deems reasonably appropriate, to the extent such Third Party Claim involves equitable or other non-monetary relief, but will not have the right to settle such Third Party Claim to the extent such Third Party Claim

involves monetary damages without the prior written consent of the Indemnifying Party. Each of the Indemnifying Party and the Indemnified Party will not make any admission of liability in respect of any Third Party Claim without the prior written consent of the other party, and the Indemnified Party will use reasonable efforts to mitigate Liabilities arising from such Third Party Claim.

16.5 **Insurance.** Each Party agrees to obtain and maintain, during the Term, commercial general liability insurance, including products liability insurance (or clinical trials insurance, if applicable), with minimum "A-" A.M. Best rated insurance carriers to cover its indemnification obligations under Section 16.2 or Section 16.3, as applicable, in each case with limits of not less than the equivalent of [\*\*\*] U.S. Dollars (US \$[\*\*]) per occurrence and in the aggregate. All deductibles and retentions will be the responsibility of the named insured. As soon as reasonably possible, but in any case (i) prior to commencing clinical trials, with respect to clinical trials insurance in a country or (ii) prior to the First Commercial Sale, with respect to commercial general liability and products liability policies in a country, BioNTech will amend its existing insurance policies in such a way that (a) Pfizer and its Affiliates will be indemnified as principal or will be added as additional insureds on BioNTech's commercial general liability and products liability policies (or clinical trials insurance, if applicable) and (b) Pfizer and its Affiliates will be provided a waiver of subrogation on BioNTech's commercial general liability and products liability policies (or clinical trials insurance, if applicable). BioNTech represents and warrants that, as of the Amendment Signing Date, Pfizer and its Affiliates have been added as additional insureds to BioNTech's primary pharma products liability insurance for the development, production and distribution of the covid19-vaccine taken out after the Effective Date for an amount equivalent to [\*\*\*] U.S. Dollars (US \$[\*\*]) per occurrence and in the aggregate, and Pfizer Inc. and its Affiliates are provided a waiver of subrogation under this policy. BioNTech undertakes to use reasonable efforts to have Pfizer and its Affiliates named as additional insureds on BioNTech's secondary pharma products liability insurance for the development, production and distribution of the covid19-vaccine. Should BioNTech be successful in reaching agreement with its pharma products liability insurers to name Pfizer and its Affiliates as additional insureds and provide them with a waiver of subrogation, BioNTech will report this and any increase to the insurance premiums to Pfizer. If there will be an increase in BioNTech's insurance premiums as a result of making the requested change to BioNTech's secondary pharma products liability insurance for the development, production and distribution of the covid19-vaccine, Pfizer shall confirm its desire for Pfizer and its Affiliates to be named on such policies and shall indemnify BioNTech against such increase in insurance premiums. For U.S. exposures, additional insured status on BioNTech's pharma products liability insurance for the development, production and distribution of the covid19-vaccine shall be via form CG20101185 or its equivalent. Pharma products liability coverage shall be maintained for three years following termination of this Agreement. To the extent of its culpability, negligence or indemnification obligations, all coverages of BioNTech will be primary and non-contributing with any similar insurance, carried by Pfizer. Notwithstanding any provision of this Section 16.5 to the contrary, Pfizer may meet its obligations under this Section 16.5 through self-insurance. Neither Party's insurance will be construed to create a limit of liability with respect to its indemnification obligations under this Section 16. A minimum of thirty (30) days written cancellation notice shall be given to the other Party for any cancellation, non-renewal or material change of coverage.

## 17. **MISCELLANEOUS**

17.1 **Assignment.** Neither this Agreement nor any interest hereunder will be assignable by a Party without the prior written consent of the other Party, except as follows: (a) subject to the provisions of

this Agreement in respect of Change of Control, as applicable, a Party may assign its rights and obligations under this Agreement by way of sale of itself or the sale of the portion of its business to which this Agreement relates, through merger, sale of assets and/or sale of stock or ownership interest, *provided that* the assignee will expressly agree to be bound by such Party's obligations under this Agreement and that such sale is not primarily for the benefit of its creditors, (b) such Party may assign its rights and obligations under this Agreement to any of its Affiliates, *provided that* the assignee will expressly agree to be bound by such Party's obligations under this Agreement and that such Party will remain liable for all of its rights and obligations under this Agreement. In addition, Pfizer may assign its rights and obligations under this Agreement to a Third Party where Pfizer or its Affiliate is required, or makes a good faith determination based on advice of counsel, to divest a Product in order to comply with Law or the order of any Governmental Authority as a result of a merger or acquisition, *provided that* the assignee will expressly agree to be bound by Pfizer's obligations under this Agreement. Each Party will promptly notify the other Party of any assignment or transfer under the provisions of this Section 17.1. This Agreement will be binding upon the successors and permitted assigns of the Parties and the name of a Party appearing herein will be deemed to include the names of such Party's successors and permitted assigns to the extent necessary to carry out the intent of this Agreement. Any assignment not in accordance with this Section 17.1 will be void.

17.2 **Further Actions.** Each Party agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of the Agreement.

17.3 **Force Majeure.** Each Party will be excused from the performance of its obligations under this Agreement to the extent that such performance is prevented by force majeure (defined below) and the nonperforming Party promptly provides notice of the prevention to the other Party. Such excuse will be continued so long as the condition constituting force majeure continues and the nonperforming Party takes Commercially Reasonable Efforts to remove the condition. For purposes of this Agreement, "force majeure" will include conditions beyond the control of the Parties, including an act of God, voluntary or involuntary compliance with any regulation, applicable Law or order of any government, war, act of terror, civil commotion, labor strike or lock-out, epidemic, failure or default of public utilities or common carriers, destruction of production facilities or materials by fire, earthquake, storm or like catastrophe.

17.4 **Interpretation.** Except where the context expressly requires otherwise, (a) the use of any gender herein will be deemed to encompass references to either or both genders, and the use of the singular will be deemed to include the plural (and vice versa), (b) the words "include", "includes" and "including" will be deemed to be followed by the phrase "without limitation", (c) the word "will" will be construed to have the same meaning and effect as the word "shall", (d) any definition of or reference to any agreement, instrument or other document herein will be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein), (e) any reference herein to any Person will be construed to include the Person's successors and assigns, (f) the words "herein", "hereof" and "hereunder", and words of similar import, will be construed to refer to this Agreement in its entirety and not to any particular provision hereof, (g) all references herein to Sections, Exhibits or Schedules will be construed to refer to Sections, Exhibits or Schedules of this Agreement, and references to this Agreement include all Exhibits and Schedules hereto, (h) the word "notice" means notice in writing (whether or not specifically stated) and will include notices, consents, approvals and other written communications contemplated under this Agreement, (i) provisions that require that a Party, the Parties or any committee



hereunder “agree,” “consent” or “approve” or the like will require that such agreement, consent or approval be specific and in writing, whether by written agreement, letter, approved minutes or otherwise (excluding e-mail or instant messaging, but a signed PDF document being acceptable), (j) references to any specific law, rule or regulation, or article, section or other division thereof, will be deemed to include the then-current amendments thereto or any replacement or successor law, rule or regulation thereof, and (k) the term “or” will be interpreted in the inclusive sense commonly associated with the term “and/or”.

17.5 **Notices.** Any notice or notification required or permitted to be provided pursuant to the terms and conditions of this Agreement (including any notice of force majeure, breach, termination, change of address, etc.) will be in writing and will be deemed given upon receipt if delivered personally or by facsimile transmission (receipt verified), and upon delivery if mailed by registered or certified mail or courier. Where delivery occurs outside normal working hours, notice will be deemed given at the start of normal working hours on the next Business Day. Notice shall be given to the Parties at the following addresses or facsimile numbers (or at such other address or facsimile number for a Party as will be specified by like notice, *provided, however*, that notices of a change of address will be effective only upon receipt thereof):

All correspondence to Pfizer will be addressed as follows:

Pfizer Inc.  
Notices: [\*\*\*]  
with a copy to:

Pfizer Inc.  
Notices: Pfizer Legal Division  
[\*\*\*]

To help expedite Pfizer’s awareness and response, copies of notices may be provided to Pfizer by email but must be supplemented by one of the following methods: (a) personal delivery, (b) first class certified mail with return receipt requested, or (c) next-day delivery by major international courier, with confirmation of delivery. Electronic copies may be sent via email to [\*\*\*].

All correspondence to BioNTech will be addressed as follows:

BioNTech SE  
[\*\*\*]

17.6 **Amendment.** No amendment, modification or supplement of any provision of this Agreement will be valid or effective unless made in writing and signed by a duly authorized officer of each Party.

17.7 **Waiver.** No provision of this Agreement will be waived by any act, omission or knowledge of a Party or its agents or employees except by an instrument in writing expressly waiving such provision and signed by a duly authorized officer of the waiving Party. The waiver by either of the Parties of any breach of any provision hereof by the other Party will not be construed to be a waiver of any succeeding breach of such provision or a waiver of the provision itself.

17.8 **Severability.** If any clause or portion thereof in this Agreement is for any reason held to be invalid, illegal or unenforceable, the same will not affect any other portion of this Agreement, as it is the

intent of the Parties that this Agreement will be construed in such fashion as to maintain its existence, validity and enforceability to the greatest extent possible. In any such event, this Agreement will be construed as if such clause of portion thereof had never been contained in this Agreement, and there will be deemed substituted therefore such provision as will most nearly carry out the intent of the Parties as expressed in this Agreement to the fullest extent permitted by applicable Law.

17.9 Descriptive Headings. The descriptive headings of this Agreement are for convenience only and will be of no force or effect in construing or interpreting any of the provisions of this Agreement.

17.10 Global Trade Control Laws. The Parties acknowledge that certain activities covered by or performed under this Agreement may be subject to Global Trade Control Laws. Each of the Parties will perform all activities under this Agreement in compliance with all applicable Global Trade Control Laws. Furthermore, with respect to the activities performed under this Agreement, each of the Parties represents, warrants and covenants that:

17.10.1 Each Party will not, for activities under this Agreement, (a) engage in any such activities in a Restricted Market; (b) involve individuals ordinarily resident in a Restricted Market; or (c) include companies, organizations, or Governmental Authorities from or located in a Restricted Market. "Restricted Market" for purposes of this Agreement means the Crimean Peninsula, Cuba, the Donbass Region, Iran, North Korea, Sudan, and Syria, or any other country or region sanctioned by the United States or European Union.

17.10.2 Each Party represents and warrants that it is not a Restricted Party and is not owned or controlled by a Restricted Party. With respect to activities performed under this Agreement, neither Party will engage or delegate to any Restricted Parties for any activities under this Agreement. Each Party will screen all relevant Third Parties involved by such Party in the activities under this Agreement under the relevant Restricted Party Lists. "Restricted Parties" for purposes of this Agreement means any individual or entity on any of the following "Restricted Party Lists": the list of sanctioned entities maintained by the United Nations; the Specially Designated Nationals List and the Sectoral Sanctions Identifications List of the U.S. Treasury Department's Office of Foreign Assets Control; the U.S. Denied Persons List, the U.S. Entity List, and the U.S. Unverified List of the U.S. Department of Commerce; entities subject to restrictive measures and the Consolidated List of Persons, Groups and Entities Subject to E.U. Financial Sanctions, as implemented by the E.U. Common Foreign & Security Policy; the List of Excluded Individuals / Entities published by the U.S. Health and Human Services' Office of Inspector General; any lists of prohibited or debarred parties established under the U.S. Federal Food Drug and Cosmetic Act; the list of parties suspended or debarred from contracting with the U.S. government; and similar lists of restricted parties maintained by the Governmental Authorities of the countries that have jurisdiction over the activities conducted under this Agreement.

17.10.3 Neither Party will knowingly transfer to the other Party any goods, software, technology or services that are (a) controlled under the U.S. International Traffic in Arms Regulations or at a level other than EAR99 under the U.S. Export Administration Regulations; or (b) specifically identified as an E.U. Dual Use Item or on an applicable export control list of another country.

17.10.4 In the event that any of the representations in this Section 17.10 changes, the Party changing its representation will immediately inform the other Party and suspend all related

activities until the Parties agree to lift the suspension and move forward. For clarity, any and all activities pursuant to this Agreement which are not affected by such change in representation in this Section 17.10 shall continue without interruption.

17.11 Dispute Resolution. If any dispute or disagreement arises between Pfizer and BioNTech in respect of this Agreement, they will follow the following procedures in an attempt to resolve the dispute or disagreement:

17.11.1 The Party claiming that such a dispute exists will give notice in writing ("Notice of Dispute") to the other Party of the nature of the dispute.

17.11.2 Within thirty (30) days of receipt of a Notice of Dispute and in advance of any meeting pursuant to Section 17.11.3, the receiving Party will provide a written response to the other Party's claims regarding the dispute.

17.11.3 Within forty-five (45) days of receipt of a Notice of Dispute, the Executive Officers will meet at a mutually agreed-upon time and location or via teleconference for the purpose of resolving such dispute to discuss the dispute or disagreement.

Notwithstanding any provision of this Agreement to the contrary, either Party may immediately initiate litigation in any court of competent jurisdiction seeking any remedy at law or in equity, including the issuance of a preliminary, temporary or permanent injunction, to preserve or enforce its rights under this Agreement. The provisions of this Section 17.11 will survive for five (5) years from the date of termination or expiration of this Agreement.

17.12 Governing Law. This Agreement is governed by, and all disputes arising under or in connection with this Agreement shall be resolved in accordance with, laws of England and Wales, without regard to conflict of law principles thereof.

17.13 Consent to Jurisdiction and Venue. The Parties irrevocably submit to the exclusive jurisdiction of the courts of England and Wales as regards any claim, dispute or matter (whether contractual or non-contractual) arising out of or in connection with this Agreement (including its formation). Notwithstanding the foregoing, this clause shall not prevent either Party from being entitled to seek urgent interim or emergency relief (such as a preliminary injunction) before any other court of competent jurisdiction in respect of any claim, dispute or matter (whether contractual or non-contractual) arising out of or in connection with this Agreement (including its formation).

17.14 Entire Agreement. This Agreement constitutes and contains the complete, final and exclusive understanding and agreement of the Parties and cancels and supersedes any and all prior negotiations, correspondence, understandings and agreements, whether oral or written, between the Parties respecting the subject matter hereof and thereof, including (a) that certain [\*\*\*] (which is hereby terminated effective as of the Effective Date, *provided that* such Confidential Disclosure Agreement will continue to govern the treatment of Confidential Information disclosed by the Parties prior to the Effective Date in accordance with its terms), (b) that certain [\*\*\*] (which is hereby terminated effective as of the Effective

Date, provided that the terms of this Agreement shall also apply to all activities made under the [\*\*\*]) and (c) [\*\*\*] (which is hereby terminated effective as of the Effective Date).

17.15 Flu Collaboration. Except as provided in Section 7.2, nothing in this Agreement varies, amends or otherwise supersedes or replaces the provisions and rights under the Flu Collaboration License, and the Flu Collaboration License and this Agreement shall be treated as separate arm's length transactions.

17.16 Relationship of the Parties.

17.16.1 **Independent Contractors**. Both Parties are independent contractors under this Agreement. Nothing herein contained will be deemed to create an employment, agency, joint venture or partnership relationship between the Parties hereto or any of their agents or employees, or any other legal arrangement that would impose liability upon one Party for the act or failure to act of the other Party. Neither Party will have any express or implied power to enter into any contracts or commitments or to incur any liabilities in the name of, or on behalf of, the other Party, or to bind the other Party in any respect whatsoever. Additionally, the Parties expressly agree that this Agreement is not intended to be treated as a partnership for taxation purposes.

17.16.2 **Personnel**. Each Party acknowledges and agrees that all of its personnel, including its Sales Managers and PSRs, are not, and are not intended to be or to be treated as, employees of the other Party or any of its Affiliates, and that such individuals are not, and are not intended to be, eligible to participate in any benefits programs or in any "employee benefit plans," as such term is defined in section 3(3) of the Employee Retirement Income Security Act of 1974, as amended, that are sponsored by the other Party or any of its Affiliates or that are offered from time to time by the other Party or its Affiliates to their own employees (the "Benefit Plans"). All matters of compensation, benefits and other terms of employment for a Party's personnel will be a matter solely between such Party and its personnel. Each Party will be solely responsible and liable for the payment of all compensation and benefits under any such Benefit Plan to its personnel. A Party will not be responsible to the other Party (the "Hiring Party") or to any Sales Manager or PSR used by the Hiring Party to promote or sell the Product for any compensation, expense reimbursements or benefits (including vacation and holiday remuneration, healthcare coverage or insurance, life insurance, pension or profit-sharing benefits and disability benefits), payroll-related taxes or withholdings, or any governmental charges or benefits (including unemployment and disability insurance contributions or benefits and workmen's compensation contributions or benefits) that may be imposed upon or be related to the performance by the Hiring Party and its Sales Managers and PSRs of its obligations under this Agreement, all of which will be the sole responsibility of the Hiring Party, even if it is subsequently determined by any court or any Governmental Authority that such individual may be deemed a common law employee of the non-Hiring Party or any of its Affiliates.

17.16.3 **Indemnification**. Each Hiring Party will indemnify, defend, and hold harmless the non-hiring Party (the "NHP") and its Affiliates, and the NHP's and its Affiliates' directors, officers, employees and agents (collectively, the "NHP Indemnitees") from and against any claims, liabilities, costs, expenses, damages, penalties, compensation or attorney fees ("Losses") that may be incurred or payable by any such NHP Indemnitee resulting from or in connection with any claim or other cause of action asserted by or on behalf of any Sales Manager or PSR of the Hiring Party arising out of the execution or performance of this Agreement that is based on or with respect to:

17.16.3.1 Losses that the NHP or its Affiliates may incur resulting from any claims for benefits that any of the Hiring Party's Sales Managers or PSRs may make under or with respect to any NHP Benefit Plans;

17.16.3.2 any payment or obligation to make a payment to any Hiring Party Sales Managers or PSRs relating in any way to any compensation, benefits of any type under any Benefit Plan, and any other bonus, stock option, stock purchase, incentive, deferred compensation, supplemental retirement, severance and other similar fringe or employee benefit plans, programs or arrangements that may be sponsored at any time by either Party or any of its Affiliates, even if it is subsequently determined by any court, the IRS or any other Governmental Authority that any of the Hiring Party's Sales Managers or PSRs may be deemed a common law employee of the NHP or any of its Affiliates;

17.16.3.3 the payment or withholding of any contributions, payroll taxes, or any other payroll-related item by or on behalf of the Hiring Party or any of its Sales Managers or PSRs with respect to which the Hiring Party or any of its Sales Managers or PSRs may be responsible hereunder or pursuant to Applicable Law to pay, make, collect, withhold or contribute, even if it is subsequently determined by any court, the IRS or by any other Governmental Authority that any of such Hiring Party's Sales Managers or PSRs may be deemed a common law employee of the NHP or any of its Affiliates; and

17.16.3.4 failure of the Hiring Party to withhold or pay required taxes or failure to file required forms with Governmental Authorities with regard to compensation and benefits incurred or extended by a Hiring Party to its Sales Managers or PSRs.

17.16.4 **Improper Conduct.** Notwithstanding anything to the contrary in this Section 17.16, a Hiring Party will have no liability to any NHP Indemnitee to the extent attributable to any discriminatory, harassing or retaliatory acts of the NHP, or any tortious acts (including acts constituting assault, battery or defamation) by the NHP, with respect to any Sales Managers or PSRs of the Hiring Party, or any breach by the NHP of this Agreement. Nothing contained in this Section 17.16 is intended to affect or limit any compensation payable by a Party to the other for the services rendered by a Party pursuant to this Agreement.

17.17 **Counterparts.** This Agreement may be executed in two (2) counterparts, each of which will be an original and both of which will constitute together the same document. Counterparts may be signed and delivered by facsimile or digital (e.g., PDF) file, each of which will be binding when received by the applicable Party.

17.18 **No Third Party Rights or Obligations.** No provision of this Agreement will be deemed or construed in any way to result in the creation of any rights or obligation in any Person not a Party to this Agreement, and this Agreement does not give rise to any rights under the Contracts (Rights of Third Parties) Act 1999 to enforce any term of this Agreement. However, Pfizer may decide, in its sole discretion, to use one or more of its Affiliates to perform its obligations and duties hereunder, *provided that* Pfizer will remain liable hereunder for the performance by any such Affiliates of any such obligations.

17.19 Conflicting Terms. In the event of any inconsistency between the terms or definitions of this Agreement and the terms or definitions (as applicable) of any Related Agreement, the terms of this Agreement will control for purposes of this Agreement except to the extent such Related Agreement specifically provides that specified terms in such Related Agreement control; *provided, however*, that any actions by a Party required for compliance with its obligations under the other Related Agreements will not constitute a breach under this Agreement and any actions by a Party required for compliance with its obligations under this Agreement will not constitute a breach under any of the Related Agreements.

*(Signature page follows)*

IN WITNESS WHEREOF, authorized representatives of the Parties have duly executed this Agreement as of the Amendment Signing Date to be effective as of the Effective Date.

**PFIZER INC.**

**BIONTECH SE**

By \_\_\_\_\_

By \_\_\_\_\_

Name:

Name:

Title:

Title:

By \_\_\_\_\_

Name:

Title:

[Signature page to Amended and Restated Collaboration Agreement]

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**Exhibit B**  
**Pfizer Anti-Bribery and Anti-Corruption Principles**

Pfizer has a longstanding corporate policy that prohibits colleagues or anyone acting on our behalf from providing any payment or benefit to any person or entity in order to improperly influence a government official or to gain an unfair business advantage. Pfizer is committed to performing with integrity, and acting ethically and legally in accordance with all applicable laws and regulations, including, but not limited to, anti-bribery and anti-corruption laws. We expect the same commitment from the consultants, agents, representatives or other companies and individuals acting on our behalf (“Business Associates”), as well as those acting on behalf of Business Associates, in connection with work for Pfizer.

**Bribery of Government Officials**

Most countries have laws that forbid making, offering or promising any payment or anything of value (directly or indirectly) to a government official when the payment is intended to influence an official act or decision to award or retain business. Under Pfizer’s policies, “government official” is broadly interpreted and includes: (i) any elected or appointed government official (e.g., a member of a ministry of health); (ii) any employee or person acting for or on behalf of a government official, agency, or enterprise performing a governmental function; (iii) any political party, candidate for public office, officer, employee, or person acting for or on behalf of a political party or candidate for public office; or (iv) an employee or person acting for or on behalf of a public international organization (e.g., the United Nations). “Government” is meant to include all levels and subdivisions of governments (i.e., local, regional, or national and administrative, legislative, or executive). Because this definition of “government official” is so broad, it is likely that Business Associates will interact with a government official in the ordinary course of their business on behalf of Pfizer. For example, doctors employed by government-owned hospitals would be considered “government officials” under Pfizer’s policies.

The U.S. Foreign Corrupt Practices Act of 1977 (the “FCPA”) prohibits making, promising, or authorizing the making of a payment or providing anything of value to a non-U.S. government official to improperly or corruptly induce that official to make any governmental act or decision to assist a company in obtaining or retaining business, or to otherwise obtain an improper advantage. The FCPA also prohibits a company or person from using another company or individual to engage in any of the foregoing activities. As a U.S. company, Pfizer must comply with the FCPA and could be held liable as a result of acts committed anywhere in the world by a Business Associate.

**Anti-Bribery and Anti-Corruption Principles Governing Interactions with Governments and Government Officials**

Business Associates must communicate and abide by the following principles with regard to their interactions with governments and government officials:

- Business Associates, and those acting on their behalf in connection with work for Pfizer, may not directly or indirectly make, promise, or authorize the making of a corrupt payment or provide anything of value to any government official to induce that government official to make any governmental act or decision to help Pfizer obtain or retain business. Business Associates, and those acting on their behalf in connection with work for Pfizer, may never make a payment to or offer a government official any item or benefit, regardless of value, as an improper inducement for such government official to approve, reimburse, prescribe, or purchase a Pfizer product, to influence the outcome of a clinical trial, or otherwise improperly to benefit Pfizer’s business activities.

- Business Associates, and those acting on their behalf in connection with work for Pfizer, need to understand whether local laws, regulations, or operating procedures (including requirements imposed by government entities such as government-owned hospitals or research institutions) impose any limits, restrictions, or disclosure requirements on compensation, financial support, donations, or gifts that may be provided to government officials. Business Associates, and those acting on their behalf in connection with work for Pfizer, must take into account and comply with any applicable restrictions in conducting their Pfizer-related activities. If a Business Associate is uncertain as to the meaning or applicability of any identified limits, restrictions, or disclosure requirements with respect to interactions with government officials, that Business Associate should consult with his or her primary Pfizer contact before undertaking their activities.
- Business Associates, and those acting on their behalf in connection with work for Pfizer, are not permitted to offer facilitation payments. A “facilitation payment” is a nominal, unofficial payment to a government official for the purpose of securing or expediting the performance of a routine, non-discretionary governmental action. Examples of facilitation payments include payments to expedite the processing of licenses, permits or visas for which all paperwork is in order. In the event that a Business Associate, or someone acting on their behalf in connection with work for Pfizer, receives or becomes aware of a request or demand for a facilitation payment or bribe in connection with work for Pfizer, the Business Associate shall report such request or demand promptly to his or her primary Pfizer contact before taking any further action.

### **Commercial Bribery**

Bribery and corruption can also occur in non-government, business to business relationships. Most countries have laws which prohibit offering, promising, giving, requesting, receiving, accepting, or agreeing to accept money or anything of value in exchange for an improper business advantage. Examples of prohibited conduct could include, but are not limited to, the provision of inappropriate gifts or hospitality, kickbacks, or investment opportunities offered to improperly induce the purchase of goods or services. Pfizer colleagues are not permitted to offer, give, solicit or accept bribes, and we expect our Business Associates, and those acting on their behalf in connection with work for Pfizer, to abide by the same principles.

### **Anti-Bribery and Anti-Corruption Principles Governing Interactions with Private Parties and Pfizer Colleagues**

Business Associates must communicate and abide by the following principles with regard to their interactions with private parties and Pfizer colleagues:

- Business Associates, and those acting on their behalf in connection with work for Pfizer, may not directly or indirectly make, promise, or authorize the making of a corrupt payment or provide anything of value to any person to induce that person to provide an unlawful business advantage for Pfizer.
- Business Associates, and those acting on their behalf in connection with work for Pfizer, may not directly or indirectly, solicit, agree to accept, or receive a payment or anything of value as an improper inducement in connection with their business activities performed for Pfizer.
- Pfizer colleagues are not permitted to receive gifts, services, perks, entertainment, or other items of more than token or nominal monetary value from Business Associates, and those acting on their behalf in connection with work for Pfizer. Moreover, gifts of nominal value are only permitted if they are received on an infrequent basis and only at appropriate occasions.

**Reporting Suspected or Actual Violations**

Business Associates, and those acting on behalf in connection with work for Pfizer, are expected to raise concerns related to potential violations of these International Anti-Bribery and Anti-Corruption Principles or the law. Such reports can be made to a Business Associate's primary point of contact at Pfizer, or if an Associate prefers, to Pfizer's Compliance Group, by e-mail at [corporate.compliance@pfizer.com](mailto:corporate.compliance@pfizer.com) or by phone at 1-212-733-3026.

## BACKGROUND

Pfizer is dedicated to helping people and animals live longer, healthier lives through the discovery and development of breakthrough medicines and therapies. Animal-based biomedical research in the pharmaceutical industry remains a vital component of the discovery, evaluation and regulatory processes, which lead to the development of products that save or improve human lives throughout the world. Pfizer's Animal Care and Use policy reflects our absolute commitment that all animals used by our business are treated humanely. This means that any research involving animals is conducted only after appropriate ethical consideration and review. This review ensures that we provide a high level of care to all animals used, and that a scientifically appropriate and validated alternative to the use of animals is not available.

### **Why We Conduct Animal-based Biomedical Research**

Pfizer is ethically and legally obliged to rigorously evaluate potential new medicines and therapies. Many of these evaluations can be, and are, accomplished by techniques that do not require the use of animals. However, given the present state of scientific knowledge, testing potential new medicines and therapies in animals is frequently critical to their evaluation, and is required by regulatory authorities worldwide to ensure the quality, efficacy and safety of the medicines we discover.

### **Pfizer's Commitment to Ethical and Humane Treatment of Animals**

Pfizer accepts its responsibility to use animals in a humane and ethical manner and expects all Colleagues to treat animals with respect. We approach the use of animals in our business with a high level of humane and ethical concern for those animals. All use is carefully planned and conducted in such a way as to minimize or avoid pain, distress, or discomfort to the animals. Every proposed use is thoroughly evaluated before being undertaken as the health and well-being of all animals under our care is a primary concern. Similarly, we expect any Third Party organization we engage to conduct animal-based research on our behalf to adhere to this Policy and to comply with all applicable laws and regulations.

### **Pfizer's Commitment to Alternatives to Animal-based Biomedical Research**

Pfizer is fully committed to the development and use of scientifically validated alternative testing methods that are acceptable to regulatory authorities and do not compromise patient safety or the effectiveness of our medicines. Pfizer continues to engage and lead cross-industry efforts aimed at developing and refining new in-vitro testing and predictive informatics-based systems that hold promise for future reduction of animal usage. Pfizer works directly with regulators and through pharmaceutical trade organizations to increase the recognition and acceptance of alternative models where such alternatives can be used appropriately.

## POLICY

For as long as it remains necessary to use animals in the discovery, development, evaluation and production of new medicines, we commit to maintaining high standards in the humane treatment of these animals. Significantly, we embrace the principles known as the "3Rs" of animal research first proposed in 1959 by Russell and Burch to describe the use of alternatives in animal research. These are:

**Replacement** of animal experiments with non-animal experiments such as mathematical models, computer simulations, and in-vitro biological systems wherever appropriate; and where animals must be used;  
**Reduction** of the numbers of animals used in each study, and of the number of studies involving animals, to the absolute minimum necessary to obtain valid results and achieve our research objectives; and  
**Refinement** of procedures involving animals to minimize the potential for pain and distress.

In addition to the 3R's, and to further assure we maintain high standards for our animals, we have adopted the following guidelines:

- When animal experimentation is necessary, great care is taken to choose the most appropriate animal species for the research and to optimize the study design to ensure that the results will be as meaningful as possible.
- Non-human primates will only be used when scientifically justified, for example in cases where other species will not provide sufficiently close analogues to the biological pathways and responses expected in humans.
- All studies are carefully designed to gain the maximum information from the fewest number of animals possible.
- Each proposed use of animals is reviewed and approved by a panel of objective experts prior to performing any experiments to ensure that the use of the animals is consistent with sound scientific practices and ethical considerations.
- Our standards of animal care and welfare meet or exceed those required by applicable local, national, or international laws and regulations.
- We regularly monitor our animals for signs of ill health or distress and take prompt action wherever appropriate. We make veterinary care available to our animals at all times.
- Our veterinarians and scientists evaluate every proposed animal procedure with an emphasis on eliminating or minimizing any potential for pain or distress which may be experienced by the animals.
- We train all Colleagues involved in the care, welfare and use of animals to ensure (a) that they are competent in the care of the animals and in the procedures required to complete the proposed work; (b) that they are aware of the ethical issues involved in the use of animals; and (c) that they demonstrate respect and humane treatment towards the animals in their care.
- We expect our contract research organizations, collaborators and vendors to maintain similar high standards. Parties conducting animal based research for Pfizer at their facilities are required to adhere to this Policy and to comply with all applicable laws and regulations. We perform welfare audits of Third Party facilities in accordance with our quality assurance policies.
- Because respect is a key tenant in our use of animals, we have also established standards regarding the use of animals in the marketing of Pfizer products. If advertisements featuring animals are used, any animal shown should be healthy and in a natural or appropriate setting. Non-human primates should not be used in the advertising of Pfizer products, and other wild animals will also not be used unless they are shown in their natural setting or portrayed through animation or computer-generated graphics.

This Policy represents Pfizer's commitment to high-quality animal care and welfare throughout our business, and to the replacement, reduction and refinement of the use of animals in research. We are equally committed to bringing important and safe new medicines to patients.

**Schedule 1.21**  
**Candidates**

[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]
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**Schedule 1.49**  
**Developing Countries List**

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**Schedule 1.50**  
**Development Budget**

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**Schedule 1.94**  
**Manufacturing Plan**

[\*\*\*]

**Schedule 4.5**  
**Potential Third Party Funders**

1. [\*\*\*]

**Schedule 4.9.5**  
**Form of Quarterly Consolidated Report and Illustrative Gross Profit Calculation**

[\*\*\*]



[**]				[**]	[**]	[**]
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**Schedule 8.1.1**  
**Responsibilities delegated to Pfizer in the USA or other countries**  
**in the Territory where it is the Lead Development Party**

[\*\*\*]



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**Schedule 9.7.1**  
**Indemnification Terms**

1. [\*\*\*]

Schedule 12.5.1  
**Public Announcements**

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**Schedule 13.3**  
**Disclosures**

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Schedule 13.11  
ABAC Compliance Certification

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COMPANY NAME: \_\_\_\_\_  
NAME: \_\_\_\_\_  
TITLE: \_\_\_\_\_  
DATE: \_\_\_\_\_

THE SYMBOL “[\*\*\*]” DENOTES PLACES WHERE CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH (i) NOT MATERIAL, AND (ii) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF PUBLICLY DISCLOSED

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ANNEX

to the

COMMISSION DECISION

of 11.11.2020

approving an Advance Purchase Agreement on COVID-19 vaccines

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EUROPEAN COMMISSION  
Directorate-General for Health and Food Safety

ADVANCE PURCHASE AGREEMENT (“APA”)<sup>1</sup> for the development, production,  
priority-purchasing options and supply of a successful COVID-19 vaccine for EU Member  
States

SANTE/2020/C3/043 - SI2.838335

1. **The European Commission**, acting on behalf and in the name of the Member States set out in Annex III (hereinafter referred to as “Participating Member States”),<sup>2</sup> being represented for the purposes of the signature of this APA by Ms Stella Kyriakides, Commissioner of Health and Food Safety

on the one part and

2. **Pfizer Inc.**

Incorporated in Delaware (Registration Number 0383418) with its registered address at 235 East 42nd Street, 10017 New York City, NY (UNITED STATES)

appointed as the leader of the group by the members of the group that submitted the joint tender (hereinafter referred to as “**Pfizer**”)

and

**BioNTech Manufacturing GmbH**

Registered with the commercial register of the lower court (*Amtsgericht*) of Mainz, Germany under HRB 47548, with its registered address at An der Goldgrube 12, 55131 MAINZ, GERMANY

(hereinafter referred to as “**BioNTech**”)

as a member of the group (collectively ‘**the Contractor**’), represented for the purposes of the signature of this APA which has the form of a framework contract by [\*\*\*]

on the other part,

<sup>1</sup> This APA is based on the agreement between the Commission and the Member States as approved by Commission Decision C(2020) 4192 final on approving the agreement with Member States on procuring Covid-19 vaccines on behalf of the Member States and related procedures.

<sup>2</sup> As provided for in Article 4(5)(b) of Council Regulation (EU) 2016/369 of 15 March 2016 on the provision of emergency support within the Union as amended by Council Regulation (EU) 2020/521 of 14 April 2020 activating the emergency support under Regulation (EU) 2016/369, and amending its provisions taking into account the COVID- 19 outbreak.

HAVE AGREED

to the **special conditions and the general conditions of this APA** and the following Annexes and Attachments:

**Annex I** – Model for Vaccine Order Form

**Annex II** – Agreement between the Commission and Member States on procuring Covid-19 vaccines on behalf of the Member States and related procedures, annexed to the Commission Decision C(2020) 4192 final of 18 June 2020

**Annex III** – Participating Member States

**Annex IV** – Subcontractors

**Annex V** – Participating Contractor Affiliates

Attachment 1 – Specifications

Attachment 2 – Delivery Documentation

Attachment 3 – Delivery Specification

Attachment 4 – Labelling and Packaging Specifications

Attachment 5 – Return and Disposal of Product Materials

which form an integral part of this APA.

The full content of the Attachments will be provided as soon as possible after Authorisation has been obtained and prior to the first shipment [\*\*\*]

This APA sets out:

1. the procedure and conditions by which the Commission and the Participating Member States will pay for the services and/or supplies from the Contractor;
2. the provisions that apply to any Vaccine Order Form which the Participating Member States and the Contractor may conclude under this APA; and
3. the obligations of the parties during and after the duration of this APA.

All documents issued by the Contractor (end-user agreements, general terms and conditions, etc.) except its tender are held inapplicable, unless explicitly mentioned in the special conditions of this APA. In all circumstances, in the event of contradiction between this APA and documents issued by the Contractor, this APA prevails, regardless of any provision to the contrary in the Contractor's documents.

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**I. SPECIAL CONDITIONS****I.1 ORDER OF PRIORITY OF PROVISIONS**

If there is any conflict between different provisions in this APA, the following rules must be applied:

- (a) The provisions set out in the special conditions and Article II.6 of the general conditions (Liability) take precedence over those in the other parts of the APA.
- (b) The other provisions set out in the general conditions take precedence over those in the Annexes and Attachments.
- (c) The provisions set out in the APA take precedence over those in the Vaccine Order Forms.

**I.2 DEFINITIONS**

The following definitions shall apply to this APA:

**‘Additional Order’**: has the meaning set forth in Article I.6.2;

**‘Additional Product’**: has the meaning set forth in Article I.6.2;

**‘Adjusted Delivery Schedule’**: has the meaning set forth in Article I.6.3(ii);

**‘Advance Payment’**: has the meaning set forth in Article I.8.1

**‘Affiliate’**: means in relation to a body corporate, any other entity which directly or indirectly Controls, is Controlled by, or is under direct or indirect common Control of that body corporate from time to time;

**‘Authorisation’**: means a Conditional Marketing Authorisation and/or Marketing Authorisation that permits the Products to be placed on the market in the European Economic Area;

**‘Best Reasonable Efforts’**: [\*\*\*]

**‘Conditional Marketing Authorisation’**: means a conditional marketing authorisation granted by the European Commission as referred to in Article 14-a of Regulation (EC) No 726/2004;

**‘Confidential Information’**: means any information disclosed to or obtained by one party to the other party, either directly or indirectly, or which the disclosing party indicates in writing at the time of disclosure to, or receipt by, the recipient is to be considered confidential or proprietary, or which such recipient knows or ought reasonably to know is information of a confidential or proprietary nature, including the terms of this APA and any Vaccine Order Form. Confidential Information shall not include any information (i) the receiving party can prove was known to it prior to the date of disclosure; (ii) the receiving party can prove was lawfully obtained from a third party without any obligation of confidentiality; (iii) is or becomes part of the public domain other than through any act or omission of the receiving

party; or (iv) is independently developed by the receiving party without use of or reference to the disclosing party's Confidential Information, as evidenced by the receiving party's records;

**'Conflict of interest'**: a situation where the impartial and objective *Implementation of the APA* by the Contractor is compromised for reasons involving family, emotional life, political or national affinity, economic interest, any other direct or indirect personal interest, or any other shared interest with the Commission, the Participating Member State or any third party related to the subject matter of the APA;

**'Contracted Doses'**: has the meaning set forth in Article I.6.2;

**'Control'**: means the possession by a person or an entity, directly or indirectly, of the power to direct or cause the direction of the management and policies of the other person or entity (whether through the ownership of voting shares, by contract or otherwise) and "**Controls**" and "**Controlled**" shall be interpreted accordingly;

**'Delivery Price'**: has the meaning set forth in Article I.8.2;

**'Delivery Schedule'**: means the Interim Delivery Schedule or the Adjusted Delivery Schedule, as applicable;

**'Effective Date'**: has the meaning set forth in Article I.4.1;

**'Force majeure'**: any unforeseeable, exceptional situation or event beyond the reasonable control of the parties that prevents either of them from fulfilling any of their obligations under the APA, [\*\*\*]

**'Formal notification'** (or 'formally notify'): form of communication between the parties made in writing by mail or email, which provides the sender with compelling evidence that the message was delivered to the specified recipient;

**'Fraud'**: an act or omission committed in order to make an unlawful gain for the perpetrator or another by causing a loss to the Union's financial interests, and relating to: i) the use or presentation of false, incorrect or incomplete statements or documents, which has as its effect the misappropriation or wrongful retention of funds or assets from the Union budget, ii) the non-disclosure of information in violation of a specific obligation, with the same effect or iii) the misapplication of such funds or assets for purposes other than those for which they were originally granted, which damages the Union's financial interests, it being understood that the Union's financial interests are impacted under this APA only by reason of the Advance Payment;

**'Good Manufacturing Practice'**: means the current practices for manufacture required by the standards, rules, principles and guidelines set out in Directive 2001/83/EC (as amended by Directive 2004/27/EC), Directive 2017/1572, Directive 2003/94/EC and EudraLex - Volume 4 of the Rules Governing Medicinal Products in the EU entitled "EU Guidelines to Good Manufacturing Practice Medicinal Products for Human and Veterinary Use";

**'Implementation of the APA'**: the purchase of services or supplies envisaged in the APA through the signature and *performance of Vaccine Order Forms*;

**‘Indemnified Persons’**: has the meaning set forth in Article I.12.1; **‘Interim Delivery Schedule’**: has the meaning set forth in Article I.6.3;

**‘Irregularity’**: any infringement of a provision of Union law resulting from an act or omission by the Contractor within the meaning of Article 1(2) of the Council (EC, Euratom) Regulation 2988/95 of 18 December 1995 on the protection of the European Communities financial interests (in OJ 23.12.95, L 312/1) , which has, or would have, the effect of prejudicing the Union’s budget, it being understood that the Union’s financial interests are impacted under this APA only by reason of the Advance Payment;

**‘Latent Defect’**: means a defect causing the Product to not conform to the applicable Specifications that the relevant Participating Member State can show was present at the time of delivery of the Product and which could not have been detected by the Participating Member State, its designee, or their personnel at delivery through visual inspection;

**‘Law(s)’**: means, collectively, all applicable supranational, national and local laws, common laws, statutes, ordinances, codes, rules, regulations, orders, decrees or other pronouncements of any government, administrative or judicial authority having the effect of law;

**‘Losses’**: has the meaning set forth in Article I.12.1;

**‘Marketing Authorisation’**: means the marketing authorisation (other than Conditional Marketing Authorisation), in respect of the Product granted by the European Commission, as amended or varied from time to time, that allows the Product to be placed on the market in the European Economic Area according to applicable Law;

**‘Non-Complying Product’**: has the meaning set forth in Article I.6.14;

**‘Notification’** (or ‘notify’): form of communication between the parties made in writing including by electronic means;

**‘Participating Contractor Affiliate’**: means an Affiliate of Pfizer or BioNTech as identified in Annex V;

**‘Product’**: means the Vaccine;

**‘Product Materials’**: means all packaging materials and components needed for delivery of the Product;

**‘Professional conflicting interest’**: a situation in which the Contractor’s previous or ongoing professional activities affect its capacity to implement the APA or to perform a Vaccine Order Form to an appropriate quality standard;

**‘Record’**: means books, documents, and other data, of all matters relating to performance of obligations under this APA;

**‘Related person’**: any natural or legal person who is a member of the administrative, management or supervisory body of the Contractor, or who has powers of representation, decision or control with regard to the Contractor;



**‘Specifications’:** means the specifications for the manufacture, testing and testing procedures, and supply of the Product as set out in Attachment 1 (Specifications), and as such specifications may be amended, supplemented or otherwise modified by the Contractor and communicated to the Commission;

**‘Taxes’:** has the meaning set forth in Article II.18.1;

**‘Term’:** means the term of the APA set out in Article I.4.2 of the APA;

**‘Thermal Shipper’:** has the meaning set forth in Article I.6.8;

**‘Third Party Claim’:** has the meaning set forth in Article I.12.4.

**‘Vaccine’:** BNT162b2, a nucleoside-modified messenger RNA (modRNA) vaccine that encodes an optimized SARS-CoV-2 full-length spike glycoprotein (S) for which a rolling submission for BNT162b2 has been initiated with the European Medicines Agency;

**‘Vaccine IP Rights’:** has the meaning set forth in Article I.11.; and

**‘Vaccine Order Form’:** has the meaning set forth in Article I.5.2I.3.

Except where the context expressly requires otherwise, (a) the use of any gender herein shall be deemed to encompass references to either or both genders, and the use of the singular shall be deemed to include the plural (and vice versa), (b) the words “include”, “includes” and “including” shall be deemed to be followed by the phrase “without limitation”, (c) the word “will” shall be construed to have the same meaning and effect as the word “shall”, (d) any definition of or reference to any agreement, instrument or other document herein shall be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein), (e) any reference herein to any person shall be construed to include the person's successors and assigns, (f) the words “herein”, “hereof” and “hereunder”, and words of similar import, shall be construed to refer to this APA in its entirety and not to any particular provision hereof, (g) all references herein to Articles, Annexes or Attachments shall be construed to refer to Articles, Annexes or Attachments of this APA, and references to this APA include all Annexes and Attachments hereto, (h) the word “notice” means notice in writing or by email (whether or not specifically stated) and shall include notices, consents, approvals and other written communications contemplated under this APA, (i) provisions that require that a party or parties “agree”, “consent” or “approve” or the like shall require that such agreement, consent or approval be specific and in writing, whether by written agreement, letter, approved minutes or otherwise (including e-mail), (j) references to any specific law, rule or regulation, or article, section or other division thereof, shall be deemed to include the then-current amendments thereto or any replacement or successor law, rule or regulation thereof.

### **I.3 SUBJECT MATTER**

The subject of the call for tenders SANTE/2020/C3/043 is securing the purchase of certain vaccine doses for the Participating Member States.

By Decision C(2020) 4192 final of 18 June 2020, the Commission approved the agreement with Member States on procuring COVID-19 vaccines on behalf of the Member States (“the Decision”). This agreement is based on Article 4(5)(b) of Regulation (EU) 2016/369 of 15

March 2016 on the provision of emergency support within the Union<sup>3</sup> (“the ESI Regulation”) which provides that the Commission may grant emergency support in the form of procurement on behalf of the Member States based on an agreement between the Commission and Member States. In order to implement such action, the Commission is running procurement procedures on behalf of Participating Member States, with a view to signing EU-level APAs with vaccine manufacturers. In view of its importance, this APA will be approved for signature on behalf and in the name of the Participating Member States by a separate individual Commission decision.

The Contractor is currently in Phase 3 clinical development of the Vaccine and is using its Best Reasonable Efforts to secure Authorisation of such vaccine candidate by the Commission, expected at the earliest in December 2020.

The Commission, on behalf of the Participating Member States, wishes to purchase the Vaccine during the pandemic period through this APA. It acknowledges that the clinical development might not be successful or regulatory approval may not be obtained and subsequently an authorised Vaccine may not be available.

On the basis of this APA, the European Commission commissions the Contractor to commit to produce and deliver in priority 200 million doses of the Vaccine which shall be ordered by the Participating Member States (via specific Vaccine Order Forms) at the price and conditions, including timeframe, agreed under this APA.

In case the Contractor succeeds to develop a safe and effective Vaccine according to the terms laid down in this APA, the Contractor or an Affiliate of the Contractor shall supply to the Participating Member States the agreed doses of the Vaccine pursuant to the Vaccine Order Forms.

The Vaccine Order Forms shall be signed by the Contractor and shall incorporate by reference this APA.

#### **I.4 ENTRY INTO FORCE AND DURATION OF THE APA**

I.4.1 The APA enters into force on the date on which the last party signs it (“**Effective Date**”).

I.4.2 The APA is concluded for a period of 24 months with effect from the Effective Date (“**Term**”).

I.4.3 Contractor and the Participating Member States may not sign any Vaccine Order Form after the APA expires.

The APA continues to apply to such Vaccine Order Forms after its expiry. [\*\*\*].

<sup>3</sup> OJ L 70, 16.3.2016, p.1, as amended by Council Regulation (EU) 2020/521 of 14 April 2020 activating the emergency support under Regulation (EU) 2016/369, and amending its provisions taking into account the COVID- 19 outbreak, OJ L 117, 15.4.2020, p. 3.

**I.4.4 Renewal of the APA**

The APA will expire automatically at the end of the Term, unless it is extended in mutual written agreement between the parties. Renewal does not change or postpone any existing obligations.

**I.5 IMPLEMENTATION OF THE APA****I.5.1 Period of provision of the supplies**

The period for the provision of the supplies starts to run as foreseen in Article I.6.3.

**I.5.2 Implementation of the APA**

The APA shall be implemented following signature between the Commission and the Contractor as follows:

In order to guarantee the right of the Participating Member States to acquire Vaccine doses in a given timeframe and at a certain price and conditions, the Commission will pay the Advance Payment.

The Contractor shall use Best Reasonable Efforts to build manufacturing capacity or utilise existing capacity to be capable of manufacturing and supplying the Product to the Commission in accordance with the provisions of this APA.

The Contractor agrees to supply an initial total number of 200 million Vaccine doses to Participating Member States collectively, upon their order, in accordance with this APA and the respective Vaccine Order Forms.

The Participating Member States shall place orders for supplies of 200 million Vaccine doses in total in accordance with the allocation communicated by the Commission to the Contractor pursuant to Article I.6.3, by sending the Contractor a completed copy of Annex I (“**Vaccine Order Form**”) in paper format or emailed pdf [\*\*\*]. This Vaccine Order Form shall be signed by an authorised representative of the Participating Member State and the Contractor.

[\*\*\*] the Contractor must send back to the Participating Member States the duly signed and dated Vaccine Order Form in paper format or emailed pdf.

**I.6 SUPPLY OF THE VACCINE****I.6.1 Creation of the Vaccine**

During the term of this APA, and subject to the successful development and authorisation of the Vaccine as set out in this APA, the Contractor shall use Best Reasonable Efforts to supply or have supplied the Product to the relevant Participating Member States, and the Participating Member States shall purchase the Product, subject to and in accordance with the terms and conditions of this APA.

### I.6.2 Product supply

At the Effective Date, the Commission orders 200 million doses (“**Contracted Doses**”) of the Product on behalf of the Participating Member States to be delivered if the Contractor succeeds to develop a safe and effective Vaccine according to the terms laid down in this APA.

The parties acknowledge that the Commission may wish to place an additional binding order (the “**Additional Order**”) for a maximum of up to 100 million doses of the Vaccine. The parties also agree that such Additional Order may be placed by the Commission only after (i) being advised by the Contractor that the Contractor has availability of supply of such additional requested doses at the time of the proposed Additional Order (the “**Additional Product**”) (ii) the Contractor agrees, in its sole discretion, to allocate the Additional Product to the Commission (iii) the Contractor confirms how many doses can be delivered and by when (iv) the Commission confirms the required allocation between Participating Member States and (v) [\*\*\*]. The Additional Order will be placed by way of an additional Vaccine Order Form and, as such, be subject to the same terms and conditions set forth in this APA.

The Commission shall communicate to the Contractor the allocation of the Contracted Doses supplied pursuant to the initial order and any Additional Product among the governments of the Participating Member States. [\*\*\*] The parties acknowledge that should resale to any third country take place, the Participating Member State reselling doses has an obligation to reimburse the Commission the Advance Payment per dose paid by the Commission to the Contractor.

### I.6.3 Supply mechanism

Vaccine supply in Europe will primarily come from [\*\*\*] manufacturing site [\*\*\*] and shall incorporate RNA produced at [\*\*\*] manufacturing sites including sites operated by the following sub-contractors [\*\*\*].

Subject to points (i) to (v) below, it is estimated that the order will be delivered as set out in the table below (the “**Interim Delivery Schedule**”) assuming Authorisation being granted by [\*\*\*]. The Interim Delivery Schedule and logistics will be further refined [\*\*\*] by the Contractor after the Commission has communicated how to apportion the 200 million Vaccine doses amongst the Participating Member States pursuant to the provisions of this Article I.6.3.

The Interim Delivery Schedule is as follows (subject to the limitations set forth below):

Quarter	[***]	[***]	[***]	[***]
Doses (million)	[***]	[***]	[***]	[***]

- (i) No doses will be shipped to the Member States prior to the Contractor receiving Authorisation.
- (ii) If Authorisation is received after [\*\*\*] then the Interim Delivery Schedule will shift accordingly and be adjusted to reflect the delay between [\*\*\*] and the date of Authorisation (“**Adjusted Delivery Schedule**”).
- (iii) [\*\*\*]

(vi) [\*\*\*]

For the avoidance of doubt, the Participating Member States will not have the right to terminate the Vaccine Order Forms [\*\*\*] in the event that the Commission has not exercised its right to terminate the APA.

If the Vaccine is successfully developed and obtains Authorisation in the foreseen time-line [\*\*\*] the Contractor shall use Best Reasonable Efforts to ensure that the doses are supplied in accordance with the Interim Delivery Schedule, or if applicable, the Adjusted Delivery Schedule. Allocations shall be made pursuant to Article I.6.3(iv) in case of insufficient supply to deliver the full amount of Contracted Doses.

Within [\*\*\*] following the Effective Date, the Commission shall communicate to the Contractor a table how to allocate the 200 million Vaccine doses amongst the Participating Member States.

Each Participating Member State shall have a commitment to purchase the number of Vaccine doses as set out in the above-mentioned allocation table and to sign a Vaccine Order Form to this effect as set out below.

To operationalise the ordering of the Vaccine, each Participating Member State will enter into a Vaccine Order Form. Each Vaccine Order Form will specify in particular the number of doses that the Participating Member State will purchase from the above-mentioned allocation table, the price of all Vaccine doses pursuant to Article I.7, and the liability and indemnification undertakings by the Participating Member State (which will be incorporated by reference from the APA into the Vaccine Order Form). [\*\*\*] For the avoidance of doubt, the Contractor shall have no obligation to supply any Vaccine doses to any Participating Member State where there is not a Vaccine Order Form, including provisions related to liability and indemnity (which will be incorporated by reference from the APA into the Vaccine Order Form executed by the Participating Member State and the Contractor). It is agreed that the Contractor may discharge its obligations under the Vaccine Order Form acting with one or more Participating Contractor Affiliates.

#### **I.6.4 Manufacturing**

The Contractor confirms that it is in possession of all necessary manufacturing authorisations to undertake the manufacturing of the Vaccine.

#### **I.6.5 Legal and regulatory filings and requests**

The Contractor shall ensure that all Product is properly labelled and packaged in accordance with the provisions of Article I.6.8 and Good Manufacturing Practice and in accordance with the applicable EU legislation on information on packaging (Title V of Directive 2001/83/EC).

Notwithstanding the above, [\*\*\*], the Contractor shall comply with all conditions (in the relevant timescales) set out in the Authorisation (where applicable), subject to any exemption, exception or waiver of requirements for the Product granted or permitted by the Participating Member State (including but not limited to serialization).

**I.6.6 Clinical trials and licensure**

The Contractor will use Best Reasonable Efforts to obtain Authorisation. [\*\*\*]

**I.6.7 Waiver**

The Commission acknowledges and agrees that the Contractor's efforts to develop and manufacture the Vaccine are aspirational in nature and subject to significant risks and uncertainties. Notwithstanding the efforts and any estimated dates set forth in this APA, the parties recognize that the Vaccine is in Phase 3 clinical trials at the date of signature of this APA and that, despite the diligent efforts of the Contractor in research, and development and manufacturing, the Vaccine may not obtain Authorisation or may not be delivered (despite the Contractor's obligation to use Best Reasonable Efforts pursuant to Articles I.6.1 and 1.6.6 of this APA) due to technical, clinical, regulatory or manufacturing, shipping, storage or other challenges or failures.

[\*\*\*]

[\*\*\*]

**I.6.8 Packaging, labelling and shipping**

At the date of execution of this APA, the Vaccine is expected to be supplied in a thermal shipping box in accordance with Schedule 4 (Labelling and Packaging Specifications) ("**Thermal Shipper**") containing up to [\*\*\*]. The costs of packaging, packing materials, addressing, labelling, loading and delivery to the agreed Participating Member States' delivery point of the Vaccine [\*\*\*].

All deliveries shall be accompanied by the documentation specified in Attachment 2 (Delivery Documentation) (which may be updated from time to time by the Contractor upon notice to the Commission), and shall be in accordance with, and subject to, the delivery specification set forth in Attachment 3 (Delivery Specification). The Product shall be labelled and packaged in accordance with the packaging specifications set forth in Attachment 4 (Labelling and Packaging Specifications)

Final specifications including package size and labels will be communicated to the Commission and to the Participating Member States prior to delivery. All specifications shall be consistent with any conditions set out in the Authorisation and applicable Law.

**I.6.9 Storage, transport and product acceptance**

Based on current knowledge and subject to updating based on Authorisation, the Vaccine is expected to be a two dose regimen in a concentration liquid formulation that needs to be stored frozen at temperatures between [\*\*\*]. The Vaccine must be thawed on the day of administration and stored at [\*\*\*].

[\*\*\*] Final storage specifications, based on the Authorisation received, will be communicated to the Participating Member State prior to delivery.

**I.6.10 Delivery**

The Contractor will deliver the doses ordered by each of the Participating Member States to one or more locations selected by the Participating Member State in accordance with the procedure set out in this Article I.6.10 and the Vaccine Order Form. [\*\*\*] For the avoidance of doubt, the Participating Member States shall bear all costs and expenses for operating these distribution hubs and for use of the Vaccine, including, but not limited to, those for storage and distribution of the Vaccine after delivery, local duties and local QA testing.

The duly authorised representative of the Participating Member State shall sign to confirm receipt of delivery (the current proposed format of which is as set out in Attachment 2 (Delivery Documentation)). The person signing for receipt must ensure the contents of the delivery match the accompanying shipping documentation proof of receipt.

The Contractor shall deliver the Product [\*\*\*] to the location agreed pursuant to this Article I.6.10.

The Contractor and the Participating Member State shall agree the location(s) for delivery of shipments of the Product; provided that (i) each location meets the requirements set forth in Attachment 3 (Delivery Specification), and (ii) all locations shall be agreed upon by the Contractor and the Participating Member State at least [\*\*\*]. [\*\*\*]

All shipments of Product [\*\*\*].

**I.6.11 Product handling**

Upon delivery of the Product, the Participating Member State shall store and handle the Product in the manner set forth in the Specifications set forth in Attachment 1 (Specifications), instructions in Attachment 3 (Delivery Specification) and the instructions provided by the Contractor to ensure stability and integrity of the Product.

The Participating Member States shall be solely responsible and liable for the proper storage, handling, distribution, transportation, administration, use and disposal of the Product in their country following delivery of the Product to the Participating Member State or its designee. Without prejudice to the generality of the foregoing, the Participating Member States ensure that: (a) recipients of the Product shall follow the return and disposal instructions in Attachment 5 (Return and Disposal of Product Materials) (as updated by the Contractor and communicated to the Participating Member State from time to time) when disposing of open and unused Product and its packaging components; and (b) such return and disposal complies with Laws regarding pharmaceutical waste, medical waste, or hazardous waste, as appropriate.

Participating Member States shall be responsible for and shall ensure that any equipment used to deliver the Product, for example [\*\*\*] are stored in an appropriate clean and secure location to protect and maintain the functionality of such equipment (in controlled conditions, with no exposure to weather or pests, etc). Within [\*\*\*] of receipt of the Product, subject to Article I.6.14, the Participating Member State shall take the necessary measures to enable the collection by the Contractor of all such equipment, including [\*\*\*] in accordance with the Contractor's instructions, consistent with the provisions of Attachment 5 (Return and Disposal of Product Materials).

The Contractor may provide Safety Data Sheets and other agreed information to Participating Member States [\*\*\*].

#### **I.6.12 Title to Product and risk of loss**

[\*\*\*]

#### **I.6.13 Quality tests and checks**

[\*\*\*]

#### **I.6.14 Rejection of Product; Disposal of rejected shipments**

A Participating Member State must visually inspect the Product [\*\*\*] following the instructions set out in Attachment 3 (Delivery Specification) and may reject any specific delivery of the Product or doses therein that does not conform [\*\*\*] ("**Non-Complying Product**") by providing notice to Pfizer Customer Service following an agreed protocol: [\*\*\*].

[\*\*\*]

[\*\*\*]

Without prejudice to the right to refer the matter to the dispute resolution procedure set out in Article I.13.2 and the provision on [\*\*\*], replacement of Non-Complying Product [\*\*\*]. The provisions of this Article I.6.14 shall survive termination or expiration of this APA.

#### **I.6.15 Maintenance and retention of Records**

Each party shall maintain [\*\*\*] with respect to its activities under this APA as required by Laws.

The Participating Member State will maintain a quality system for receipt, inspection, storage, traceability to further delivery points, and recall activities. If the Participating Member State does not have a quality system for the activities defined, the Contractor may share details of a proposed quality system for the Participating Member State's compliance.

#### **I.6.16 Diversion issues**

All Product delivered to a Participating Member State shall be: (a) stored securely by the Participating Member State; and (b) without prejudice to Article I.6.2, distributed by the Participating Member State in a secure manner appropriate to the transportation route and destination, in each case (a) and (b) to guard against and deter theft, diversion, tampering, substitution (with, for example, counterfeits) or unauthorised resale or export out of the Participating Member State, and to protect and preserve the integrity and efficacy of the Product. [\*\*\*]



**I.7 PRICES**

The price of the Vaccine to the Commission and the Participating Member States for the 200 million Contracted Doses will be [\*\*\*]

[***]	[***]	[***]
[***]	[***]	[***]

[\*\*\*]

[\*\*\*]

**I.8 PAYMENT ARRANGEMENTS**

**I.8.1 Advance Payment**

The Commission agrees to pay [\*\*\*] to the Contractor (the “**Advance Payment**”). The Advance Payment [\*\*\*] shall be counted as a payment towards the Delivery Price as defined below.

The Commission shall pay to Contractor the Advance Payment, on behalf of the Participating Member States, [\*\*\*] after the date of Contractor’s invoice in respect thereof.

[\*\*\*]

**I.8.2 Delivery Price**

After the Advance Payment is made, the remainder of the contracted price per dose (the “**Delivery Price**”) for the Contracted Doses is to be paid by the Participating Member State to the Participating Contractor Affiliate [\*\*\*].

The full contracted price per dose for any Additional Order (as set out in Article I.7 above) is to be paid to the Participating Contractor Affiliate [\*\*\*].

[\*\*\*]

The Participating Contractor Affiliate may claim the payment of the balance in accordance with Article I.8.2. The Participating Contractor Affiliate must send an invoice in paper format or emailed pdf for payment of the balance due under a Vaccine Order Form for each provision of supplies to the Participating Member States.

Invoices shall be established by the Participating Contractor Affiliate for a given order of supplies and for an identified delivery scheduled within the Vaccine Order Form.

The Participating Contractor Affiliate may not send an invoice to a Participating Member State before it receives from the Participating Member State [\*\*\*] in respect of which such invoice is established, which [\*\*\*].

The Participating Contractor Affiliate must send an invoice in paper format or emailed pdf or by electronic systems for payment due under the Vaccine Order Form accompanied by the following:

- [\*\*\*]

Each invoice must contain the following information:

- Name of the Participating Member State concerned
- APA and Vaccine Order Form number/reference
- Order reference
- Billing address
- Product [\*\*\*]
- Quantity [\*\*\*]
- [\*\*\*] reference and date
- Price
- Any applicable taxes, transportation charges or other charges provided for in the Vaccine Order Form
- The ship-to destination
- [\*\*\*]
- Participating Contractor Affiliate name and bank account.

The Participating Member States must approve the submitted documents or deliverables as conforming to the above requirements and pay [\*\*\*]. Any payment which falls due on a date which is not a business day may be made on the next succeeding business day. Any dispute by a Participating Member State of an invoice shall be provided to the Participating Contractor Affiliate in writing (along with substantiating documentation and a reasonably detailed description of the dispute) [\*\*\*]. A Participating Member State will be deemed to have accepted all invoices for which the Participating Contractor Affiliate does not receive timely notification of disputes, and shall pay all undisputed amounts due under such invoices within the period set forth in this Article I.8.2. The parties shall seek to resolve all such disputes expeditiously and in good faith.

In addition to all other remedies available under this APA or at Law, if a Participating Member State fails to pay any undisputed amounts when due under this APA, the Contractor [\*\*\*].

The Commission and the Participating Member States shall not, and acknowledge that they will have no right, under this APA, any Vaccine Order Form, any order, any other agreement, document or Law, to withhold, offset, recoup or debit any amounts owed (or to become due and owing) to the Participating Contractor Affiliate, against any other amount owed (or to become due and owing) to it by the Contractor or an Affiliate.

[\*\*\*]

### **I.8.3 Bank account**

Payments by the Commission must be made [\*\*\*]

[\*\*\*]

**I.9 COMMUNICATION DETAILS**

For the purpose of this APA, communications must be sent to the following addresses:

[\*\*\*]

By derogation from this Article I.9, different contact details for the Commission, the Participating Member States or the Contractor may be provided in Vaccine Order Form.

**I.10 PROJECT MANAGEMENT**

Pfizer, BioNTech and the Commission will each nominate a project manager that will be the sole contact point for and responsible for managing the overall relationship between the parties. Each Participating Member State shall in addition appoint an expert to work on APA implementation at Participating Member State level. Project meetings with the Commission and Participating Member State experts will be held regularly on a timeframe to be determined following execution of the APA to report, amongst other things, on progress of clinical studies, licensing activities, manufacturing status, forecast and deliveries. Details specific to each Participating Member State such as logistics and payments shall be handled directly by the respective Participating Member State experts.

**I.11 EXPLOITATION OF THE RESULTS OF THE APA<sup>4</sup>**

The Commission acknowledges and agrees [\*\*\*] (collectively, the “Vaccine IP Rights”). [\*\*\*]

All rights not expressly granted by the Contractor hereunder are reserved by the Contractor.

**I.12 INDEMNIFICATION**

I.12.1 The Commission, on behalf of the Participating Member States, declares that the use of Vaccines produced under this APA will happen under epidemic conditions requiring such use, and that the administration of Vaccines will therefore be conducted under the sole responsibility of the Participating Member States. [\*\*\*]

**I.13 APPLICABLE LAW AND SETTLEMENT OF DISPUTES**

I.13.1 This APA shall be governed by the laws of Belgium.

[\*\*\*]

4

This article must be adapted with care. In particular where the FWC is in essence only a licence on pre-existing materials (with no actual production of new materials specifically for the Union), as is the case for instance for a subscription contract to a database service provider, this article must be adapted accordingly. All information is in the Explanatory note on IPR on: <http://myintracomm.ec.testa.eu/budgweb/EN/imp/procurement/Documents/ipr-note-en.pdf>.

**I.14 OTHER SPECIAL CONDITIONS**

The Contractor shall keep the Commission and the Participating Member States informed [\*\*\*] during the pharmacovigilance or vaccine monitoring programmes in relation to the Vaccines which are the object of this APA [\*\*\*]

(Signature page follows)

**SIGNATURES**

For the Contractor,

[\*\*\*]

[\*\*\*]

Signature:

Done at ,

In duplicate in English

For the Commission, on behalf and in the name of the Participating Member States,

Stella Kyriakides  
Commissioner of Health and Food Safety

Signature:

Done at ,

## **II. GENERAL CONDITIONS FOR THE FRAMEWORK CONTRACT FOR SERVICES**

### **II.1 DEFINITIONS**

All definitions are contained in Article I.2

### **II.2 ROLES AND RESPONSIBILITIES IN THE EVENT OF A JOINT TENDER**

In the event of a joint tender submitted by a group of economic operators and where the group does not have legal personality or legal capacity, one member of the group is appointed as leader of the group.

### **II.3 SEVERABILITY**

Each provision of this APA is severable and distinct from the others. If a provision is or becomes illegal, invalid or unenforceable to any extent, it must be severed from the remainder of the APA. This does not affect the legality, validity or enforceability of any other provisions of the APA, which continue in full force and effect. The illegal, invalid or unenforceable provision must be replaced by a legal, valid and enforceable substitute provision which corresponds as closely as possible with the actual intent of the parties under the illegal, invalid or unenforceable provision. The replacement of such a provision must be made in good faith between the parties. The APA must be interpreted as if it had contained the substitute provision as from its entry into force.

### **II.4 PROVISION OF SERVICES AND SUPPLIES**

II.4.1 All periods specified in the APA are calculated in calendar days, unless otherwise specified.

II.4.2 The Contractor must immediately inform the Commission of any changes in the exclusion situations as declared, according to Article 137 (1) of Regulation (EU) 2018/1046.

### **II.5 COMMUNICATION BETWEEN THE PARTIES**

#### **II.5.1 Form and means of communication**

Any communication of information, notices or documents under the APA must:

- (a) be made in writing in paper or electronic format in the language of the contract;
- (b) bear the APA number and, if applicable, the Vaccine Order Form number;
- (c) be made using the relevant communication details set out in Article I.9; and
- (d) be sent by mail or email.

If a party requests written confirmation of an e-mail within a reasonable time, the other party must provide an original signed paper version of the communication as soon as possible.

The parties agree that any communication made by email has full legal effect and is admissible as evidence in judicial proceedings.

#### II.5.2 Date of communications by mail and email

Any communication is deemed to have been made when the receiving party receives it, unless this APA refers to the date when the communication was sent.

E-mail is deemed to have been received by the receiving party on the day of dispatch of that email, provided that it is sent to the e-mail address indicated in Article I.9. The sending party must be able to prove the date of dispatch. In the event that the sending party receives a nondelivery report, it must make every effort to ensure that the other party actually receives the communication by email or mail. In such a case, the sending party is not held in breach of its obligation to send such communication within a specified deadline.

Mail sent to the Commission or the Participating Member State is deemed to have been received on the date on which the department responsible referred to in Article I.9 registers it.

*Formal notifications* are considered to have been received by the receiving party on the date of receipt indicated in the proof received by the sending party that the message was delivered to the specified recipient.

#### II.6 LIABILITY

II.6.1 During the term of this APA, [\*\*\*].

II.6.2 [\*\*\*]

II.6.3 The Commission and the Participating Member States shall [\*\*\*] to mitigate both (1) the damages that would otherwise be recoverable from the other pursuant to this APA and the Vaccine Order Forms, and (2) any costs, fees, expenses or losses that may be incurred by the Commission or the Participating Member State, or for which the Contractor may be responsible, under this APA and/or any Vaccine Order Form, by taking appropriate and reasonable actions to reduce or limit the amount of such damages, costs, fees, expenses or losses.

#### II.6.4 Limits on liability

(i) Taking into account the unprecedented nature of the current COVID-19

situation and the exceptional circumstances under which the Vaccine shall be delivered, the parties explicitly agree that [\*\*\*].

(ii) [\*\*\*]

(iii) The aggregate liability of the Contractor and its Affiliates towards the Commission arising out of or relating to this APA and/or the Vaccine Order Forms (whether arising contractually or extracontractually), shall not exceed [\*\*\*].

- (iv) The aggregate liability of the Contractor and its Affiliates towards any of the Participating Member States arising out of or relating to this APA and/or the Vaccine Order Form concluded with that Participating Member State (whether arising contractually or extracontractually), shall not exceed [\*\*\*].

[\*\*\*]

#### II.6.5 No limitation of liability

- (i) Nothing in this APA excludes or limits the liability of either party for:

[\*\*\*]

#### II.6.6 Waiver of sovereign immunity

Each Participating Member State represents that it has adequate statutory or regulatory authority and adequate funding appropriation to undertake and completely fulfil the indemnification obligations pursuant to Article I.12 of this APA.

#### II.6.7 Recall

In the event of a recall of the Vaccine, [\*\*\*]

#### II.7 CONFLICT OF INTEREST AND PROFESSIONAL CONFLICTING INTERESTS

- II.7.1 The Contractor must take all the necessary measures to prevent any situation of *conflict of interest* or *professional conflicting interest*.
- II.7.2 The Contractor must *notify* the Commission in writing as soon as possible of any situation that could constitute a *conflict of interest* or a *professional conflicting interest* during the Implementation of the APA. The Contractor must immediately take action to rectify the situation.

The Commission may do any of the following:

- (a) verify that the Contractor's action is appropriate;
- (b) require the Contractor to take further action within a specified deadline;
- (c) decide not to award a Vaccine Order Form to the Contractor. II.7.3 The Contractor must pass on all the relevant obligations in writing to:
  - (a) its personnel which is directly involved in the performance of this APA;
  - (b) any natural person with the power to represent it or take decisions on its behalf;
  - (c) third parties involved in the Implementation of the APA, including subcontractors.

The Contractor must also ensure that the persons referred to above are not placed in a situation which could give rise to conflicts of interest.



**II.8 Representations and warranties****II.8.1 Mutual representations and warranties**

The parties each represent and warrant to each other the following:

- (i) Organization and authority. They have full right, power and authority to enter into this APA and to perform their respective obligations under this APA;
- (ii) No conflicts or violations. The execution and delivery of this APA by such party and the performance of such party's obligations hereunder (i) do not conflict with or violate any laws existing as of the date of entry into force of the APA and applicable to such party and (ii) do not conflict with, violate, breach or constitute a default under, and are not prohibited or materially restricted by, any contractual obligations of such party existing as of the date of entry into force of the APA; and
- (iii) Valid execution. Such party is duly authorised to execute and deliver this APA, and the person executing this APA on behalf of such party is duly authorised to execute and bind such party to the terms set forth herein.

The above warranties shall also be given by the Participating Member States in respect of the Vaccine Orders Forms and their obligations contained therein.

**II.8.2 Warranties of either party**

The Contractor warrants to the Commission and the Participating Member States that:

[\*\*\*]

In the event of any breach of the Contractor's warranties or undertakings relating to the Vaccine, the Commission's and the Participating Member States' [\*\*\*]

The Commission warrants that the APA is awarded and each Vaccine Order Form is concluded in accordance with applicable Laws.

**II.8.3 Anti-bribery/anti-corruption**

The parties represent and warrant that, beyond the mutual consideration set forth in this APA, neither they nor their agents have provided or requested, or will provide or request, any additional incentive or benefit to or from the other party or its agents to induce either party to enter into this APA or perform any part of this APA.

The Contractor has not made, and will not make, in the performance of this APA directly or indirectly any payment, offer, promise, or authorisation of payment of money or anything of value to a government official, political party, candidate for political office, or any other person, and has not sought and will not seek improperly or corruptly to influence any government official, political party, candidate for political office, or any other person, in order to gain an improper business advantage.

**II.8.4 No other warranty**

Except to the extent set out expressly in this APA, all conditions, warranties or other terms which might have effect between the parties or be implied or incorporated into this APA (whether by statute, common law or otherwise) are hereby excluded to the fullest extent permitted by applicable Law. [\*\*\*]

**II.9 CONFIDENTIALITY**

- II.9.1 Neither the Commission, a Participating Member State nor the Contractor shall, at any time, without the disclosing party's prior written consent, disclose to any third party any of the other party's Confidential Information.
- II.9.2 The Commission, the Participating Member State and the Contractor shall:
- (a) use such Confidential Information solely for the purposes for which it was provided;
  - (b) take all reasonable precautions to prevent any unauthorised use or disclosure;
  - (c) not disclose or distribute any Confidential Information to any third party except as and to the extent authorised in writing to do so by the disclosing party.
- II.9.3 The receiving party shall be permitted to disclose Confidential Information that is required or requested to be disclosed by a governmental authority pursuant to applicable law in connection with any other legal or administrative proceeding, provided that it (i) notifies the disclosing party of any such disclosure requirement or request as soon as practicable and (ii) furnishes only that portion of the Confidential Information which, in the opinion of the receiving party or their legal counsel, is responsive to such requirement or request and (iii) asks the court or other public body, if applicable, to treat the Confidential Information as confidential.
- II.9.4 The receiving party shall disclose Confidential Information only to such of its representatives who have a need to know such Confidential Information to fulfil its obligations under this APA; provided, however, before any disclosure of Confidential Information, the receiving party shall bind its representatives receiving such Confidential Information to a written agreement of confidentiality at least as restrictive as contained in this APA; and prior to any disclosure, the receiving party shall instruct its representatives of the confidential nature of, and to maintain the confidentiality of, the Confidential Information. The receiving party shall be responsible for all actions of its representatives, including any breach of the terms hereof, regardless of whether or not such representatives remain employed or in contractual privity with the receiving party.
- II.9.5 Notwithstanding the foregoing, in all cases, [\*\*\*], and (b) the Contractor may disclose Confidential Information to their Affiliates without prior written consent of the Participating Member States.
- II.9.6 The confidentiality obligations set out in this Article II.9 are binding on the Commission, the Participating Member State and the Contractor during the

Implementation of the APA and for as long as the information or documents remain confidential unless:

- (a) the disclosing party agrees to release the receiving party from the confidentiality obligation earlier;
- (b) the Confidential Information or documents become public through other means than a breach of the confidentiality obligation;
- (c) the applicable Law requires the disclosure of the Confidential Information or documents.

II.9.7 The Contractor must obtain from any natural person with the power to represent it or take decisions on its behalf, as well as from third parties involved in the Implementation of the APA a commitment that they will comply with this Article. At the request of the Commission, the Contractor must provide a document providing evidence of this commitment.

II.9.8 Neither this APA nor the performance by either party hereunder shall transfer to the receiving party any proprietary right, title, interest or claim in or to any of the disclosing party's Confidential Information (including, but not limited to, any intellectual property rights subsisting therein) or be construed as granting a license in its Confidential Information.

II.9.9 The provisions of this Article II.9 shall survive the termination or expiration of this APA for [\*\*\*], except with respect to any information that constitutes a trade secret (as defined by the applicable Law), in which case the recipient of such information will continue to be bound by its obligations under this Article II.9 for so long as such information continues to constitute a trade secret, but in no event for a period of less than [\*\*\*] specified above.

II.9.10 The Contractor acknowledges that the Commission is subject to requirements laid down under Regulation (EC) 1049/2001. The Commission commits that it will consult with the Contractor on any disclosure request concerning documents containing Confidential Information as provided for in Article 4(4) of said Regulation.

## **II.10 ANNOUNCEMENTS AND PUBLICITY**

The parties shall consult together on the timing, contents and manner of any press release relating to the execution of this APA. Other than the foregoing, no party shall make, or permit any person to make, any public announcement concerning the existence, subject matter or terms of this APA or a Vaccine Order Form, the wider transactions contemplated by them, or the relationship between the parties, without the prior written consent of the other party (such consent not to be unreasonably withheld or delayed), except (i) as required by law, any governmental or regulatory authority (including, without limitation, any relevant securities exchange), any court or other authority of competent jurisdiction; or (ii) on terms that are consistent and do not go further than the matters covered in any agreed press release. For clarity, unless consent is granted pursuant to this clause II.10, no announcement or disclosure will include or infer [\*\*\*]

A party shall not use the name, trade name, service marks, trademarks, trade dress or logos of the other party in publicity releases, advertising or any other publication, without the other party's prior written consent in each instance, provided, however, that consent is granted for public announcements pursuant to above sub-clause (ii) in this Article II.10.

## II.11 PROCESSING OF PERSONAL DATA

### II.11.1 Processing of personal data by the Commission

Any personal data included in or relating to the APA, including its implementation, shall be processed in accordance with Regulation (EU) 2018/1725. Such data shall be processed solely for the purposes of the implementation, management and monitoring of the APA by the data controller. For the purpose of this provision, the data controller for the Commission shall be the Director-General of the European Commission's Directorate-General for Health and Food Safety. The data protection notice is available at [https://ec.europa.eu/info/data-protection-public-procurement-procedures\\_en](https://ec.europa.eu/info/data-protection-public-procurement-procedures_en).

The Contractor or any other person whose personal data is processed by the data controller in relation to this APA has specific rights as a data subject under Chapter III (Articles 14-25) of Regulation (EU) 2018/1725, in particular the right to access, rectify or erase their personal data and the right to restrict or, where applicable, the right to object to processing or the right to data portability.

Should the Contractor or any other person whose personal data is processed in relation to this APA have any queries concerning the processing of its personal data, it shall address itself to the data controller. They may also address themselves to the Data Protection Officer of the data controller. They have the right to lodge a complaint at any time to the European Data Protection Supervisor.

### II.11.2 Processing of personal data by the Contractor

The processing of personal data by the Contractor shall meet the requirements of Regulation (EU) 2016/679 and be processed solely for the purposes set out by the Controller.

## II.12 SUBCONTRACTING

II.12.1 The Contractor may not subcontract and have the APA implemented by third parties beyond the third parties already mentioned in its tender without [\*\*\*]

II.12.2 In the case of subcontracting, the Contractor remains bound by its contractual obligations and is solely responsible for the *Implementation of the APA*.

II.12.3 The Contractor must ensure that the subcontract does not affect the rights of the Commission and the Participating Member States under this APA.

[\*\*\*]

## II.13 AMENDMENTS

II.13.1 Any amendment to the APA or a Vaccine Order Form must be made in writing before all contractual obligations have been fulfilled. A Vaccine Order Form does not constitute an amendment to the APA.

II.13.2 No amendment can make changes to the APA or a Vaccine Order Form that might alter the initial conditions of the procurement procedure or result in unequal treatment of tenderers or contractors.

#### II.14 ASSIGNMENT

Neither this APA nor any interest hereunder will be assignable by a party without the prior written consent of the other party, except as follows: [\*\*\*].

#### II.15 FORCE MAJEURE

II.15.1 If a party is affected by *Force majeure*, it must immediately *notify* the other party, stating the nature of the circumstances, their likely duration and foreseeable effects.

II.15.2 A party is not liable for any delay or failure to perform its obligations under the APA or Vaccine Order Form if that delay or failure is a *result of Force majeure*. [\*\*\*].

II.15.3 The parties must take all necessary measures to limit any damage due to *Force majeure* and shall use commercially reasonable efforts to avoid or minimize the delay in performance of their respective obligations affected by *Force majeure*.

#### II.16 SUSPENSION OF THE IMPLEMENTATION OF THE APA

##### II.16.1 Suspension by the Contractor

If the Contractor or a Participating Contractor Affiliate is affected by *Force majeure*, it may suspend the provision of the services under a Vaccine Order Form.

The Contractor or the Participating Contractor Affiliate must immediately *notify* the Commission of the suspension. The *notification* must include a description of the *Force majeure* and state when the Contractor or the Participating Contractor Affiliate expects to resume the provision of services.

The Contractor or the Participating Contractor Affiliate must *notify* the Commission as soon as it is able to resume *performance of the Vaccine Order Form*, unless the Commission has already terminated the APA or the Vaccine Order Form.

##### II.16.2 Suspension by the Commission or the Participating Member State

Pursuant to the Financial Regulation, the Commission or the Participating Member State may suspend the Implementation of the APA or performance of a Vaccine Order Form or any part of it:

(a) if the procedure for awarding the APA or a Vaccine Order Form or the Implementation of the APA proves to have been subject to Irregularities, Fraud (in the sense of the Financial Regulation) or breach of obligations;

(b) in order to verify whether the presumed Irregularities, Fraud (in the sense of the Financial Regulation) or breach of obligations have actually occurred.

The Commission or the Participating Member State in question must formally notify the Contractor of the suspension and the reasons for it. Suspension takes effect on the date of formal notification, or at a later date if the formal notification so provides.

The Commission or the Participating Member State in question must notify the Contractor as soon as the verification is completed whether:

- (a) it is lifting the suspension; or
- (b) it intends to terminate the APA or a Vaccine Order Form under Article II.17.1, (f) or (i).

The Contractor is not entitled to compensation for suspension of any part of the APA or a Vaccine Order Form. For the avoidance of doubt, the Contractor shall not be under any obligation to deliver any Contracted Doses during the suspension period, and the Delivery Schedule shall be adjusted to take into account the period of such suspension. Equally for the avoidance of doubt, the Contractor shall complete the delivery of any Contracted Doses that were already in transit on the date of the formal notification or at the later date indicated in the formal notification.

## II.17 TERMINATION OF THE APA

### II.17.1 Grounds for termination by the Commission

The Commission may terminate the APA or the Participating Member State may terminate any on-going Vaccine Order Form (depending on whether the event affects the APA or the Vaccine Order Form) solely in the following circumstances:

- (a) [\*\*\*]
- (b) if the Contractor does not implement the APA or perform the Vaccine Order Form in accordance with material aspects of the APA or the Vaccine Order Form (as applicable) or is otherwise in material breach of another substantial contractual obligation;
- (c) [\*\*\*]
- (d) if the Contractor or any person that assumes unlimited liability for the debts of the Contractor is in one of the situations provided for in points (a) and (b) of Article 136(1) of the Financial Regulation<sup>5</sup>;
- (e) if the Contractor or any Related person is in one of the situations provided for in points

<sup>5</sup> Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules

applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and

- (c) to (h) of Article 136(1) or Article 136(2) of the Financial Regulation;
- (f) if the procedure for awarding the APA or the Implementation of the APA prove to have been subject to Irregularities, Fraud (in the sense of the Financial Regulation) or breach of obligations;
- (g) if the Contractor is in a situation that does constitute a Conflict of interest or a Professional conflicting interest which would have a material adverse impact on the performance of the APA;
- (h) in case of a change regarding the exclusion situations listed in Article 136 of Regulation (EU) 2018/1046 that calls into question the decision to award the contract;
- (i) [\*\*\*]

#### II.17.2 Grounds for termination by the Contractor

The Contractor may terminate the APA or any on-going Vaccine Order Form solely in the following circumstances:

- (a) if the Commission or the Participating Member State does not implement the APA or perform the Vaccine Order Form in accordance with material aspects of the APA or the Vaccine Order Form (as applicable) or is otherwise in material breach of another substantial contractual obligation, [\*\*\*].
- (b) [\*\*\*].

#### II.17.3 Procedure for termination

A party must *formally notify* the other party of its intention to terminate the APA or a Vaccine Order Form and the grounds for termination.

The other party [\*\*\*] following the date of receipt to submit observations, including the measures it has taken or will take to continue fulfilling its contractual obligations. Failing that, the decision to terminate becomes enforceable the day after the time limit for submitting observations has elapsed in the event the grounds giving rise to termination have not been cured.

If the other party submits observations, the party intending to terminate must *formally notify* it.

#### II.17.4 Effects of termination

Within [\*\*\*] date of termination, the Contractor must submit any invoice required for services that were provided before the date of termination. [\*\*\*].

The termination or expiration of this APA shall not affect the survival and continuing validity of Articles I.1, I.2, I.4, I.6.7, I.6.9, I.6.11, I.6.12, I.6.14, I.6.16, I.7 to I.9, I.11 to I.14, II.3, II.5, II.6, II.8.2, II.8.4, II.9 to II.11, II.15, II.17.4, II.18 to II.28, Attachment 3 (Delivery Specification) and Attachment 5 (Return and Disposal of Product Materials) or of any other provision which is expressly or by implication intended to continue in force after such termination or expiration.

Expiry or termination of this APA for any reason shall be without prejudice to either party's other rights and remedies or to any accrued rights and liabilities as the date of such expiry or termination; [\*\*\*].

## **II.18 INVOICES, VALUE ADDED TAX AND E-INVOICING**

### **II.18.1 Invoices and value added tax**

Invoices must contain the Contractor's or the Participating Contractor Affiliate's (or leader's in the case of a joint tender) identification data, the amount, the currency and the date, as well as the APA reference and reference to the Vaccine Order Form.

Invoices must indicate the place of taxation of the Contractor or the Participating Contractor Affiliate (or leader in the case of a joint tender) for value added tax (VAT) purposes and must specify separately amounts not including VAT and amounts including VAT.

The Commission is exempt from all taxes and duties, including VAT, in accordance with Articles 3 and 4 of the Protocol 7 of the Treaty on the Functioning of the European Union on the privileges and immunities of the European Union.

It is understood and agreed between the parties that any prices stated under this APA and Vaccine Order Form are exclusive of any VAT or similar tax and all other taxes which are incurred as a result of manufacturing and supplying the Product (including custom duties, levies and charges and all local taxes) ("**Taxes**"), which shall be added thereon as applicable. Where Taxes are properly chargeable on any amounts payable under this APA or Vaccine Order Form, the party making the payment will pay the amount of Taxes, as specified on the invoice, in accordance with the laws and regulations of the country in which the Taxes are chargeable.

[\*\*\*]

## **II.19 PAYMENTS AND GUARANTEES**

### **II.19.1 Date of payment**

The date of payment is deemed to be the date on which [\*\*\*]

### **II.19.2 Currency**

Payments are made in euros or, for non-Eurozone countries, the local functional currency of the Participating Member State. For non-Eurozone countries, the Vaccine Order Form shall set forth the Delivery Price in the local functional currency converted from euro at the exchange rate existing one (1) day prior to the Effective Date of the APA as of 4:00pm London time published in Bloomberg FX Fixings (BFIX), such rates being found via Bloomberg or the website [www.bloomberg.com/markets/currencies/fix-fixings](http://www.bloomberg.com/markets/currencies/fix-fixings).

### **II.19.3 Costs of transfer**

The costs of the transfer are borne as follows:



- (a) the Commission or the Participating Member State in question bears the costs of dispatch charged by its bank;
- (b) the Contractor or the Participating Contractor Affiliate bears the costs of receipt charged by its bank;
- (c) the party causing repetition of the transfer bears the costs for repeated transfer.

#### **II.19.4 Suspension of the time allowed for payment**

The Commission or the Participating Member State in question may suspend the payment periods specified in Article I.8 at any time by *notifying* the Contractor or the Participating Contractor Affiliate (or leader in the case of a joint tender) that its invoice cannot be processed. [\*\*\*]

Suspension takes effect on the date the Commission or the Participating Member State in question sends the *notification*. The remaining payment period resumes from the date on which the requested information or revised documents are received or the necessary further verification, including on-the-spot checks, is carried out. [\*\*\*]

#### **II.19.5 Interest on late payment**

On expiry of the payment periods specified in Article I.8, the Contractor or the Participating Contractor Affiliate (or leader in the case of a joint tender) is entitled to interest on late payment at the higher of (a) the rate applied by the European Central Bank for its main refinancing operations in euros (the reference rate) [\*\*\*] (or such centralized bank reference rate set forth in the Vaccine Order Form) and (b) [\*\*\*]%. The reference rate is the rate in force, as published in the C series of the *Official Journal of the European Union*, on the first day of the month in which the payment period ends.

Suspension of the payment period as provided for in Article II.19.4 is not considered as giving rise to late payment.

Interest on late payment covers the period running from the day following the due date for payment up to and including the date of payment as defined in Article II.19.1.

### **II.20 RECOVERY**

#### **II.20.1 Recovery procedure**

In all cases where the recovery procedure as described in the Financial Regulation applies, the parties shall follow the procedure set out in this Article.

Before recovery, the Commission or the Participating Member State in question must formally notify the Contractor of its intention to recover the amount it claims, specifying the amount due and the reasons for recovery and inviting the Contractor to make any observations [\*\*\*]

If no observations have been submitted or if, despite the observations submitted, the Commission or the Participating Member State in question decides to pursue the recovery procedure, it must confirm recovery by formally notifying a debit note to the Contractor,

specifying the date of payment. The Contractor must pay in accordance with the provisions specified in the debit note.

If the Contractor does not pay by the due date, the Commission or the Participating Member State in question may, after informing the Contractor in writing, recover the amounts due:

- (a) by offsetting them against any amounts owed to the Contractor by the Commission or the Participating Member State in question; by taking legal action.

#### II.20.2 Interest on late payment

If the Contractor does not honour the obligation to pay the amount due by the date set by the Commission or the Participating Member State in question, the amount due bears interest at the rate indicated in Article II.19.5. Interest on late payments will cover the period starting on the day after the due date for payment and ending on the date when the Commission or the Participating Member State in question receives the full amount owed.

Any partial payment is first entered against charges and interest on late payment and then against the principal amount.

#### II.21 CHECKS AND AUDITS

- II.21.1 The Commission and the European Anti-Fraud Office may check or require an audit on the Implementation of the APA. This may be carried out either by OLAF's own staff or by any outside body authorised to do so on its behalf, provided that the auditor may not be a competitor of the Contractor.

Such checks and audits may be initiated at any moment during business hours during the provision of the services and up to [\*\*\*] starting from the payment of the balance of the last specific contract issued under this APA.

The audit procedure is initiated on the date of receipt of the relevant letter sent by the Commission. Audits are carried out on a confidential basis.

- II.21.2 The Contractor must keep all original documents stored on any appropriate medium, including digitised originals if authorised under national law, for a period of [\*\*\*] starting from the payment of the balance of the last specific contract issued under this APA.

- II.21.3 The Contractor must grant the appropriate right of access to sites and premises where the APA is implemented, [\*\*\*] needed to conduct such checks and audits. The Contractor must ensure that the information is readily available at the moment of the check or audit and, if so requested, that information is handed over in an appropriate format. The auditor must, insofar possible, comply with all applicable and reasonable security measures notified to Commission by the Contractor subject to this not creating any material obstacles for the performance of the auditor's tasks.

- II.21.4 On the basis of the findings made during the audit, a provisional report is drawn up. The Commission or its authorised representative must send it to the Contractor, who has [\*\*\*] following the date of receipt to submit observations. The Contractor must

receive the final report within [\*\*\*] following the expiry of the deadline to submit observations.

On the basis of the final audit findings, the Commission or the Participating Member State in question may recover all or part of the payments made in accordance with Article II.20 and may take any other measures which it considers necessary.

II.21.5 In accordance with Council Regulation (Euratom, EC) No 2185/96 of 11 November 1996 concerning on-the-spot checks and inspection carried out by the Commission in order to protect the European Communities' financial interests against fraud and other irregularities and Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council of 11 September 2013 concerning investigations conducted by the European Anti-Fraud Office, the European Anti-Fraud Office may carry out investigations, including on the spot checks and inspections, to establish whether there has been fraud, corruption or any other illegal activity under the contract affecting the financial interests of the Union. Findings arising from an investigation may lead to criminal prosecution under national law.

The investigations may be carried out at any moment during the provision of the services and up to [\*\*\*] starting from the payment of the balance of the last specific contract issued under this APA.

II.21.6 The Court of Auditors and the European Public Prosecutor's Office established by Council Regulation (EU) 2017/19398 ('the EPPO') have the same rights as the Commission, particularly right of access, for the purpose of checks, audits and investigations.

#### **II.22 RELATIONSHIP OF THE PARTIES**

The relationship hereby established between the Contractor and the Commission is solely that of independent contractors. Neither party has authority to act or make any agreements or representations on behalf of the other party. This APA is not intended to create, and shall not be construed as creating, between the parties, the relationship of principal and agent, employer and employee, joint venturers, co-partners, or any other such relationship, the existence of which is expressly denied.

#### **II.23 WAIVER**

A waiver by any party of any term or condition of this APA in any instance shall not be deemed or construed to be a waiver of such term or condition for the future, or of any subsequent breach thereof. All remedies specified in this APA shall be cumulative and in addition to any other remedies provided at Law or in equity, except where expressly otherwise agreed.

#### **II.24 FURTHER DOCUMENTS**

Each party hereto agrees to execute such further documents and take such further steps as may be reasonably necessary or desirable to effectuate the purposes of this APA.

**II.25 HEADINGS**

Headings of Articles or other parts of this APA are included herein for convenience of reference only and shall not constitute a part of this APA or change the meaning of this APA.

**II.26 ELECTRONIC DELIVERY AND STORAGE**

Delivery of a signed APA by reliable electronic means, including facsimile or email (with receipt electronically confirmed), shall be an effective method of delivery of the executed APA.

This APA may be stored by electronic means and either an original or an electronically stored copy of this APA can be used for all purposes, including in any proceeding to enforce the rights or obligations of the parties to this APA.

**II.27 ENTIRE AGREEMENT**

This APA, together with any Annexes and Attachments, which are hereby incorporated by reference, constitute the entire agreement of the parties with respect to its subject matter and merges and supersedes all prior discussions and writings with respect to thereto.

**II.28 COSTS**

Each party will bear its own legal costs in preparing and concluding this APA.

ANNEX I: VACCINE ORDER FORM

This Vaccine Order Form is submitted by:

[The Government of [\*]] (the “**Participating Member State**”), represented for the purposes of signing this Vaccine Order Form by [forename, surname, function, department of authorising officer],

to:

[Add details for Contractor]

The Participating Member State and Contractor are together referred to as the “**Parties**” and each individually as a “**Party**”.

WHEREAS

- Contractor and the European Commission, acting on behalf of and in the name of the Participating Member States, entered into an Advance Purchase Agreement for the purchase and supply of Contractor’s Vaccine for EU Member States dated [\*] 2020 (the “**APA**”), the terms of which are binding on the Participating Member States and must be read in conjunction with this Vaccine Order Form.
- The APA provides that each Participating Member State will submit to Contractor a Vaccine Order Form through which Contractor shall make available and deliver to the relevant Participating Member State a proportion of the Contracted Doses or Additional Order as applicable, in accordance with the allocation provided by the Commission pursuant to Article I.6.3 of the APA and at the price and conditions as set out in the APA.
- In accordance with Article I.5.2 of the APA, the [name of Participating Member State] hereby places its order for its full allocated portion of the Contracted Doses or Additional Order (as applicable).

**Article I**

**Subject matter**

1. This Vaccine Order Form is submitted by [name of the Participating Member State] to Contractor in accordance with the terms of the APA, and forms an integral part of the APA. The terms and conditions of the APA are incorporated into this Vaccine Order Form by reference. In the event of contradiction between this Vaccine Order Form and the APA, the terms of the APA prevail regardless of any provision to the contrary. Any capitalised terms in this Vaccine Order Form will have the meaning attributed to them in the definitions list included in Article I.2 of the APA.
2. This Vaccine Order Form relates to the order for the Participating Member State’s full allocated portion of the Contracted Doses or the relevant Additional Order (as applicable) as set out in the allocation provided by the Commission to Contractor pursuant to Article I.6.2 of the APA. The submission of this signed Vaccine Order Form

by the Member State to Contractor constitutes a binding order by the Member State for the purchase of its full allocated portion of the Contracted Doses or the relevant Additional Order (as applicable) as follows

- a. [Name of the Member State] will purchase [insert amount] number of doses of [Contracted Doses] [Additional Order] of the Vaccine, on the basis of the following delivery schedule: [\*\*\*].
- b. The Delivery Price of Contracted Doses is [insert price here] euros per dose excl. VAT.  
The total amount payable by the Participating Member State for the [Contracted Doses] [Additional Order] is [insert amount], excluding [insert applicable percentage]% VAT.

3. By signature of this Vaccine Order Form, the undersigned Member State warrants to Contractor that:

- a. it is irrevocably and unconditionally bound by the terms of the APA (as concluded by the Commission on behalf and in the name of the Participating Member States), including the indemnification obligations and the liability, limitation of liability and exclusions terms set out therein;
- b. the provisions of the APA are enforceable against it in accordance with its terms;
- c. it shall indemnify the Indemnified Persons in accordance with Article I.12 (*Indemnification*) of the APA;
- d. it has full right, power and authority to enter into this Vaccine Order Form and to perform its respective obligations under it;
- e. the person executing this Vaccine Order Form is duly authorized to execute and bind the undersigned Participating Member State to the terms set forth herein and incorporated by reference.

4. [\*\*\*].

5. The Participating Member State represents and warrants that all necessary permissions and approvals have been or will be obtained prior to the time for performance by the Participating Member State, to authorise performance of all of the obligations contained herein.

**Article II****Delivery, Supply**

1. **Delivery Address.** The Delivery Address for the Participating Member State is as follows:

[• - Member State to enter location of its distribution hub]

2. **Supply of the Products**

The Contractor shall supply the Products as further described in the APA: [**Note:** Include any additional details concerning the supply here.]

**Article III****Invoices; Notices**

1. **Invoice and Payments.** Contractor shall invoice the Participating Member State in accordance with the terms of the APA. All payments to Contractor or its designated Affiliate shall be made in accordance with the terms of the APA.

Payment shall be made in the following currency pursuant to the provisions of Article II.19.2: [to be completed].

2. **Notice.** Any notice given under this Vaccine Order Form must a) be made in writing in English in paper or electronic format; b) bear the APA number and the number of this Vaccine Order Form; c) be made using the relevant communication details set out below with respect to the Member State and Contractor (as applicable); d) be sent by mail and email:

Participating Member State:

[Name of Participating Member State]

[Full official address of Participating Member State]

[Full name of addressee physical person (contact person)]

[Function of addressee physical person (contact person)]

E-mail: [complete email of addressee physical person (contact person)]

Contractor: [Add details]

**Article IV.****Entry into Force and Duration**

1. This Vaccine Order Form shall enter into force on the date of signature by the Parties and will remain into force until termination of the APA, or if the APA expires, until the last delivery of Product [\*\*\*].

**Article V.**

**Applicable Law and Settlement of Disputes**

1. For the avoidance of doubt, Article 1.13 (*Applicable Law and Settlement of Disputes*) of the APA shall apply to any dispute arising out of the implementation of or in connection with this Vaccine Order Form and the Participating Member State irrevocably agrees to be bound by the provisions set out therein.

(Signature page follows)



**SIGNATURES**

For the **Participating Member State**,

[*forename/surname/position*]

Signature: \_\_\_\_\_

Done at [*place*], [*date*]

For acceptance of the Vaccine Order Form,

[Contractor],

[*forename/surname/position*]

Signature: \_\_\_\_\_

Done at [*place*], [*date*]

The invoice will be paid only once the Contractor has returned the signed Vaccine Order Form.

**ANNEX II: AGREEMENT BETWEEN THE COMMISSION AND MEMBER STATES ON PROCURING COVID-19 VACCINES ON BEHALF OF THE MEMBER STATES AND RELATED PROCEDURES, ANNEXED TO THE COMMISSION DECISION C(2020) 4192 FINAL OF 18 JUNE 2020**

**Agreement**

**Preamble**

Having regard to Article 4(5)(b) of Council regulation (EU) 2016/369 on the provision of emergency support within the Union<sup>1</sup> as amended by Council regulation (EU) 2020/521 of 14 April 2020 activating the emergency support under regulation (EU) 2016/369, and amending its provisions taking into account the COVID-19 outbreak (hereinafter “ESI” or “ESI regulation”);

\*\*\*

The European Commission (“the Commission”)

and

The following Member States: (XXX), hereinafter referred to as “the Participating Member States”

Together referred to as “the Parties”

Agree on the Following:

**Article 1: Objective and mandate of the Commission**

On the basis of the present agreement, the Commission is mandated to conclude, on behalf of the Participating Member States, Advance Purchase Agreements (“APA”) with vaccine manufacturers with the objective to procure vaccines for the purposes of combatting the COVID 19 pandemic at Union level.

The Annex to this agreement sets out the negotiating directives for this purpose.

**Article 2: Acquisition of vaccine doses**

It is the Participating Member States, and not the Commission, that shall acquire vaccine doses from the manufacturers on the basis of the APAs unless otherwise agreed. All relevant vaccination policies shall therefore remain matters for the Participating Member States.

**Article 3: APAs containing a right to acquire vaccine doses**

Where the Commission concludes an APA in conformity with the present agreement that provides the right for the Participating Member States to acquire vaccine doses, the use of such a right shall take place by means of the conclusion of contracts between the Participating Member States and the vaccine manufacturers. There shall be no obligation for any Participating Member State to conclude such a contract on the basis of the APA. The APA shall contain a clause to this end.

#### Article 4: APAs containing an obligation to acquire vaccine doses

Where the Commission intends to conclude, in conformity with the present agreement, an APA containing an obligation to acquire vaccine doses, it shall inform the Participating Member

States of such intention and the detailed terms. In case a Participating Member State does not agree with the conclusion of an APA containing an obligation to acquire vaccine doses or its terms, it has the right to opt out by explicit notification to the Commission within 5 working days after the Commission has communicated its intention to conclude the APA. All Participating Member States not having opted out within the period of 5 working days are deemed to have authorised the Commission to negotiate and conclude the APA with the vaccine manufacturer in their name and on their behalf.

#### Article 5: The legally binding nature of APAs

Once concluded, the terms of the APA shall be legally binding on the Participating Member States, except for those who have exercised their right to opt out.

#### Article 6: Responsibility and liability

The present Agreement regulates only the division of potential liability and indemnification between the Commission and the Participating Member States. It does not regulate the extent to or the conditions under which potential liability of the vaccine manufacturer may be taken over or indemnified under the APAs.

The Commission shall be exclusively responsible for the procurement process and the conclusion of APAs including any liability arising out of the conduct of the negotiations.

Participating Member States acquiring a vaccine shall be responsible for the deployment and use of the vaccines under their national vaccination strategies, [and shall bear any liability associated with such use and deployment. This shall extend to and include any indemnification of vaccine manufacturers under the terms and conditions of the relevant APA for liability related to the use and deployment of vaccines normally borne by such manufacturer.]

#### Article 7: Obligation not to negotiate separately

By signing the present Agreement, the Participating Member States confirm their participation in the procedure and agree not to launch their own procedures for advance purchase of that vaccine with the same manufacturers.

In case an APA containing an obligation to acquire vaccine doses has been concluded with a specific manufacturer, the Member States having made use of the opt-out provided under the present Agreement can enter into separate negotiations with the same manufacturer after the APA under the present Agreement has been signed.

## Annex

### Initial considerations

A permanent solution to the COVID-19 crisis is most likely to be brought about by the development and deployment of a safe and effective vaccine against the virus. Every month gained in the deployment of a vaccine will save many lives, many jobs and billions of euros.

Therefore, it is the objective of the present Agreement that the EU takes steps to secure sufficient supplies of a safe and effective vaccine for Member States.

### Structure and purpose of the procurement

Work on a COVID-19 vaccine is challenging for many reasons: the shortened development timeframe, the large upfront costs for manufacturers, the high failure rate during clinical trials. If vaccine producers follow their usual practice of making investments in production capacity only when they are sure of a viable product, this will result in considerably longer waiting times for a vaccine. Investments need to be made now in order to ensure that vaccines are being produced at the scale required as early as possible.

Under the present agreement, this challenge will be addressed through concluding EU-level Advance Purchase Agreements (“APA”) with vaccine manufacturers when necessary, to secure access to vaccine candidates where they are successful, including up-front EU financing to de-risk essential investments to increase the speed and scale of manufacturing successful vaccines. Funding for the up-front payments will come from the Emergency Support Instrument (ESI).

The Parties understand that developing a safe and effective vaccine is a highly complex process and the risk of failure in any such venture is very high. Therefore, the aim is to put in place APAs with a number of manufacturers of leading vaccine candidates, to maximise the chances of having access to at least one successful vaccine.

The Commission will invite all vaccine manufacturers to manifest interest. In general, the Commission will give priority to negotiating specific APAs with those manufacturers that (a) have entered or have firm plans to enter clinical trials still in 2020, (b) have the capacity to develop a successful vaccine and (c) have a proven capacity to produce at scale already in 2021.

### Process and governance

In order to run the procurement centrally and efficiently, the European Commission will set up a steering board for the process subject to Article 6 of the present Agreement. It will be co-chaired by the European Commission and a Participating Member State with experience in the negotiations and production capacities for vaccines. The steering board will include senior officials from all Participating Member States to assist and provide guidance throughout the evaluation process.

The co-chairs of the steering board will propose a team of a limited number of experts with relevant experience for the ongoing negotiations from six Participating Member States with production capacities for vaccines. These experts will join with the European Commission in a negotiation team (“joint negotiation team”), which will work on a continuous basis as one

unit. That joint negotiation team will start work immediately building on previous contacts with individual companies by the European Commission and Participating Member States. In order to launch negotiations with a specific manufacturer, there needs to be support from at least four Participating Member States. The joint negotiation team will make its best effort to take the advice of the steering board into account in the negotiations and will report back to the steering board on a regular basis on the progress made in negotiating with individual companies.

For compliance with the applicable rules, all members of the steering board and the joint negotiation team will obtain the status of experts associated to the procurement process as provided in the Financial Regulation. Given their access to highly sensitive business information, all those members will be required to sign strict confidentiality and no-conflict-of-interest agreements.

Assisted by the steering board, the European Commission will then decide which of the resulting APAs should be concluded, in particular if financing under ESI is insufficient to finance all relevant packages. The Commission will only consider those APAs for financing where at least four Participating Member States have expressed agreement. Before making any final decisions, the Commission

will seek independent scientific advice on the state of progress and the available data on quality, safety and efficacy for the vaccine candidate in question.

Should financing under ESI be insufficient, Participating Member States can decide to top up ESI funding to make up the gap to finance all packages. In such a case where there are opportunities to conclude further APAs but money from ESI is no longer sufficient, Participating Member States will have the opportunity to express their interest in such opportunities. If at least four Participating Member States express interest, those Participating Member States will make use of the possibility of a voluntary contribution to ESI to the required amount allowing the Commission to proceed with signing the APA only on behalf of those Member States that have expressed interest and contributed the funds to ESI.

For full transparency, the European Commission will report to the IPCR at least once every two weeks on overall progress more generally.

#### **Advanced Purchase Agreements and conditions**

To conclude APAs, the joint negotiating team will negotiate funding packages with individual vaccine producers in return for the right to buy a specific number of vaccine doses in a given timeframe and at a certain price.

As outlined in the present Agreement, the European Commission also has the possibility to conclude APAs including an obligation to procure the vaccine if it becomes available, where the conditions (notably the pricing) of those APAs make this worthwhile and in line with the conditions in the present Agreement. If in such a case the distinction between upfront payments and purchase price is difficult to draw, the Commission will share the total cost related to the vaccine purchase but will in any case contribute no more than [50%] of the total cost.

Funding provided up front will be considered as an advance payment for any eventual purchase by Member States, thus reducing the amount that Member States will have to pay when eventually purchasing that vaccine.

The up-front payments under the APAs shall be used by manufacturers to de-risk the necessary investments related to both vaccine development and clinical trials, and the preparation of the at-scale production capacity along the entire vaccine production value chain in the EU required for a rapid deployment of millions of doses of an eventual vaccine. The relevant payments should be structured according to the need of the manufacturer, but subject to the state of the vaccine development, in particular relying on transparency of the associated clinical data and its assessment, at the time of payment. This is in order to avoid obligations to pay in situations where the development work has shown a vaccine candidate likely to be unsuccessful.

The purchase price of the vaccine, as well as the amount of funding provided up front will take into account a transparent estimation of production costs (supported by independent audits where available), as well as the resources already granted from other public sources. Under the APA, the manufacturer can be asked to provide ex post proof supported by independent audits concerning the activities financed by these payments.

The aim of the negotiation is to conclude APAs with individual companies under the best possible conditions. These APAs should specify details with respect to:

- a) Payments to be made, such as payment amounts, payment schedules, type of payments requested and the use of those payments related to de-risk investment, financing clinical trials, providing working capital and scaling-up production capacity;
- b) Delivery details of the vaccine if successful, such as price per person immunised (or alternatively, number of doses required per person immunised and price per dose), quantity of doses to be delivered and delivery timeline following approval;  
and
- c) Any other relevant conditions, such as production capacity built or used in the EU or liability arrangements.

For liability arrangements, the joint negotiation team will make its best effort to limit what is required by individual companies for the purpose of indemnification to be included in the terms and conditions of the APA.

The APAs will contain provisions to clarify the law applicable to both the APA and resulting purchase orders as well as the competent courts. The Participating Member States agree that each APA negotiated by the Commission on their behalf with a vaccine manufacturer will have the same applicable law for all Participating Member States, and that the courts corresponding to that applicable law will be competent to hear disputes arising from that APA.

When taking a decision to finance individual APAs, the European Commission, in consultation with the steering board, will take into account the following elements: any available data on quality, safety and efficacy of the vaccine at time of negotiation of the contract, speed of

delivery at scale, cost, risk-sharing, diversification of technologies, capacity to supply through development of production capacity within the EU, possible flexible future use of any capacity funded, engagement at an early stage with EU regulators with the intention to apply for an EU marketing authorisation for the candidate vaccine(s), commitment to supply vulnerable countries.

The procedure outlined above complies with the ESI Regulation and the Financial Regulation. The latter is aligned to the European procurement Directives, which also provide the basis for national procurement rules. Participating Member States may rely on the procedure run by the European Commission to directly purchase vaccines from the manufacturers as and when any of the vaccines becomes available based on the conditions laid down in the APA. Access to vaccine doses will be allocated to Participating Member States according to the population distribution key.

In the negotiations with the pharmaceutical industry under the present Agreement, the Commission will promote a Covid-19 vaccine as a global public good. This promotion will include access for low and middle income countries to these vaccines in sufficient quantity and at low prices. The Commission will seek to promote related questions with the pharmaceutical industry regarding intellectual property sharing, especially when such IP has been developed with public support, in order to these objectives. Any vaccines available for purchase under the APAs concluded but not needed and purchased by Participating Member States can be made available to the global solidarity effort.

ANNEX III: PARTICIPATING MEMBER STATES

Germany  
France  
Italy  
Spain  
Austria  
Greece  
Cyprus  
Malta  
Denmark  
Sweden  
Finland  
Ireland  
Portugal  
Belgium  
Luxembourg  
Netherlands  
Poland  
Romania  
Bulgaria  
Slovenia  
Croatia  
Czech Republic  
Hungary  
Slovakia  
Lithuania  
Latvia  
Estonia



**ANNEX IV: SUBCONTRACTORS**

[\*\*\*]

**ANNEX V – PARTICIPATING CONTRACTOR AFFILIATES**

<b>Country</b>	<b>Participating Contractor Affiliate</b>
Germany	BioNTech Europe GmbH
France	Pfizer SAS
Italy	Pfizer S.r.l.
Spain	Pfizer S.L.U.
Austria	Pfizer Corporation Austria GmbH
Greece	Pfizer Hellas SA
Cyprus	Pfizer Hellas SA
Malta	Pfizer Hellas SA
Denmark	Pfizer ApS
Sweden	Pfizer Innovations AB
Finland	Pfizer Finland Oy
Ireland	Pfizer Healthcare Ireland
Portugal	Pfizer Biofarmacêutica Sociedade Unipessoal, Lda
Belgium	Pfizer SA
Luxembourg	Pfizer Luxembourg S.A.R.L.
Netherlands	Pfizer BV
Poland	Pfizer Trading Polska sp. z o.o.
Romania	Pfizer Romania SRL
Bulgaria	Pfizer Export B.V.
Slovenia	Pfizer Export B.V.
Croatia	Pfizer Export B.V.
Czech Republic	Pfizer PFE, spol. s r.o. After 1/12 shall be merged into Pfizer, spol. s r.o.
Hungary	Pfizer Gyógyszerkereskedelmi Kft.
Slovakia	Pfizer Export B.V.
Lithuania	Pfizer Export B.V.
Latvia	Pfizer Export B.V.
Estonia	Pfizer Export B.V.

ATTACHMENT 1: SPECIFICATIONS

[\*\*]ATTACHMENT 2: DELIVERY DOCUMENTATION

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ATTACHMENT 3: DELIVERY SPECIFICATIONS

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THE SYMBOL “[\*\*\*]” DENOTES PLACES WHERE CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH (i) NOT MATERIAL, AND (ii) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF PUBLICLY DISCLOSED

EUROPEAN COMMISSION  
Directorate-General for Health and Food Safety



PURCHASE AGREEMENT (“PA”)<sup>1</sup> for the further development, production, purchasing options and supply of the successful COVID-19 Vaccine for EU Member States

NUMBER — [complete]

1. **The European Commission**, acting on behalf and in the name of the Member States set out in Annex III (hereinafter referred to as “Participating Member States”),<sup>2</sup> being represented for the purposes of the signature of this PA by Ms Stella Kyriakides, Commissioner of Health and Food Safety

on the one part and

2. **Pfizer Inc.**

Incorporated in Delaware (Registration Number 0383418) with its registered address at 235 East 42nd Street

10017 New York City, NY (UNITED STATES)

appointed as the leader of the group by the members of the group that submitted the joint tender

(hereinafter referred to as “Pfizer”)

and

**BioNTech Manufacturing GmbH**

Registered with the commercial register of the lower court (*Amtsgericht*) of Mainz, Germany under HRB 47548, with its registered address at An der Goldgrube 12

1

This PA is based on the agreement between the Commission and the Member States as approved by Commission Decision C(2020) 4192 final on approving the agreement with Member States on procuring Covid-19 vaccines on behalf of the Member States and related procedures.

2

As provided for in Article 4(5)(b) of Council Regulation (EU) 2016/369 of 15 March 2016 on the provision of emergency support within the Union as amended by Council Regulation (EU) 2020/521 of 14 April 2020 activating the emergency support under Regulation (EU) 2016/369, and amending its provisions taking into account the COVID-19 outbreak.

55131 MAINZ, GERMANY  
(hereinafter referred to as “**BioNTech**”)

as a member of the group (collectively ‘**the Contractor**’), represented for the purposes of the signature of this PA which has the form of a framework contract by [\*\*\*].  
on the other part,

HAVE AGREED

to the **special conditions and the general conditions of this PA** and the following Annexes and Attachments:

**Annex I** – Model for Vaccine Order Form

**Annex II** – Agreement between the Commission and Member States on procuring Covid-19 vaccines on behalf of the Member States and related procedures, annexed to the Commission Decision C(2020) 4192 final of 18 June 2020

**Annex III** – Participating Member States

**Annex IV** – Subcontractors

**Annex V** – Participating Contractor Affiliates

Attachment 1 – Specifications

Attachment 2 – Delivery Documentation

Attachment 3 – Delivery Specification

Attachment 4 – Labelling and Packaging Specifications

Attachment 5 – Return and Disposal of Product Materials

which form an integral part of this PA.

[\*\*\*].

This PA sets out:

1. the procedure and conditions by which the Participating Member States will pay for the services and/or supplies from the Contractor;
  2. the provisions that apply to any Vaccine Order Form which the Participating Member States and the Contractor may conclude under this PA; and
  3. the obligations of the parties during and after the duration of this PA.
-

All documents issued by the Contractor (end-user agreements, general terms and conditions, etc.) except its tender are held inapplicable, unless explicitly mentioned in the special conditions of this PA. In all circumstances, in the event of contradiction between this PA and documents issued by the Contractor, this PA prevails, regardless of any provision to the contrary in the Contractor's documents.

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## I. SPECIAL CONDITIONS

### I.1 ORDER OF PRIORITY OF PROVISIONS

If there is any conflict between different provisions in this PA, the following rules must be applied:

- (a) The provisions set out in the special conditions and Article II.6 of the general conditions (Liability) take precedence over those in the other parts of the PA.
- (b) The other provisions set out in the general conditions take precedence over those in the Annexes and Attachments.
- (c) The provisions set out in the PA take precedence over those in the Vaccine Order Forms.

### I.2 DEFINITIONS

The following definitions shall apply to this PA:

**‘Additional Order’**: has the meaning set forth in Article I.6.2;

**‘Additional Product’**: has the meaning set forth in Article I.6.2;

**‘Affiliate’**: means in relation to a body corporate, any other entity which directly or indirectly Controls, is Controlled by, or is under direct or indirect common Control of that body corporate from time to time;

**‘Authorisation’**: means a Conditional Marketing Authorisation and/or Marketing Authorisation that permits the Products to be placed on the market in the European Economic Area;

**‘Best Reasonable Efforts’**: [\*\*\*];

**‘Conditional Marketing Authorisation’**: means a conditional marketing authorisation granted by the European Commission as referred to in Article 14-a of Regulation (EC) No 726/2004;

**‘Confidential Information’**: means any information disclosed to or obtained by one party to the other party, either directly or indirectly, or which the disclosing party indicates in writing at the time of disclosure to, or receipt by, the recipient is to be considered confidential or proprietary, or which such recipient knows or ought reasonably to know is information of a confidential or proprietary nature, including the terms of this PA and any Vaccine Order Form. Confidential Information shall not include any information (i) the receiving party can prove was known to it prior to the date of disclosure; (ii) the receiving party can prove was lawfully obtained from a third party without any obligation of confidentiality; (iii) is or becomes part of the public domain other than through any act or omission of the receiving party; or (iv) is independently developed by the receiving party without use of or reference to the disclosing party’s Confidential Information, as evidenced by the receiving party’s records;

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**‘Conflict of interest’:** a situation where the impartial and objective *Implementation of the PA* by the Contractor is compromised for reasons involving family, emotional life, political or national affinity, economic interest, any other direct or indirect personal interest, or any other shared interest with the Commission, the Participating Member State or any third party related to the subject matter of the PA;

**‘Contracted Doses’:** has the meaning set forth in Article I.6.2;

**‘Control’:** means the possession by a person or an entity, directly or indirectly, of the power to direct or cause the direction of the management and policies of the other person or entity (whether through the ownership of voting shares, by contract or otherwise) and **"Controls"** and **"Controlled"** shall be interpreted accordingly;

**‘Delivery Price’:** has the meaning set forth in Article I.8.2;

**‘Delivery Schedule’:** has the meaning set forth in Article I.6.3

**‘Effective Date’:** has the meaning set forth in Article I.4.1;

**‘Force majeure’:** any unforeseeable, exceptional situation or event beyond the reasonable control of the parties that prevents either of them from fulfilling any of their obligations under the PA [\*\*\*];

**‘Formal notification’** (or ‘formally notify’): form of communication between the parties made in writing by mail or email, which provides the sender with compelling evidence that the message was delivered to the specified recipient;

**‘Fraud’:** an act or omission committed in order to make an unlawful gain for the perpetrator or another by causing a loss to the Union's financial interests, and relating to: i) the use or presentation of false, incorrect or incomplete statements or documents, which has as its effect the misappropriation or wrongful retention of funds or assets from the Union budget, ii) the non-disclosure of information in violation of a specific obligation, with the same effect or iii) the misapplication of such funds or assets for purposes other than those for which they were originally granted, which damages the Union's financial interests, it being understood that the Union's financial interests are impacted within the framework of this PA as the Union is engaging resources into the coordination and preparation of the PA, resulting from Decision C(2020) 4192 final of 18 June 2020 which approved the agreement with Member States on procuring COVID-19 vaccines on behalf of the Member States (“the Decision”), this agreement being based on Article 4(5)(b) of Regulation (EU) 2016/369 of 15 March 2016 on the provision of emergency support within the Union<sup>3</sup> (“the ESI Regulation”);

**‘Good Manufacturing Practice’:** means the current practices for manufacture required by the standards, rules, principles and guidelines set out in Directive 2001/83/EC (as amended by Directive 2004/27/EC), Directive 2017/1572, Directive 2003/94/EC and EudraLex - Volume 4 of the Rules Governing Medicinal Products in the EU entitled “EU Guidelines to Good Manufacturing Practice Medicinal Products for Human and Veterinary Use”;

**‘Implementation of the PA’**: the purchase of services or supplies envisaged in the PA through the signature and *performance of Vaccine Order Forms*;

**‘Indemnified Persons’**: has the meaning set forth in Article I.12.1;

**‘Irregularity’**: any infringement of a provision of Union law resulting from an act or omission by the Contractor within the meaning of Article 1(2) of the Council (EC, Euratom) Regulation 2988/95 of 18 December 1995 on the protection of the European Communities financial interests (in OJ 23.12.95, L 312/1) , which has, or would have, the effect of prejudicing the Union’s budget, it being understood that the Union’s financial interests are impacted within the framework of this PA, as the Union is engaging resources into the coordination and preparation of the PA, resulting from the Decision which approved the agreement with Member States on procuring COVID-19 vaccines on behalf of the Member States, this agreement being based on Article 4(5)(b) of the ESI Regulation;

[\*\*\*]

**‘Latent Defect’**: means a defect causing the Product to not conform to the applicable Specifications that the relevant Participating Member State can show was present at the time of delivery of the Product and which could not have been detected by the Participating Member State, its designee, or their personnel at delivery through visual inspection;

**‘Law(s)’**: means, collectively, all applicable supranational, national and local laws, common laws, statutes, ordinances, codes, rules, regulations, orders, decrees or other pronouncements of any government, administrative or judicial authority having the effect of law;

**‘Losses’**: has the meaning set forth in Article I.12.1;

**‘Marketing Authorisation’**: means the marketing authorisation (other than Conditional Marketing Authorisation), in respect of the Product granted by the European Commission, as amended or varied from time to time, that allows the Product to be placed on the market in the European Economic Area according to applicable Law;

**‘Non-Complying Product’**: has the meaning set forth in Article I.6.14;

**‘Notification’** (or ‘notify’): form of communication between the parties made in writing including by electronic means;

**‘Participating Contractor Affiliate’**: means an Affiliate of Pfizer or BioNTech as identified in Annex V;

**‘Product’**: means the Vaccine;

**‘Product Materials’**: means all packaging materials and components needed for delivery of the Product;

**‘Professional conflicting interest’**: a situation in which the Contractor’s previous or ongoing professional activities affect its capacity to implement the PA or to perform a Vaccine Order Form to an appropriate quality standard;

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**‘Record’**: means books, documents, and other data, of all matters relating to performance of obligations under this PA;

**‘Related person’**: any natural or legal person who is a member of the administrative, management or supervisory body of the Contractor, or who has powers of representation, decision or control with regard to the Contractor;

**‘Specifications’**: means the specifications for the manufacture, testing and testing procedures, and supply of the Product as set out in Attachment 1 (Specifications), and as such specifications may be amended, supplemented or otherwise modified by the Contractor and communicated to the Commission;

**‘Taxes’**: has the meaning set forth in Article II.18.1;

**‘Term’**: means the term of the PA set out in Article I.4.2 of the PA;

**‘Thermal Shipper’**: has the meaning set forth in Article I.6.8;

**‘Third Party Claim’**: has the meaning set forth in Article I.12.4.

**‘Vaccine’**: the medicinal product, being BNT162b2, a nucleoside-modified messenger RNA (mRNA) vaccine that encodes an optimized SARS-CoV-2 full-length spike glycoprotein (S) for which Authorisation has been granted, including any subsequent variations approved by the Commission. [\*\*\*].

**‘Vaccine IP Rights’**: has the meaning set forth in Article I.11; and

**‘Vaccine Order Form’**: has the meaning set forth in Article I.5.2.

Except where the context expressly requires otherwise, (a) the use of any gender herein shall be deemed to encompass references to either or both genders, and the use of the singular shall be deemed to include the plural (and vice versa), (b) the words “include”, “includes” and “including” shall be deemed to be followed by the phrase “without limitation”, (c) the word “will” shall be construed to have the same meaning and effect as the word “shall”, (d) any definition of or reference to any agreement, instrument or other document herein shall be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein), (e) any reference herein to any person shall be construed to include the person’s successors and assigns, (f) the words “herein”, “hereof” and “hereunder”, and words of similar import, shall be construed to refer to this PA in its entirety and not to any particular provision hereof, (g) all references herein to Articles, Annexes or Attachments shall be construed to refer to Articles, Annexes or Attachments of this PA, and references to this PA include all Annexes and Attachments hereto, (h) the word “notice” means notice in writing or by email (whether or not specifically stated) and shall include notices, consents, approvals and other written communications contemplated under this PA, (i) provisions that require that a party or parties “agree”, “consent” or “approve” or the like shall require that such agreement, consent or approval be specific and in writing, whether by written agreement, letter, approved minutes or otherwise (including e-mail), (j) references to any specific law, rule or regulation, or article, section or other division thereof, shall be deemed to include the then-current amendments thereto or any replacement or successor law, rule or regulation thereof.

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### I.3 SUBJECT MATTER

The subject of the call for tenders SANTE/2021/C3/005 is securing the purchase of certain vaccine doses for the Participating Member States.

Following the Decision, taken in accordance with Article 4(5)(b) of the ESI Regulation, the Commission is running procurement procedures on behalf of Participating Member States, with a view to signing EU-level Advance Purchase Agreements (“APAs”) with vaccine manufacturers.

An APA between the Parties was signed on 20 November 2020.

In compliance with Article 164(1)(d) as well as Annex I, Point 11.1(c) of the Financial Regulation, the Commission launched on 12 January 2021 a negotiated procedure without prior publication of a contract notice for the procurement of additional doses of vaccines. This procedure was justified by the need to quickly secure additional doses of vaccines to reach a turning point in the epidemic. This PA is for such additional doses, and while it is organised following the Decision it is entirely separate from the APA between the Parties.

In view of its importance, this PA will be approved for signature on behalf and in the name of the Participating Member States by a separate individual Commission decision.

The Conditional Marketing Authorisation for the Vaccine was granted on 21 December 2020.

The Commission, on behalf of the Participating Member States, wishes to purchase the Vaccine during the pandemic period through this PA.

On the basis of this PA, the European Commission commissions the Contractor to commit to produce and deliver 200 million doses of the Vaccine which shall be ordered by the Participating Member States (via specific Vaccine Order Forms) at the price and conditions, including timeframe, agreed under this PA, with the option to obtain a further 100 million doses of the Vaccine subject to the conditions set out in this PA.

The Contractor or a Participating Contractor Affiliate shall supply to the Participating Member States the agreed doses of the Vaccine pursuant to the Vaccine Order Forms.

The Vaccine Order Forms shall be signed by the Contractor and shall incorporate by reference this PA.

### I.4 ENTRY INTO FORCE AND DURATION OF THE PA

I.4.1 The PA enters into force on the date on which the last party signs it (“**Effective Date**”).

I.4.2 The PA is concluded for a period of eighteen (18) months with effect from the Effective Date (“**Term**”).

I.4.3 Contractor and the Participating Member States may not sign any Vaccine Order Form after the PA expires.

The PA continues to apply to such Vaccine Order Forms after its expiry. [\*\*\*].

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#### **I.4.4 Renewal of the PA**

The PA will expire automatically at the end of the Term, unless it is extended in mutual written agreement between the parties. Renewal does not change or postpone any existing obligations.

### **I.5 IMPLEMENTATION OF THE PA**

#### **I.5.1 Period of provision of the supplies**

The period for the provision of the supplies starts to run as foreseen in Article I.6.3.

#### **I.5.2 Implementation of the PA**

The PA shall be implemented following signature between the Commission and the Contractor as follows:

The Contractor shall use Best Reasonable Efforts to obtain manufacturing capacity or utilise existing capacity to be capable of manufacturing and supplying the Product to the Commission on behalf of the Participating Member States in accordance with the provisions of this PA.

The Contractor agrees to supply an initial total number of 200 million Vaccine doses to Participating Member States collectively, upon their order, in accordance with this PA and the respective Vaccine Order Forms.

The Participating Member States shall place orders for supplies of 200 million Vaccine doses in total in accordance with the allocation communicated by the Commission to the Contractor pursuant to Article I.6.3, by sending the Contractor a completed copy of Annex I (“**Vaccine Order Form**”) in paper format or emailed pdf [\*\*\*]. This Vaccine Order Form shall be signed by an authorised representative of the Participating Member State and the Contractor.

[\*\*\*] the Contractor must send back to the Participating Member States the duly signed and dated Vaccine Order Form in paper format or emailed pdf.

### **I.6 SUPPLY OF THE VACCINE**

#### **I.6.1 General**

During the term of this PA, the Contractor shall supply or have supplied the Product to the relevant Participating Member States, and the Participating Member States shall purchase the Product, subject to and in accordance with the terms and conditions of this PA.

#### **I.6.2 Product supply**

At the Effective Date, the Commission orders 200 million doses (“**Contracted Doses**”) of the Product on behalf of the Participating Member States [\*\*\*] according to the terms laid down in this PA.

The parties acknowledge that the Commission may wish to place an additional binding order (the “**Additional Order**”) for a maximum of up to 100 million doses of the Vaccine. The parties also agree that such Additional Order may be placed by the Commission only after (i) being advised by the Contractor that the Contractor has availability of supply of such additional requested doses at the time of the proposed Additional Order (the “**Additional Product**”) (ii)

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the Contractor agrees, in its sole discretion, to allocate the Additional Product to the Commission (iii) the Contractor confirms how many doses can be delivered and by when (iv) the Commission confirms the required allocation between Participating Member States and (v) [\*\*\*]. The Additional Order will be placed by way of an additional Vaccine Order Form and, as such, be subject to the same terms and conditions set forth in this PA. [\*\*\*].

The Commission shall communicate to the Contractor the allocation of the Contracted Doses supplied pursuant to the initial order and any Additional Product among the governments of the Participating Member States. [\*\*\*]

[\*\*\*]

### I.6.3 Supply mechanism

Vaccine supply in Europe will primarily come from [\*\*\*] manufacturing site [\*\*\*] and shall incorporate RNA produced at [\*\*\*] manufacturing sites including sites operated by the following sub-contractors:

[\*\*\*]

The Delivery Schedule is as follows (subject to the limitations set forth below):

Quarter	[***]	[***]	[***]
Doses (million)	[***]	[***]	[***]

The Delivery Schedule and logistics will be further refined [\*\*\*] by the Contractor after the Commission has communicated how to apportion the 200 million Vaccine doses amongst the Participating Member States pursuant to the provisions of this Article I.6.3. [\*\*\*].

- (i) [\*\*\*]
- (ii) [\*\*\*]

For the avoidance of doubt, the Participating Member States will not have the right to terminate the Vaccine Order Forms [\*\*\*] in the event that the Commission has not exercised its right to terminate the PA.

The Contractor shall use Best Reasonable Efforts to ensure that the doses are supplied in accordance with the Delivery Schedule, the estimated monthly and weekly schedules and the dates set out in the Vaccine Order Forms. [\*\*\*] Allocations shall be made pursuant to Article I.6.3(i) in case of insufficient supply to deliver the full amount of Contracted Doses.

Within [\*\*\*] following the Effective Date, the Commission shall communicate to the Contractor a table how to allocate the 200 million Vaccine doses amongst the Participating Member States.

Each Participating Member State shall have a commitment to purchase the number of Vaccine doses as set out in the above-mentioned allocation table and to sign a Vaccine Order Form to this effect as set out below.

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To operationalise the ordering of the Vaccine, each Participating Member State will enter into a Vaccine Order Form. Each Vaccine Order Form will specify in particular the number of doses that the Participating Member State will purchase from the above-mentioned allocation table, the price of all Vaccine doses pursuant to Article I.7, and the liability and indemnification undertakings by the Participating Member State (which will be incorporated by reference from the PA into the Vaccine Order Form). [\*\*\*] For the avoidance of doubt, the Contractor shall have no obligation to supply any Vaccine doses to any Participating Member State where there is not a Vaccine Order Form, including provisions related to liability and indemnity (which will be incorporated by reference from the PA into the Vaccine Order Form executed by the Participating Member State and the Contractor). It is agreed that the Contractor may discharge its obligations under the Vaccine Order Form acting with one or more Participating Contractor Affiliates.

#### **I.6.4 Manufacturing**

The Contractor confirms that it is in possession of all necessary manufacturing authorisations to undertake the manufacturing of the Vaccine.

#### **I.6.5 Legal and regulatory filings and requests**

The Contractor shall ensure that all Product is properly labelled and packaged in accordance with the provisions of Article I.6.8 and Good Manufacturing Practice and in accordance with the applicable EU legislation on information on packaging (Title V of Directive 2001/83/EC).

Notwithstanding the above, [\*\*\*] the Contractor shall comply with all conditions (in the relevant timescales) set out in the Authorisation (where applicable), subject to any exemption, exception or waiver of requirements for the Product granted or permitted by the Participating Member State (including but not limited to serialization).

#### **I.6.6 Clinical trials and licensure**

[\*\*\*]

#### **I.6.7 Waiver**

The Commission acknowledges and agrees that the Contractor's efforts to continue to develop and manufacture the Vaccine are aspirational in nature and subject to significant risks and uncertainties. Notwithstanding the efforts and any estimated dates set forth in this PA, the parties acknowledge that the Vaccine might not be delivered fully according to the Delivery Schedule due to technical, clinical, regulatory or manufacturing, shipping, storage or other challenges or failures.

[\*\*\*]

#### **I.6.8 Packaging, labelling and shipping**

At the date of execution of this PA, the Vaccine is expected to be supplied in a thermal shipping box in accordance with Attachment 4 (Labelling and Packaging Specifications) (“**Thermal Shipper**”). [\*\*\*]. The costs of packaging, packing materials, addressing, labelling, loading and delivery to the agreed Participating Member States' delivery point of the Vaccine [\*\*\*].

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All deliveries shall be accompanied by the documentation specified in Attachment 2 (Delivery Documentation) (which may be updated from time to time by the Contractor upon notice to the Commission), and shall be in accordance with, and subject to, the delivery specification set forth in Attachment 3 (Delivery Specification). The Product shall be labelled and packaged in accordance with the packaging specifications set forth in Attachment 4 (Labelling and Packaging Specifications).

Final specifications including package size and labels will be communicated to the Commission and to the Participating Member States prior to delivery. All specifications shall be consistent with any conditions set out in the Authorisation and applicable Law.

**I.6.9 Storage, transport and product acceptance**

[\*\*\*]

[\*\*\*] Final storage specifications, based on the Authorisation received, will be communicated to the Participating Member State prior to delivery.

**I.6.10 Delivery**

The Contractor will deliver the doses ordered by each of the Participating Member States to one or more locations selected by the Participating Member State in accordance with the procedure set out in this Article I.6.10 and the Vaccine Order Form. [\*\*\*] For the avoidance of doubt, the Participating Member States shall bear all costs and expenses for operating these distribution hubs and for use of the Vaccine, including, but not limited to, those for storage and distribution of the Vaccine after delivery, local duties and local QA testing.

The duly authorised representative of the Participating Member State shall sign to confirm receipt of delivery (the current proposed format of which is as set out in Attachment 2 (Delivery Documentation)). The person signing for receipt must ensure the contents of the delivery match the accompanying shipping documentation proof of receipt.

The Contractor shall deliver the Product [\*\*\*] to the location agreed pursuant to this Article I.6.10.

The Contractor and the Participating Member State shall agree the location(s) for delivery of shipments of the Product; provided that (i) each location meets the requirements set forth in Attachment 3 (Delivery Specification), and (ii) all locations which are additional to those approved in advance by the Contractor prior to the Effective Date shall be agreed upon by the Contractor and the Participating Member State at least [\*\*\*].

All shipments of Product [\*\*\*], or such other amount as notified to the Commission from time to time by the Contractor in accordance with the terms of this PA.

**I.6.11 Product handling**

Upon delivery of the Product, the Participating Member State shall store and handle the Product in the manner set forth in the Specifications set forth in Attachment 1 (Specifications), instructions in Attachment 3 (Delivery Specification) and the instructions provided by the Contractor to ensure stability and integrity of the Product.

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The Participating Member States shall be solely responsible and liable for the proper storage, handling, distribution, transportation, administration, use and disposal of the Product in their [\*\*\*] following delivery of the Product to the Participating Member State or its designee. Without prejudice to the generality of the foregoing, the Participating Member States ensure that: (a) recipients of the Product shall follow the return and disposal instructions in Attachment 5 (Return and Disposal of Product Materials) (as updated by the Contractor and communicated to the Participating Member State from time to time) when disposing of open and unused Product and its packaging components; and (b) such return and disposal complies with Laws regarding pharmaceutical waste, medical waste, or hazardous waste, as appropriate.

Participating Member States shall be responsible for and shall ensure that any equipment used to deliver the Product, for example [\*\*\*], are stored in an appropriate clean and secure location to protect and maintain the functionality of such equipment (in controlled conditions, with no exposure to weather or pests, etc). Within [\*\*\*] of receipt of the Product, subject to Article I.6.14, the Participating Member State shall take the necessary measures to enable the collection by the Contractor of all such equipment, including [\*\*\*], in accordance with the Contractor's instructions, consistent with the provisions of Attachment 5 (Return and Disposal of Product Materials).

The Contractor may provide Safety Data Sheets and other agreed information to Participating Member States [\*\*\*].

[\*\*\*]

**I.6.12 Title to Product and risk of loss**

[\*\*\*]

**I.6.13 Quality tests and checks**

[\*\*\*]

**I.6.14 Rejection of Product; Disposal of rejected shipments**

A Participating Member State must visually inspect the Product [\*\*\*] following the instructions set out in Attachment 3 (Delivery Specification) and may reject any specific delivery of the Product or doses therein that does not conform [\*\*\*] ("**Non-Complying Product**") by providing notice to Pfizer Customer Service following an agreed protocol: [\*\*\*].

[\*\*\*]

Without prejudice to the right to refer the matter to the dispute resolution procedure set out in Article I.13.2 and the provision on [\*\*\*], replacement of Non-Complying Product [\*\*\*]. The provisions of this Article I.6.14 shall survive termination or expiration of this PA.

**I.6.15 Maintenance and retention of Records**

Each party shall maintain [\*\*\*] with respect to its activities under this PA as required by Laws.

The Participating Member State will maintain a quality system for receipt, inspection, storage, traceability to further delivery points, and recall activities. If the Participating Member State

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does not have a quality system for the activities defined, the Contractor may share details of a proposed quality system for the Participating Member State's compliance.

**I.6.16 Diversion issues**

All Product delivered to a Participating Member State shall be: (a) stored securely by the Participating Member State; and (b) without prejudice to Article I.6.2, distributed by the Participating Member State in a secure manner appropriate to the transportation route and destination, in each case (a) and (b) to guard against and deter theft, diversion, tampering, substitution (with, for example, counterfeits) or unauthorised resale or export out of the Participating Member State, and to protect and preserve the integrity and efficacy of the Product. [\*\*\*].

**I.7 PRICES**

The price of the Vaccine to the Commission and the Participating Member States for the 200 million Contracted Doses and any Additional Order will be [\*\*\*].

**I.8 PAYMENT ARRANGEMENTS**

**I.8.1 [\*\*\*]**

**I.8.2 Delivery Price**

The **Delivery Price** for the Contracted Doses and any Additional Order is to be paid by the Participating Member State to the Participating Contractor Affiliate [\*\*\*]. [\*\*\*]

[\*\*\*]

The Participating Contractor Affiliate may claim the payment of the balance in accordance with Article I.8.2. The Participating Contractor Affiliate must send an invoice in paper format or emailed pdf for payment of the balance due under a Vaccine Order Form for each provision of supplies to the Participating Member States.

Invoices shall be established by the Participating Contractor Affiliate for a given order of supplies and for an identified delivery scheduled within the Vaccine Order Form.

The Participating Contractor Affiliate may not send an invoice to a Participating Member State before it receives from the Participating Member State [\*\*\*] in respect of which such invoice is established, which [\*\*\*].

The Participating Contractor Affiliate must send an invoice in paper format or emailed pdf or by electronic systems for payment due under the Vaccine Order Form accompanied by the following:

[\*\*\*]

Each invoice must contain the following information:

- Name of the Participating Member State concerned
  - PA and Vaccine Order Form number/reference
  - Order reference
-

- Billing address
- Product [\*\*\*]
- Quantity [\*\*\*]
- [\*\*\*] reference and date
- Price
- Any applicable taxes, transportation charges or other charges provided for in the Vaccine Order Form
- The ship-to destination
- [\*\*\*]
- Participating Contractor Affiliate name and bank account.

The Participating Member States must approve the submitted documents or deliverables as conforming to the above requirements and pay [\*\*\*]. Any payment which falls due on a date which is not a business day may be made on the next succeeding business day. Any dispute by a Participating Member State of an invoice shall be provided to the Participating Contractor Affiliate in writing (along with substantiating documentation and a reasonably detailed description of the dispute) [\*\*\*]. A Participating Member State will be deemed to have accepted all invoices for which the Participating Contractor Affiliate does not receive timely notification of disputes, and shall pay all undisputed amounts due under such invoices within the period set forth in this Article I.8.2. The parties shall seek to resolve all such disputes expeditiously and in good faith.

In addition to all other remedies available under this PA or at Law, if a Participating Member State fails to pay any undisputed amounts when due under this PA, the Contractor [\*\*\*].

The Commission and the Participating Member States shall not, and acknowledge that they will have no right, under this PA, any Vaccine Order Form, any order, any other agreement, document or Law, to withhold, offset, recoup or debit any amounts owed (or to become due and owing) to the Participating Contractor Affiliate, against any other amount owed (or to become due and owing) to it by the Contractor or an Affiliate.[\*\*\*]

### **I.8.3 Bank account**

Payments by the Commission must be made [\*\*\*]

### **I.9 COMMUNICATION DETAILS**

For the purpose of this PA, communications must be sent to the following addresses:

[\*\*\*]

By derogation from this Article I.9, different contact details for the Commission, the Participating Member States or the Contractor may be provided in Vaccine Order Form.

### **I.10 PROJECT MANAGEMENT**

Pfizer, BioNTech and the Commission will each nominate a project manager that will be the sole contact point for and responsible for managing the overall relationship between the parties. Each Participating Member State shall in addition appoint an expert to work on PA implementation at Participating Member State level. Project meetings with the Commission and Participating Member State experts will be held regularly on a timeframe to be determined

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following execution of the PA to report, amongst other things, on progress of clinical studies, licensing activities, manufacturing status, forecast and deliveries. Details specific to each Participating Member State such as logistics and payments shall be handled directly by the respective Participating Member State experts.

#### **I.11 EXPLOITATION OF THE RESULTS OF THE PA**

The Commission acknowledges and agrees [\*\*\*] (collectively, the “**Vaccine IP Rights**”). [\*\*\*] All rights not expressly granted by the Contractor hereunder are reserved by the Contractor.

#### **I.12 INDEMNIFICATION**

The Commission, on behalf of the Participating Member States, declares that the use of Vaccines produced under this PA will happen under epidemic conditions requiring such use, and that the administration of Vaccines will therefore be conducted under the sole responsibility of the Participating Member States. [\*\*\*]

[\*\*\*]

#### **I.13 APPLICABLE LAW AND SETTLEMENT OF DISPUTES**

This PA shall be governed by the laws of Belgium.

[\*\*\*]

#### **I.14 OTHER SPECIAL CONDITIONS**

The Contractor shall keep the Commission and the Participating Member States informed [\*\*\*] during the pharmacovigilance or vaccine monitoring programmes in relation to the Vaccines which are the object of this PA [\*\*\*].

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**SIGNATURES**

For the Contractor,

[\*\*\*]

[\*\*\*]

For the Commission, on behalf and in the name of the Participating Member States,

[forename/surname/position]

Signature:

Done at *[place]*, *[date]*

In duplicate in English.

Signature:

Done at *[place]*, *[date]*

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## **II. GENERAL CONDITIONS FOR THE FRAMEWORK CONTRACT FOR SERVICES**

### **II.1 DEFINITIONS**

All definitions are contained in Article I.2

### **II.2 ROLES AND RESPONSIBILITIES IN THE EVENT OF A JOINT TENDER**

In the event of a joint tender submitted by a group of economic operators and where the group does not have legal personality or legal capacity, one member of the group is appointed as leader of the group.

### **II.3 SEVERABILITY**

Each provision of this PA is severable and distinct from the others. If a provision is or becomes illegal, invalid or unenforceable to any extent, it must be severed from the remainder of the PA. This does not affect the legality, validity or enforceability of any other provisions of the PA, which continue in full force and effect. The illegal, invalid or unenforceable provision must be replaced by a legal, valid and enforceable substitute provision which corresponds as closely as possible with the actual intent of the parties under the illegal, invalid or unenforceable provision. The replacement of such a provision must be made in good faith between the parties. The PA must be interpreted as if it had contained the substitute provision as from its entry into force.

### **II.4 PROVISION OF SERVICES AND SUPPLIES**

II.4.1 All periods specified in the PA are calculated in calendar days, unless otherwise specified.

II.4.2 The Contractor must immediately inform the Commission of any changes in the exclusion situations as declared, according to Article 137 (1) of Regulation (EU) 2018/1046.

### **II.5 COMMUNICATION BETWEEN THE PARTIES**

#### **II.5.1 Form and means of communication**

Any communication of information, notices or documents under the PA must:

- (a) be made in writing in paper or electronic format in the language of the contract;
- (b) bear the PA number and, if applicable, the Vaccine Order Form number;
- (c) be made using the relevant communication details set out in Article I.9; and
- (d) be sent by mail or email.

If a party requests written confirmation of an e-mail within a reasonable time, the other party must provide an original signed paper version of the communication as soon as possible.

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The parties agree that any communication made by email has full legal effect and is admissible as evidence in judicial proceedings.

#### II.5.2 Date of communications by mail and email

Any communication is deemed to have been made when the receiving party receives it, unless this PA refers to the date when the communication was sent.

E-mail is deemed to have been received by the receiving party on the day of dispatch of that e-mail, provided that it is sent to the e-mail address indicated in Article I.9. The sending party must be able to prove the date of dispatch. In the event that the sending party receives a non-delivery report, it must make every effort to ensure that the other party actually receives the communication by email or mail. In such a case, the sending party is not held in breach of its obligation to send such communication within a specified deadline.

Mail sent to the Commission or the Participating Member State is deemed to have been received on the date on which the department responsible referred to in Article I.9 registers it.

*Formal notifications* are considered to have been received by the receiving party on the date of receipt indicated in the proof received by the sending party that the message was delivered to the specified recipient.

#### II.6 LIABILITY

II.6.1 During the term of this PA, [\*\*\*].

II.6.2 [\*\*\*]

II.6.3 The Commission and the Participating Member States shall [\*\*\*] to mitigate both (1) the damages that would otherwise be recoverable from the other or the Contractor pursuant to this PA and the Vaccine Order Forms, and (2) any costs, fees, expenses or losses that may be incurred by the Commission or the Participating Member State, or for which the Contractor may be responsible, under this PA and/or any Vaccine Order Form, by taking appropriate and reasonable actions to reduce or limit the amount of such damages, costs, fees, expenses or losses.

#### II.6.4 Limits on liability

- (i) Taking into account the unprecedented nature of the current COVID-19 situation and the exceptional circumstances under which the Vaccine shall be delivered, the parties explicitly agree that [\*\*\*]
  - (ii) [\*\*\*]
  - (iii) The aggregate liability of the Contractor and its Affiliates towards the Commission arising out of or relating to this PA and/or the Vaccine Order Forms (whether arising contractually or extra-contractually), shall not exceed [\*\*\*].
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(iv) The aggregate liability of the Contractor and its Affiliates towards any of the Participating Member States arising out of or relating to this PA and/or the Vaccine Order Form concluded with that Participating Member State (whether arising contractually or extra contractually), shall not exceed [\*\*\*].

(v) [\*\*\*]

#### **II.6.5 No limitation of liability**

(i) Nothing in this PA excludes or limits the liability of either party for:

[\*\*\*]

#### **II.6.6 Waiver of sovereign immunity**

Each Participating Member State represents that it has adequate statutory or regulatory authority and adequate funding appropriation to undertake and completely fulfil the indemnification obligations pursuant to Article I.12 of this PA.

#### **II.6.7 Recall**

In the event of a recall of the Vaccine [\*\*\*].

### **II.7 CONFLICT OF INTEREST AND PROFESSIONAL CONFLICTING INTERESTS**

II.7.1 The Contractor must take all the necessary measures to prevent any situation of *conflict of interest or professional conflicting interest*.

II.7.2 The Contractor must *notify* the Commission in writing as soon as possible of any situation that could constitute a *conflict of interest or a professional conflicting interest* during the Implementation of the PA. The Contractor must immediately take action to rectify the situation.

The Commission may do any of the following:

- (a) verify that the Contractor's action is appropriate;
- (b) require the Contractor to take further action within a specified deadline;
- (c) decide not to award a Vaccine Order Form to the Contractor.

II.7.3 The Contractor must pass on all the relevant obligations in writing to:

- (a) its personnel which is directly involved in the performance of this PA;
- (b) any natural person with the power to represent it or take decisions on its behalf;
- (c) third parties involved in the Implementation of the PA, including subcontractors.

The Contractor must also ensure that the persons referred to above are not placed in a situation which could give rise to conflicts of interest.

### **II.8 Representations and warranties**

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### **II.8.1 Mutual representations and warranties**

The parties each represent and warrant to each other the following:

- (i) Organization and authority. They have full right, power and authority to enter into this PA and to perform their respective obligations under this PA;
- (ii) No conflicts or violations. The execution and delivery of this PA by such party and the performance of such party's obligations hereunder (i) do not conflict with or violate any laws existing as of the date of entry into force of the PA and applicable to such party and (ii) do not conflict with, violate, breach or constitute a default under, and are not prohibited or materially restricted by, any contractual obligations of such party existing as of the date of entry into force of the PA; and
- (iii) Valid execution. Such party is duly authorised to execute and deliver this PA, and the person executing this PA on behalf of such party is duly authorised to execute and bind such party to the terms set forth herein.

The above warranties shall also be given by the Participating Member States in respect of the Vaccine Orders Forms and their obligations contained therein.

### **II.8.2 Warranties of either party**

The Contractor warrants to the Commission and the Participating Member States that:

[\*\*\*]

In the event of any breach of the Contractor's warranties or undertakings relating to the Vaccine, the Commission's and the Participating Member States' [\*\*\*].

The Commission and the Participating Member State warrant that the PA is awarded and each Vaccine Order Form is concluded in accordance with applicable Laws.

### **II.8.3 Anti-bribery/anti-corruption**

The parties represent and warrant that, beyond the mutual consideration set forth in this PA, neither they nor their agents have provided or requested, or will provide or request, any additional incentive or benefit to or from the other party or its agents to induce either party to enter into this PA or perform any part of this PA.

The Contractor has not made, and will not make, in the performance of this PA directly or indirectly any payment, offer, promise, or authorisation of payment of money or anything of value to a government official, political party, candidate for political office, or any other person, and has not sought and will not seek improperly or corruptly to influence any government official, political party, candidate for political office, or any other person, in order to gain an improper business advantage.

### **II.8.4 No other warranty**

Except to the extent set out expressly in this PA, all conditions, warranties or other terms which might have effect between the parties or be implied or incorporated into this PA (whether by

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statute, common law or otherwise) are hereby excluded to the fullest extent permitted by applicable Law. [\*\*\*].

#### II.9 CONFIDENTIALITY

- II.9.1 Neither the Commission, a Participating Member State nor the Contractor shall, at any time, without the disclosing party's prior written consent, disclose to any third party any of the other party's Confidential Information.
- II.9.2 The Commission, the Participating Member State and the Contractor shall:
- (a) use such Confidential Information solely for the purposes for which it was provided;
  - (b) take all reasonable precautions to prevent any unauthorised use or disclosure;
  - (c) not disclose or distribute any Confidential Information to any third party except as and to the extent authorised in writing to do so by the disclosing party.
- II.9.3 The receiving party shall be permitted to disclose Confidential Information that is required or requested to be disclosed by a governmental authority pursuant to applicable law in connection with any other legal or administrative proceeding, provided that it (i) notifies the disclosing party of any such disclosure requirement or request as soon as practicable and (ii) furnishes only that portion of the Confidential Information which, in the opinion of the receiving party or their legal counsel, is responsive to such requirement or request and (iii) asks the court or other public body, if applicable, to treat the Confidential Information as confidential.
- II.9.4 The receiving party shall disclose Confidential Information only to such of its representatives who have a need to know such Confidential Information to fulfil its obligations under this PA; provided, however, before any disclosure of Confidential Information, the receiving party shall bind its representatives receiving such Confidential Information to a written agreement of confidentiality at least as restrictive as contained in this PA; and prior to any disclosure, the receiving party shall instruct its representatives of the confidential nature of, and to maintain the confidentiality of, the Confidential Information. The receiving party shall be responsible for all actions of its representatives, including any breach of the terms hereof, regardless of whether or not such representatives remain employed or in contractual privity with the receiving party.
- II.9.5 Notwithstanding the foregoing, in all cases, (a) [\*\*\*], and (b) the Contractor may disclose Confidential Information to their Affiliates without prior written consent of the Participating Member States.
- II.9.6 The confidentiality obligations set out in this Article II.9 are binding on the Commission, the Participating Member State and the Contractor during the Implementation of the PA and for as long as the information or documents remain confidential unless:
- (a) the disclosing party agrees to release the receiving party from the confidentiality obligation earlier;
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- (b) the Confidential Information or documents become public through other means than a breach of the confidentiality obligation;
- (c) the applicable Law requires the disclosure of the Confidential Information or documents.

- II.9.7 The Contractor must obtain from any natural person with the power to represent it or take decisions on its behalf, as well as from third parties involved in the Implementation of the PA a commitment that they will comply with this Article. At the request of the Commission, the Contractor must provide a document providing evidence of this commitment.
- II.9.8 Neither this PA nor the performance by either party hereunder shall transfer to the receiving party any proprietary right, title, interest or claim in or to any of the disclosing party's Confidential Information (including, but not limited to, any intellectual property rights subsisting therein) or be construed as granting a license in its Confidential Information.
- II.9.9 The provisions of this Article II.9 shall survive the termination or expiration of this PA for [\*\*\*], except with respect to any information that constitutes a trade secret (as defined by the applicable Law), in which case the recipient of such information will continue to be bound by its obligations under this Article II.9 for so long as such information continues to constitute a trade secret, but in no event for a period of less than [\*\*\*] specified above.
- II.9.10 The Contractor acknowledges that the Commission is subject to requirements laid down under Regulation (EC) 1049/2001. The Commission commits that it will consult with the Contractor on any disclosure request concerning documents containing Confidential Information as provided for in Article 4(4) of said Regulation.

#### **II.10 ANNOUNCEMENTS AND PUBLICITY**

The parties shall consult together on the timing, contents and manner of any press release relating to the execution of this PA. Other than the foregoing, no party shall make, or permit any person to make, any public announcement concerning the existence, subject matter or terms of this PA or a Vaccine Order Form, the wider transactions contemplated by them, or the relationship between the parties, without the prior written consent of the other party (such consent not to be unreasonably withheld or delayed), except (i) as required by law, any governmental or regulatory authority (including, without limitation, any relevant securities exchange), any court or other authority of competent jurisdiction; or (ii) on terms that are consistent and do not go further than the matters covered in any agreed press release. For clarity, unless consent is granted pursuant to this Article II.10, no announcement or disclosure will (i) include or infer [\*\*\*].

A party shall not use the name, trade name, service marks, trademarks, trade dress or logos of the other party in publicity releases, advertising or any other publication, without the other party's prior written consent in each instance, provided, however, that consent is granted for public announcements pursuant to above sub-clause (ii) in this Article II.10.

#### **II.11 PROCESSING OF PERSONAL DATA**

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### II.11.1 Processing of personal data by the Commission

Any personal data included in or relating to the PA, including its implementation, shall be processed in accordance with Regulation (EU) 2018/1725. Such data shall be processed solely for the purposes of the implementation, management and monitoring of the PA by the data controller. For the purpose of this provision, the data controller for the Commission shall be the Director-General of the European Commission's Directorate-General for Health and Food Safety. The data protection notice is available at [https://ec.europa.eu/info/data-protection-public-procurement-procedures\\_en](https://ec.europa.eu/info/data-protection-public-procurement-procedures_en).

The Contractor or any other person whose personal data is processed by the data controller in relation to this PA has specific rights as a data subject under Chapter III (Articles 14-25) of Regulation (EU) 2018/1725, in particular the right to access, rectify or erase their personal data and the right to restrict or, where applicable, the right to object to processing or the right to data portability.

Should the Contractor or any other person whose personal data is processed in relation to this PA have any queries concerning the processing of its personal data, it shall address itself to the data controller. They may also address themselves to the Data Protection Officer of the data controller. They have the right to lodge a complaint at any time to the European Data Protection Supervisor.

### II.11.2 Processing of personal data by the Contractor

The processing of personal data by the Contractor shall meet the requirements of Regulation (EU) 2016/679 and be processed solely for the purposes set out by the controller.

#### II.12 SUBCONTRACTING

- II.12.1 The Contractor may not subcontract and have the PA implemented by third parties beyond the third parties already mentioned in its tender [\*\*\*].
- II.12.2 In the case of subcontracting, the Contractor remains bound by its contractual obligations and is solely responsible for the *Implementation of the PA*.
- II.12.3 The Contractor must ensure that the subcontract does not affect the rights of the Commission and the Participating Member States under this PA.
- II.12.4 [\*\*\*]

#### II.13 AMENDMENTS

- II.13.1 Any amendment to the PA or a Vaccine Order Form must be made in writing before all contractual obligations have been fulfilled. A Vaccine Order Form does not constitute an amendment to the PA.
  - II.13.2 No amendment can make changes to the PA or a Vaccine Order Form that might alter the initial conditions of the procurement procedure or result in unequal treatment of tenderers or contractors.
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## II.14 ASSIGNMENT

Neither this PA nor any interest hereunder will be assignable by a party without the prior written consent of the other party, except as follows: [\*\*\*]

## II.15 FORCE MAJEURE

- II.15.1 If a party is affected by *Force majeure*, it must immediately *notify* the other party, stating the nature of the circumstances, their likely duration and foreseeable effects.
- II.15.2 A party is not liable for any delay or failure to perform its obligations under the PA or Vaccine Order Form if that delay or failure is a *result of Force majeure*. [\*\*\*]
- II.15.3 The parties must take all necessary measures to limit any damage due to *Force majeure* and shall use commercially reasonable efforts to avoid or minimize the delay in performance of their respective obligations affected by *Force majeure*.

## II.16 SUSPENSION OF THE IMPLEMENTATION OF THE PA

### II.16.1 Suspension by the Contractor

If the Contractor or a Participating Contractor Affiliate is affected by *Force majeure*, it may suspend the provision of the services under a Vaccine Order Form.

The Contractor or the Participating Contractor Affiliate must immediately *notify* the Commission of the suspension. The *notification* must include a description of the *Force majeure* and state when the Contractor or the Participating Contractor Affiliate expects to resume the provision of services.

The Contractor or the Participating Contractor Affiliate must *notify* the Commission as soon as it is able to resume *performance of the Vaccine Order Form*, unless the Commission has already terminated the PA or the Vaccine Order Form.

### II.16.2 Suspension by the Commission or the Participating Member State

Pursuant to the Financial Regulation, the Commission or the Participating Member State may suspend the Implementation of the PA or performance of a Vaccine Order Form or any part of it:

- (a) if the procedure for awarding the PA or a Vaccine Order Form or the Implementation of the PA proves to have been subject to Irregularities, Fraud (in the sense of the Financial Regulation) or breach of obligations;
- (b) in order to verify whether the presumed Irregularities, Fraud (in the sense of the Financial Regulation) or breach of obligations have actually occurred.

The Commission or the Participating Member State in question must formally notify the Contractor of the suspension and the reasons for it. Suspension takes effect on the date of formal notification, or at a later date if the formal notification so provides.

The Commission or the Participating Member State in question must notify the Contractor as soon as the verification is completed whether:

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- (a) it is lifting the suspension; or
- (b) it intends to terminate the PA or a Vaccine Order Form under Article II.17.1, (f) or (i).

The Contractor is not entitled to compensation for suspension of any part of the PA or a Vaccine Order Form. For the avoidance of doubt, the Contractor shall not be under any obligation to deliver any Contracted Doses or the Additional Order during the suspension period, and the Delivery Schedule shall be adjusted to take into account the period of such suspension. Equally for the avoidance of doubt, the Contractor shall complete the delivery of any Contracted Doses or Additional Order that were already in transit on the date of the formal notification or at the later date indicated in the formal notification.

## II.17 TERMINATION OF THE PA

### II.17.1 Grounds for termination by the Commission

The Commission may terminate the PA or the Participating Member State may terminate any on-going Vaccine Order Form (depending on whether the event affects the PA or the Vaccine Order Form) solely in the following circumstances:

- (a) [\*\*\*]
- (b) if the Contractor does not implement the PA or perform the Vaccine Order Form in accordance with material aspects of the PA or the Vaccine Order Form (as applicable) or is otherwise in material breach of another substantial contractual obligation;
- (c) [\*\*\*]
- (d) if the Contractor or any person that assumes unlimited liability for the debts of the Contractor is in one of the situations provided for in points (a) and (b) of Article 136(1) of the Financial Regulation<sup>4</sup>;
- (e) if the Contractor or any Related person is in one of the situations provided for in points (c) to (h) of Article 136(1) or Article 136(2) of the Financial Regulation;
- (f) if the procedure for awarding the PA or the Implementation of the PA prove to have been subject to Irregularities, Fraud (in the sense of the Financial Regulation) or breach of obligations;
- (g) if the Contractor is in a situation that does constitute a Conflict of interest or a Professional conflicting interest which would have a material adverse impact on the performance of the PA;
- (h) in case of a change regarding the exclusion situations listed in Article 136 of Regulation (EU) 2018/1046 that calls into question the decision to award the contract;

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Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012, OJ L 193 of 30.7.2018, p.1 <https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1544791836334&uri=CELEX:32018R1046>

(i) [\*\*\*]

#### **II.17.2 Grounds for termination by the Contractor**

The Contractor may terminate the PA or any on-going Vaccine Order Form solely in the following circumstances:

- (a) if the Commission or the Participating Member State does not implement the PA or does not perform the Vaccine Order Form in accordance with material aspects of the PA or the Vaccine Order Form (as applicable) or is otherwise in material breach of another substantial contractual obligation, [\*\*\*]
- (b) [\*\*\*].

#### **II.17.3 Procedure for termination**

A party must *formally notify* the other party of its intention to terminate the PA or a Vaccine Order Form and the grounds for termination.

The other party [\*\*\*] following the date of receipt to submit observations, including the measures it has taken or will take to continue fulfilling its contractual obligations. Failing that, the decision to terminate becomes enforceable the day after the time limit for submitting observations has elapsed in the event the grounds giving rise to termination have not been cured.

If the other party submits observations, the party intending to terminate must *formally notify* it.

#### **II.17.4 Effects of termination**

Within [\*\*\*] date of termination, the Contractor must submit any invoice required for services that were provided before the date of termination.

The termination or expiration of this PA shall not affect the survival and continuing validity of Articles I.1, I.2, I.4, I.6.7, I.6.9, I.6.11, I.6.12, I.6.14, I.6.16, I.7 to I.9, I.11 to I.14, II.3, II.5, II.6, II.8.2, II.8.4, II.9 to II.11, II.15, II.17.4, II.18 to II.28, Attachment 3 (Delivery Specification) and Attachment 5 (Return and Disposal of Product Materials) or of any other provision which is expressly or by implication intended to continue in force after such termination or expiration.

Expiry or termination of this PA for any reason shall be without prejudice to either party's other rights and remedies or to any accrued rights and liabilities as the date of such expiry or termination [\*\*\*].

### **II.18 INVOICES, VALUE ADDED TAX AND E-INVOICING**

#### **II.18.1 Invoices and value added tax**

Invoices must contain the Contractor's or the Participating Contractor Affiliate's (or leader's in the case of a joint tender) identification data, the amount, the currency and the date, as well as the PA reference and reference to the Vaccine Order Form.

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Invoices must indicate the place of taxation of the Contractor or the Participating Contractor Affiliate (or leader in the case of a joint tender) for value added tax (VAT) purposes and must specify separately amounts not including VAT and amounts including VAT.

It is understood and agreed between the parties that any prices stated under this PA and Vaccine Order Form are exclusive of any VAT or similar tax and all other taxes which are incurred as a result of manufacturing and supplying the Product (including custom duties, levies and charges and all local taxes) (“**Taxes**”), which shall be added thereon as applicable. Where Taxes are properly chargeable on any amounts payable under this PA or Vaccine Order Form, the party making the payment will pay the amount of Taxes, as specified on the invoice, in accordance with the laws and regulations of the country in which the Taxes are chargeable.

[\*\*\*]

## **II.19 PAYMENTS AND GUARANTEES**

### **II.19.1 Date of payment**

The date of payment is deemed to be the date on which [\*\*\*].

### **II.19.2 Currency**

Payments are made in euros or, for non-Eurozone countries, the local functional currency of the Participating Member State. For non-Eurozone countries, the Vaccine Order Form shall set forth the Delivery Price in the local functional currency converted from euro at the exchange rate existing one (1) day prior to the Effective Date of the PA as of 4:00pm London time published in Bloomberg FX Fixings (BFIX), such rates being found via Bloomberg or the website [www.bloomberg.com/markets/currencies/fx-fixings](http://www.bloomberg.com/markets/currencies/fx-fixings).

### **II.19.3 Costs of transfer**

The costs of the transfer are borne as follows:

- (a) the Commission or the Participating Member State in question bears the costs of dispatch charged by its bank;
- (b) the Contractor or the Participating Contractor Affiliate bears the costs of receipt charged by its bank;
- (c) the party causing repetition of the transfer bears the costs for repeated transfer.

### **II.19.4 Suspension of the time allowed for payment**

The Commission or the Participating Member State in question may suspend the payment periods specified in Article I.8 at any time by *notifying* the Contractor or the Participating Contractor Affiliate (or leader in the case of a joint tender) that its invoice cannot be processed. [\*\*\*]

Suspension takes effect on the date the Commission or the Participating Member State in question sends the *notification*. The remaining payment period resumes from the date on which the requested information or revised documents are received or the necessary further verification, including on-the-spot checks, is carried out. [\*\*\*]

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### **II.19.5 Interest on late payment**

On expiry of the payment periods specified in Article I.8, the Contractor or the Participating Contractor Affiliate (or leader in the case of a joint tender) is entitled to interest on late payment at the higher of (a) the rate applied by the European Central Bank for its main refinancing operations in euros (the reference rate) [\*\*\*] (or such centralized bank reference rate set forth in the Vaccine Order Form) and (b) [\*\*\*]%. The reference rate is the rate in force, as published in the C series of the *Official Journal of the European Union*, on the first day of the month in which the payment period ends.

Suspension of the payment period as provided for in Article II.19.4 is not considered as giving rise to late payment.

Interest on late payment covers the period running from the day following the due date for payment up to and including the date of payment as defined in Article II.19.1.

### **II.20 RECOVERY**

#### **II.20.1 Recovery procedure**

In all cases where the recovery procedure as described in the Financial Regulation applies, the parties shall follow the procedure set out in this Article.

Before recovery, the Commission or the Participating Member State in question must formally notify the Contractor of its intention to recover the amount it claims, specifying the amount due and the reasons for recovery and inviting the Contractor to make any observations [\*\*\*].

If no observations have been submitted or if, despite the observations submitted, the Commission or the Participating Member State in question decides to pursue the recovery procedure, it must confirm recovery by formally notifying a debit note to the Contractor, specifying the date of payment. The Contractor must pay in accordance with the provisions specified in the debit note.

If the Contractor does not pay by the due date, the Commission or the Participating Member State in question may, after informing the Contractor in writing, recover the amounts due:

- (a) by offsetting them against any amounts owed to the Contractor by the Commission or the Participating Member State in question;
- (b) by taking legal action.

#### **II.20.2 Interest on late payment**

If the Contractor does not honour the obligation to pay the amount due by the date set by the Commission or the Participating Member State in question, the amount due bears interest at the rate indicated in Article II.19.5. Interest on late payments will cover the period starting on the day after the due date for payment and ending on the date when the Commission or the Participating Member State in question receives the full amount owed.

Any partial payment is first entered against charges and interest on late payment and then against the principal amount.

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## II.21 CHECKS AND AUDITS

- II.21.1 The Commission and the European Anti-Fraud Office may check or require an audit on the Implementation of the PA. This may be carried out either by OLAF's own staff or by any outside body authorised to do so on its behalf, provided that the auditor may not be a competitor of the Contractor.
- Such checks and audits may be initiated at any moment during business hours during the provision of the services and up to [\*\*\*] starting from the payment of the balance of the last specific contract issued under this PA.
- The audit procedure is initiated on the date of receipt of the relevant letter sent by the Commission. Audits are carried out on a confidential basis.
- II.21.2 The Contractor must keep all original documents stored on any appropriate medium, including digitised originals if authorised under national law, for a period of [\*\*\*] starting from the payment of the balance of the last specific contract issued under this PA.
- II.21.3 The Contractor must grant the appropriate right of access to sites and premises where the PA is implemented, [\*\*\*], needed to conduct such checks and audits. The Contractor must ensure that the information is readily available at the moment of the check or audit and, if so requested, that information is handed over in an appropriate format. The auditor must, insofar possible, comply with all applicable and reasonable security measures notified to Commission by the Contractor subject to this not creating any material obstacles for the performance of the auditor's tasks.
- II.21.4 On the basis of the findings made during the audit, a provisional report is drawn up. The Commission or its authorised representative must send it to the Contractor, who has [\*\*\*] following the date of receipt to submit observations. The Contractor must receive the final report within [\*\*\*] following the expiry of the deadline to submit observations.
- On the basis of the final audit findings, the Participating Member State in question may recover all or part of the payments made in accordance with Article II.20 and may take any other measures which it considers necessary.
- II.21.5 In accordance with Council Regulation (Euratom, EC) No 2185/96 of 11 November 1996 concerning on-the-spot checks and inspection carried out by the Commission in order to protect the European Communities' financial interests against fraud and other irregularities and Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council of 11 September 2013 concerning investigations conducted by the European Anti-Fraud Office, the European Anti-Fraud Office may carry out investigations, including on the spot checks and inspections, to establish whether there has been fraud, corruption or any other illegal activity under the contract affecting the financial interests of the Union. Findings arising from an investigation may lead to criminal prosecution under national law.
- The investigations may be carried out at any moment during the provision of the services and up to [\*\*\*] starting from the payment of the balance of the last specific contract issued under this PA.
-

II.21.6 The Court of Auditors and the European Public Prosecutor's Office established by Council Regulation (EU) 2017/19398 ('the EPPO') have the same rights as the Commission, particularly right of access, for the purpose of checks, audits and investigations.

#### **II.22 RELATIONSHIP OF THE PARTIES**

The relationship hereby established between the Contractor and the Commission is solely that of independent contractors. Neither party has authority to act or make any agreements or representations on behalf of the other party. This PA is not intended to create, and shall not be construed as creating, between the parties, the relationship of principal and agent, employer and employee, joint venturers, co-partners, or any other such relationship, the existence of which is expressly denied.

#### **II.23 WAIVER**

A waiver by any party of any term or condition of this PA in any instance shall not be deemed or construed to be a waiver of such term or condition for the future, or of any subsequent breach thereof. All remedies specified in this PA shall be cumulative and in addition to any other remedies provided at Law or in equity, except where expressly otherwise agreed.

#### **II.24 FURTHER DOCUMENTS**

Each party hereto agrees to execute such further documents and take such further steps as may be reasonably necessary or desirable to effectuate the purposes of this PA.

#### **II.25 HEADINGS**

Headings of Articles or other parts of this PA are included herein for convenience of reference only and shall not constitute a part of this PA or change the meaning of this PA.

#### **II.26 ELECTRONIC DELIVERY AND STORAGE**

Delivery of a signed PA by reliable electronic means, including facsimile or email (with receipt electronically confirmed), shall be an effective method of delivery of the executed PA. This PA may be stored by electronic means and either an original or an electronically stored copy of this PA can be used for all purposes, including in any proceeding to enforce the rights or obligations of the parties to this PA.

#### **II.27 ENTIRE AGREEMENT**

This PA, together with any Annexes and Attachments, which are hereby incorporated by reference, constitute the entire agreement of the parties with respect to its subject matter and merges and supersedes all prior discussions and writings with respect to thereto.

#### **II.28 COSTS**

Each party will bear its own legal costs in preparing and concluding this PA.

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ANNEX I: VACCINE ORDER FORM

This Vaccine Order Form is submitted by:

[The Government of [•]] (the “**Participating Member State**”), represented for the purposes of signing this Vaccine Order Form by [forename, surname, function, department of authorising officer],

to:

Pfizer Inc, incorporated in Delaware (Registration Number 0383418) with its registered address at 235 East 42nd Street, 10017 New York City, NY (UNITED STATES) (“**Pfizer**”);

and

BioNTech Manufacturing GmbH, registered with the commercial register of the lower court (Amtsgericht) of Mainz, Germany under HRB 47548, with its registered address at An der Goldgrube 12, 55131 Mainz, Germany (“**BioNTech**”),

(Pfizer and BioNTech together the “**Contractor**”, represented for the purposes of signing this Vaccine Order Form by [\*\*\*]).

The Participating Member State and Contractor are together referred to as the “**Parties**” and each individually as a “**Party**”.

WHEREAS

- Contractor and the European Commission, acting on behalf of and in the name of the Participating Member States, entered into a Purchase Agreement for the purchase and supply of Contractor’s Vaccine for EU Member States dated [•] 2021 (the “**PA**”), the terms of which are binding on the Participating Member States and must be read in conjunction with this Vaccine Order Form.
  - The PA provides that each Participating Member State will submit to Contractor a Vaccine Order Form through which Contractor shall make available and deliver to the relevant Participating Member State a proportion of the Contracted Doses or Additional Order as applicable, in accordance with the allocation provided by the Commission pursuant to Article 1.6.3 of the PA and at the price and conditions as set out in the PA.
  - In accordance with Article 1.5.2 of the PA, the Participating Member State hereby places its order for its full allocated portion of the Contracted Doses or Additional Order (as applicable).
-

**Article I**

**Subject matter**

1. This Vaccine Order Form is submitted by the Participating Member State to Contractor in accordance with the terms of the PA, and forms an integral part of the PA. The terms and conditions of the PA are incorporated into this Vaccine Order Form by reference. In the event of contradiction between this Vaccine Order Form and the PA, the terms of the PA prevail regardless of any provision to the contrary. Any capitalised terms in this Vaccine Order Form will have the meaning attributed to them in the definitions list included in Article I.2 of the PA.
2. This Vaccine Order Form relates to the order for the Participating Member State's full allocated portion of the Contracted Doses or the relevant Additional Order (as applicable) as set out in the allocation provided by the Commission to Contractor pursuant to Article I.6.2 of the PA. The submission of this signed Vaccine Order Form by the Participating Member State to Contractor constitutes a binding order by the Participating Member State for the purchase of its full allocated portion of the Contracted Doses or the relevant Additional Order (as applicable) as follows

- a. Participating Member State will purchase [insert amount] number of doses of [Contracted Doses] [Additional Order] of the Vaccine, on the basis of the following delivery schedule:

[***]				
[***]				

- b. The Delivery Price of [Contracted Doses] [Additional Order] is [\*\*\*].

The total amount payable by the Participating Member State for the [Contracted Doses] [Additional Order] is [insert amount] [\*\*\*].

3. By signature of this Vaccine Order Form, the undersigned Participating Member State warrants to Contractor that:
    - a. it is irrevocably and unconditionally bound by the terms of the PA (as concluded by the Commission on behalf and in the name of the Participating Member States), including the indemnification obligations and the liability, limitation of liability and exclusions terms set out therein;
    - b. the provisions of the PA are enforceable against it in accordance with its terms;
    - c. it shall indemnify the Indemnified Persons in accordance with Article I.12 (*Indemnification*) of the PA;
    - d. it has full right, power and authority to enter into this Vaccine Order Form and to perform its respective obligations under it;
-



e the person executing this Vaccine Order Form is duly authorized to execute and bind the undersigned Participating Member State to the terms set forth herein and incorporated by reference.

4. [\*\*\*]

5. The Participating Member State represents and warrants that all necessary permissions and approvals have been or will be obtained prior to the time for performance by the Participating Member State, to authorise performance of all of the obligations contained herein.

## **Article II Delivery, Supply**

1. Delivery Address. The Delivery Address for the Participating Member State is as follows:

[• - *Participating Member State to enter location of its distribution hub*]

2. Supply of the Products

The Contractor shall supply the Products as further described in the PA: [**Note:** Include any additional details concerning the supply here.]

## **Article III Invoices; Notices**

1. Invoice and Payments. Contractor shall invoice the Participating Member State in accordance with the terms of the PA. All payments to Contractor or its designated Affiliate shall be made in accordance with the terms of the PA.

Payment shall be made in the following currency pursuant to the provisions of Article II.19.2: [to be completed].

2. Notice. Any notice given under this Vaccine Order Form must a) be made in writing in English in paper or electronic format; b) bear the PA number and the number of this Vaccine Order Form; c) be made using the relevant communication details set out below with respect to the Participating Member State and Contractor (as applicable); d) be sent by mail and email:

Participating Member State:

[*Name of Participating Member State*]

[*Full official address of Participating Member State*]

[*Full name of addressee physical person (contact person)*]

[*Function of addressee physical person (contact person)*]

E-mail: [*complete email of addressee physical person (contact person)*]

Contractor:

[Add details]

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**Article IV.**

**Entry into Force and Duration**

1. This Vaccine Order Form shall enter into force on the date of signature by the Parties and will remain into force until termination of the PA, or if the PA expires, until the last delivery of Product [\*\*\*].

**Article V.**

**Applicable Law and Settlement of Disputes**

1. For the avoidance of doubt, Article I.13 (*Applicable Law and Settlement of Disputes*) of the PA shall apply to any dispute arising out of the implementation of or in connection with this Vaccine Order Form and the Participating Member State irrevocably agrees to be bound by the provisions set out therein.

(Signature page follows)

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**SIGNATURES**

For the **Participating Member State**,

[*forename/surname/position*]

Signature: \_\_\_\_\_

Done at [*place*], [*date*]

For acceptance of the Vaccine Order Form,

Contractor,

[\*\*\*]

Signature: \_\_\_\_\_

Done at [*place*], [*date*]

The invoice will be paid only once the Contractor has returned the signed Vaccine Order Form.

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## Agreement

### Preamble

Having regard to Article 4(5)(b) of Council regulation (EU) 2016/369 on the provision of emergency support within the Union<sup>1</sup>as amended by Council regulation (EU) 2020/521 of 14 April 2020 activating the emergency support under regulation (EU) 2016/369, and amending its provisions taking into account the COVID-19 outbreak (hereinafter “ESI” or “ESI regulation”);

\*\*\*

The European Commission (“the Commission”)

and

The following Member States: (XXX), hereinafter referred to as “the Participating Member States”

Together referred to as “the Parties”

Agree on the Following:

#### Article 1: Objective and mandate of the Commission

On the basis of the present agreement, the Commission is mandated to conclude, on behalf of the Participating Member States, Advance Purchase Agreements (“APA”) with vaccine manufacturers with the objective to procure vaccines for the purposes of combatting the COVID 19 pandemic at Union level.

The Annex to this agreement sets out the negotiating directives for this purpose.

#### Article 2: Acquisition of vaccine doses

It is the Participating Member States, and not the Commission, that shall acquire vaccine doses from the manufacturers on the basis of the APAs unless otherwise agreed. All relevant vaccination policies shall therefore remain matters for the Participating Member States.

#### Article 3: APAs containing a right to acquire vaccine doses

Where the Commission concludes an APA in conformity with the present agreement that provides the right for the Participating Member States to acquire vaccine doses, the use of such a right shall take place by means of the conclusion of contracts between the Participating Member States and the vaccine manufacturers. There shall be no obligation for any

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Participating Member State to conclude such a contract on the basis of the APA. The APA shall contain a clause to this end.

Article 4: APAs containing an obligation to acquire vaccine doses

Where the Commission intends to conclude, in conformity with the present agreement, an APA containing an obligation to acquire vaccine doses, it shall inform the Participating Member States of such intention and the detailed terms. In case a Participating Member State does not agree with the conclusion of an APA containing an obligation to acquire vaccine doses or its terms, it has the right to opt out by explicit notification to the Commission within 5 working days after the Commission has communicated its intention to conclude the APA. All Participating Member States not having opted out within the period of 5 working days are deemed to have authorised the Commission to negotiate and conclude the APA with the vaccine manufacturer in their name and on their behalf.

Article 5: The legally binding nature of APAs

Once concluded, the terms of the APA shall be legally binding on the Participating Member States, except for those who have exercised their right to opt out.

Article 6: Responsibility and liability

The present Agreement regulates only the division of potential liability and indemnification between the Commission and the Participating Member States. It does not regulate the extent to or the conditions under which potential liability of the vaccine manufacturer may be taken over or indemnified under the APAs.

The Commission shall be exclusively responsible for the procurement process and the conclusion of APAs including any liability arising out of the conduct of the negotiations.

Participating Member States acquiring a vaccine shall be responsible for the deployment and use of the vaccines under their national vaccination strategies, and shall bear any liability associated with such use and deployment. This shall extend to and include any indemnification of vaccine manufacturers under the terms and conditions of the relevant APA for liability related to the use and deployment of vaccines normally borne by such manufacturer.

Article 7: Obligation not to negotiate separately

By signing the present Agreement, the Participating Member States confirm their participation in the procedure and agree not to launch their own procedures for advance purchase of that vaccine with the same manufacturers.

In case an APA containing an obligation to acquire vaccine doses has been concluded with a specific manufacturer, the Member States having made use of the opt-out provided under the present Agreement can enter into separate negotiations with the same manufacturer after the APA under the present Agreement has been signed.

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**Initial considerations**

A permanent solution to the COVID-19 crisis is most likely to be brought about by the development and deployment of a safe and effective vaccine against the virus. Every month gained in the deployment of a vaccine will save many lives, many jobs and billions of euros.

Therefore, it is the objective of the present Agreement that the EU takes steps to secure sufficient supplies of a safe and effective vaccine for Member States.

**Structure and purpose of the procurement**

Work on a COVID-19 vaccine is challenging for many reasons: the shortened development timeframe, the large upfront costs for manufacturers, the high failure rate during clinical trials. If vaccine producers follow their usual practice of making investments in production capacity only when they are sure of a viable product, this will result in considerably longer waiting times for a vaccine. Investments need to be made now in order to ensure that vaccines are being produced at the scale required as early as possible.

Under the present agreement, this challenge will be addressed through concluding EU-level Advance Purchase Agreements (“APA”) with vaccine manufacturers when necessary, to secure access to vaccine candidates where they are successful, including up-front EU financing to de-risk essential investments to increase the speed and scale of manufacturing successful vaccines. Funding for the up-front payments will come from the Emergency Support Instrument (ESI).

The Parties understand that developing a safe and effective vaccine is a highly complex process and the risk of failure in any such venture is very high. Therefore, the aim is to put in place APAs with a number of manufacturers of leading vaccine candidates, to maximise the chances of having access to at least one successful vaccine.

The Commission will invite all vaccine manufacturers to manifest interest. In general, the Commission will give priority to negotiating specific APAs with those manufacturers that (a) have entered or have firm plans to enter clinical trials still in 2020, (b) have the capacity to develop a successful vaccine and (c) have a proven capacity to produce at scale already in 2021.

**Process and governance**

In order to run the procurement centrally and efficiently, the European Commission will set up a steering board for the process subject to Article 6 of the present Agreement. It will be co-chaired by the European Commission and a Participating Member State with experience in the negotiations and production capacities for vaccines. The steering board will include senior officials from all Participating Member States to assist and provide guidance throughout the evaluation process.

The co-chairs of the steering board will propose a team of a limited number of experts with relevant experience for the ongoing negotiations from six Participating Member States with production capacities for vaccines. These experts will join with the European Commission in a negotiation team (“joint negotiation team”), which will work on a continuous basis as one

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unit. That joint negotiation team will start work immediately building on previous contacts with individual companies by the European Commission and Participating Member States. In order to launch negotiations with a specific manufacturer, there needs to be support from at least four Participating Member States. The joint negotiation team will make its best effort to take the advice of the steering board into account in the negotiations and will report back to the steering board on a regular basis on the progress made in negotiating with individual companies.

For compliance with the applicable rules, all members of the steering board and the joint negotiation team will obtain the status of experts associated to the procurement process as provided in the Financial Regulation. Given their access to highly sensitive business information, all those members will be required to sign strict confidentiality and no-conflict-of-interest agreements.

Assisted by the steering board, the European Commission will then decide which of the resulting APAs should be concluded, in particular if financing under ESI is insufficient to finance all relevant packages. The Commission will only consider those APAs for financing where at least four Participating Member States have expressed agreement. Before making any final decisions, the Commission will seek independent scientific advice on the state of progress and the available data on quality, safety and efficacy for the vaccine candidate in question.

Should financing under ESI be insufficient, Participating Member States can decide to top up ESI funding to make up the gap to finance all packages. In such a case where there are opportunities to conclude further APAs but money from ESI is no longer sufficient, Participating Member States will have the opportunity to express their interest in such opportunities. If at least four Participating Member States express interest, those Participating Member States will make use of the possibility of a voluntary contribution to ESI to the required amount allowing the Commission to proceed with signing the APA only on behalf of those Member States that have expressed interest and contributed the funds to ESI.

For full transparency, the European Commission will report to the IPCR at least once every two weeks on overall progress more generally.

#### **Advanced Purchase Agreements and conditions**

To conclude APAs, the joint negotiating team will negotiate funding packages with individual vaccine producers in return for the right to buy a specific number of vaccine doses in a given timeframe and at a certain price.

As outlined in the present Agreement, the European Commission also has the possibility to conclude APAs including an obligation to procure the vaccine if it becomes available, where the conditions (notably the pricing) of those APAs make this worthwhile and in line with the conditions in the present Agreement. If in such a case the distinction between upfront payments and purchase price is difficult to draw, the Commission will share the total cost related to the vaccine purchase but will in any case contribute no more than 50% of the total cost.

Funding provided up front will be considered as an advance payment for any eventual purchase by Member States, thus reducing the amount that Member States will have to pay when eventually purchasing that vaccine.

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The up-front payments under the APAs shall be used by manufacturers to de-risk the necessary investments related to both vaccine development and clinical trials, and the preparation of the at-scale production capacity along the entire vaccine production value chain in the EU required for a rapid deployment of millions of doses of an eventual vaccine. The relevant payments should be structured according to the need of the manufacturer, but subject to the state of the vaccine development, in particular relying on transparency of the associated clinical data and its assessment, at the time of payment. This is in order to avoid obligations to pay in situations where the development work has shown a vaccine candidate likely to be unsuccessful.

The purchase price of the vaccine, as well as the amount of funding provided up front will take into account a transparent estimation of production costs (supported by independent audits where available), as well as the resources already granted from other public sources. Under the APA, the manufacturer can be asked to provide ex post proof supported by independent audits concerning the activities financed by these payments.

The aim of the negotiation is to conclude APAs with individual companies under the best possible conditions. These APAs should specify details with respect to:

- a) Payments to be made, such as payment amounts, payment schedules, type of payments requested and the use of those payments related to de-risk investment, financing clinical trials, providing working capital and scaling-up production capacity;
- b) Delivery details of the vaccine if successful, such as price per person immunised (or alternatively, number of doses required per person immunised and price per dose), quantity of doses to be delivered and delivery timeline following approval;

and

- c) Any other relevant conditions, such as production capacity built or used in the EU or liability arrangements.

For liability arrangements, the joint negotiation team will make its best effort to limit what is required by individual companies for the purpose of indemnification to be included in the terms and conditions of the APA.

The APAs will contain provisions to clarify the law applicable to both the APA and resulting purchase orders as well as the competent courts. The Participating Member States agree that each APA negotiated by the Commission on their behalf with a vaccine manufacturer will have the same applicable law for all Participating Member States, and that the courts corresponding to that applicable law will be competent to hear disputes arising from that APA.

When taking a decision to finance individual APAs, the European Commission, in consultation with the steering board, will take into account the following elements: any available data on quality, safety and efficacy of the vaccine at time of negotiation of the contract, speed of delivery at scale, cost, risk-sharing, diversification of technologies, capacity to supply through development of production capacity within the EU, possible flexible future use of any capacity funded, engagement at an early stage with EU regulators with the intention to apply for an EU marketing authorisation for the candidate vaccine(s), commitment to supply vulnerable countries.

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The procedure outlined above complies with the ESI Regulation and the Financial Regulation. The latter is aligned to the European procurement Directives, which also provide the basis for national procurement rules. Participating Member States may rely on the procedure run by the European Commission to directly purchase vaccines from the manufacturers as and when any of the vaccines becomes available based on the conditions laid down in the APA. Access to vaccine doses will be allocated to Participating Member States according to the population distribution key.

In the negotiations with the pharmaceutical industry under the present Agreement, the Commission will promote a Covid-19 vaccine as a global public good. This promotion will include access for low and middle income countries to these vaccines in sufficient quantity and at low prices. The Commission will seek to promote related questions with the pharmaceutical industry regarding intellectual property sharing, especially when such IP has been developed with public support, in order to these objectives. Any vaccines available for purchase under the APAs concluded but not needed and purchased by Participating Member States can be made available to the global solidarity effort.

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ANNEX III: PARTICIPATING MEMBER STATES

Germany  
France  
Italy  
Spain  
Austria  
Greece  
Cyprus  
Malta  
Denmark  
Sweden  
Finland  
Ireland  
Portugal  
Belgium  
Luxembourg  
Netherlands  
Poland  
Romania  
Bulgaria  
Slovenia  
Croatia  
Czech Republic  
Hungary  
Slovakia  
Lithuania  
Latvia  
Estonia

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ANNEX IV: SUBCONTRACTORS

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**ANNEX V – PARTICIPATING CONTRACTOR AFFILIATES**

<b>Country</b>	<b>Participating Contractor Affiliate</b>
Germany	BioNTech Europe GmbH
France	Pfizer SAS
Italy	Pfizer S.r.l.
Spain	Pfizer S.L.U.
Austria	Pfizer Corporation Austria GmbH
Greece	Pfizer Hellas SA
Cyprus	Pfizer Hellas SA
Malta	Pfizer Hellas SA
Denmark	Pfizer ApS
Sweden	Pfizer Innovations AB
Finland	Pfizer Finland Oy
Ireland	Pfizer Healthcare Ireland
Portugal	Pfizer Biofarmacêutica Sociedade Unipessoal, Lda
Belgium	Pfizer SA
Luxembourg	Pfizer Luxembourg S.A.R.L.
Netherlands	Pfizer BV
Poland	Pfizer Trading Polska sp. z o.o.
Romania	Pfizer Romania SRL
Bulgaria	Pfizer Export B.V.
Slovenia	Pfizer Export B.V.
Croatia	Pfizer Export B.V.
Czech Republic	Pfizer PFE, spol. s r.o. After 1/12 shall be merged into Pfizer, spol. s r.o.
Hungary	Pfizer Gyógyszerkereskedelmi Kft.
Slovakia	Pfizer Export B.V.
Lithuania	Pfizer Export B.V.
Latvia	Pfizer Export B.V.
Estonia	Pfizer Export B.V.

In addition, any Contractor Affiliate which is involved in the sale or distribution of Product which is resold or donated by a Participating Member State shall be deemed to be a Participating Contractor Affiliate.

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**ATTACHMENT 1: SPECIFICATIONS**

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[\*\*\*]

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[\*\*\*]

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[\*\*\*]

THE SYMBOL “[\*\*\*]” DENOTES PLACES WHERE CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH (i) NOT MATERIAL, AND (ii) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF PUBLICLY DISCLOSED

Lease

concerning

Areas and Spaces in Buildings H028 and H030

(Buildings H028 and H30 are hereinafter jointly referred to as “Building H028”)

at the Behringwerke Site in Marburg

between

**Pharmaserv GmbH**

Emil-von-Behring-Strasse 76, 35041 Marburg

- hereinafter referred to as the “Lessor” –

and

**Novartis Manufacturing GmbH**

Emil-von-Behring-Strasse 76, 35041 Marburg

- hereinafter referred to as the “Lessee” –

The Lessor and Lessee are also referred to individually as a “Party” or jointly as the “Parties”

Preamble

[\*\*\*]

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**Section 1**  
**Leased Object**

- (1) The **Lessor**, in its capacity as the owner, leases to the **Lessee** the areas and spaces marked in green within the Buildings H028 and H030 (Buildings H028 and H30 will be hereinafter also referred to jointly as "Building H028") shown in **Annex 1.4** ("Site Plan"), at the Behringwerke Site, Emil-von-Behring-Strasse 76, 35041 Marburg, including the traffic areas and ancillary areas, to the extent that these traffic areas and ancillary areas are marked in "green" instead of "grey" in **Annex 1.1** (hereinafter jointly referred to as the "**Leased Object**").
- (2) The areas and spaces marked in green in **Annex 1.2** (hereinafter referred to as the "**Additional Areas**") will be included in the Lease as from 01.01.2025. However, by way of deviation from the previous sentence, the Additional Areas will be included in the Lease as early as 01.01.2024 if the **Lessor** informs the **Lessee** in writing of the earlier lease start date by no later than 31.12.2022.
- From the date of inclusion of the Additional Areas in the Lease, the **Leased Object** will comprise the areas and spaces as shown in **Annex 1.3** to this Lease.
- (3) The technical areas marked in blue may be jointly used by the **Lessee** free of charge for the installation of the **Lessee**'s own technical equipment, depending on the space available.
- The external roof areas, façade surfaces and external parts of the building are not included in the Lease. The **Lessee** is permitted to use these roof areas and façade surfaces free of charge in agreement with the **Lessor** only if they are required in order to fulfil the purpose of the Lease as set out in Section 2 of this Lease.
- Components of the **Leased Object** include its building construction, facilities and installations, only insofar as and to the extent that these are listed in **Annex 2.1**, **Annex 2.2** (Additional Areas) and **Annex 2.3**.
- If the building construction, facilities and installations are not listed in Annex 2.1), Annex 2.2) (Additional Areas) and Annex 2.3), they do not form part of the **Leased Object**. More specifically, the Lease does not cover the extension to the **Leased Object** for pharmaceutical purposes (building construction, facilities and installations) carried out in the **Leased Object** by the **Lessee** and the previous lessees, [\*\*\*].
- The Lease also does not cover – and it is therefore not listed as leased in **Annex 2.1**, **Annex 2.2) and Annex 2.3)** – the necessary infrastructure for energy and media transmission, such as supply lines, from the output terminal of the main distributor, and from the first shut-off valve in the central energy room. This infrastructure is in the possession of [\*\*\*], and the **Lessee** will agree with [\*\*\*] on the usage and transfer of this infrastructure outside the scope of this Lease.
- (4) The **Lessee** is permitted sole use of the area for storing waste containers allocated to Building H028 as per **Annex 1.4**) and listed as such therein, on the eastern side of Talstrasse, to the north of Building H028, and joint use of the area to the south of Building H028 with the other users of Building H028, free of charge and in accordance with all applicable legal provisions, more specifically to an extent that corresponds to the proportion of the **Leased Object** surface area provided to the **Lessee** in m<sup>2</sup> in relation to the surface area of all leasable areas in Building H028.

- (5) The description of the **Leased Object** in this Lease merely constitutes an agreement on quality rather than a guaranteed characteristic.
- (6) The **Lessor** is authorised to have the technical equipment available in the **Leased Object**, in particular fire alarms and fault indication systems, including the infrastructure necessary for these, and to install, reposition, dismantle, extend, operate, and renew them. The **Lessor** is authorised to enter the **Leased Object** at any time for this purpose in agreement with the **Lessee** or arrange for it to be entered by appointed third parties. In the event of imminent danger, entry is authorised even without agreement; however, the **Lessor** must notify the **Lessee** after it has carried out the work.

**Section 2**  
**Purpose of the Lease, Value Added Tax,**  
**Orders, Requirements, Approvals**

- (1) The **Lessor** provides the **Lessee** with the **Leased Object** for the purpose of carrying out pharmaceutical activities, using its own expansions and the **Lessor's** expansions, which the **Lessee** purchases directly from the previous lessee independent of this Lease. The areas leased in Building H030 are leased only for the storage of the goods described in more detail in **Annex 8**) to this Lease.
- (2) If special installations, fittings (for example floor coverings or air conditioning units) or structural amendments beyond those set out in **Annex 2.1), Annex 2.2),**(Additional Areas) and **Annex 2.3)** are required for a special use within the scope of the agreed purpose of the Lease, it is the responsibility of the **Lessee** to arrange for these within the framework of the existing building permit, at its own risk and expense, and to obtain any necessary further approvals. In the event of termination of the Lease, Section 14 of this Lease will apply.
- The **Lessor** approves these installations, fittings or structural amendments within the framework of the existing building consent. However, the **Lessor** assumes no liability for the suitability of the provided rooms and areas for a renovation and for special use by the **Lessee**, and more specifically it assumes no liability for compliance with the public-law provisions applicable to the operation envisaged by the **Lessee**, the accident prevention regulations, the VDS [*German corporate security and safety*] and TÜV [*German technical inspection association*] guidelines and the availability of the supply, disposal and sanitary facilities required for use by the **Lessee**. It is up to the **Lessee** alone, at its own expense and risk and under its own responsibility, to provide all necessary conditions, and in particular comply with the public laws (e.g. building consent) and technical and structural requirements for the amendments to the **Leased Object** in the areas and spaces provided, made by the previous lessees and the **Lessee** and any amendment to be made by it in the future, and for the usage envisaged by the **Lessee**, and to meet the requirements imposed by authorities at its own expense. If installations, fittings or structural amendments require an adjustment to the building consent, these require the consent of the **Lessor**, which will only refuse this if there is an important reason to do so.
- (3) The **Lessee** commits to putting in place and maintaining the required fire protection in the **Leased Object** with respect to the extension already carried out or to be carried out in the future by it or by third parties, at its own expense. This also applies accordingly to all future amendments to be made in the **Leased Object** by the **Lessee** itself.
- (4) The Lease is for business purposes within the meaning of the German Value Added Tax Act.
- The **Lessee** declares that it and any future sublessees will use the **Leased Object** exclusively for revenues that do not preclude input tax deduction by the **Lessor** (Sections 9 (2) of the German Value Added Tax Act, 27 (2) of the German Value Added Tax Act). Where requested to do so by the **Lessor**, the **Lessee** will provide it with suitable evidence of the fact that it and any future sublessees are using or have used the **Leased Object** exclusively for revenue that does not preclude input tax deduction by the **Lessor**. The **Lessee** warrants that it will impose on any future sublessees the obligation to use the **Leased Object** exclusively for revenues that do not preclude input tax deduction by the **Lessor**.

If the **Lessee** or any future sublessees generate revenues in the **Leased Object** that preclude input tax deduction by the **Lessor** contrary to the above provision, it must notify the **Lessor** of

this immediately. In this case, it is obliged to compensate the **Lessor** for any proven disadvantage suffered by it as a result of the lost input tax deduction. The **Lessee** is obliged to produce any relevant evidence requested by the Tax Authority.

- (5) A change of use in accordance with paragraph (1) above requires the prior written consent of the **Lessor**, to which the **Lessee** has no entitlement.
- (6) Official orders and requirements and necessary approvals which are exclusively based on or required due to the general quality and/or location of the **Leased Object** must be fulfilled or obtained by the **Lessor** at its own expense, for the entire term of the Lease.

If official requirements and/or the obtaining/retention of official permits results from the **Lessee**'s personal or special operational circumstances or from the special circumstances of its commercial operations, the **Lessee** will be solely responsible for the related measures and costs.

To this extent, the **Lessee** must also fulfil any official orders and requirements issued in relation to the **Leased Object** during the term of the Lease at its own expense, even if they are directed at the **Lessor**. The **Lessor** will provide the **Lessee** with the necessary and reasonable support in this regard.

### **Section 3** **Term of the Lease**

- (1) The Lease begins
- on 01.07.2019 for the areas described in more detail in **Annex 1.1**,
  - for the Additional Areas, in accordance with the provision laid down in Section 1 (2) of the Lease. The date from which the Additional Areas will also be included in the Lease will be agreed by the Parties in an amendment to this Lease which complies with the written form requirement.

For all areas as a single unit, the Lease will end on 31.12.2034 ("Fixed Lease Term") without any Party being required to give notice to terminate.

- (2) The **Lessee** has the right by unilateral declaration to extend the term of this Lease after expiry of the Fixed Lease Term for a period of five years on three consecutive occasions ("**Option Right**") and the provisions of the Lease will continue to apply. The extension of the Fixed Lease Term by five years in each case will be hereinafter referred to as the "**Extended Period**". The adjustment of the rent excluding utilities during the Extended Periods is provided for in Section 6 of this Lease. The **Lessee** must declare in writing to the **Lessor** that it is exercising its Option Right no later than 12 months before expiry of the Fixed Lease Term, and otherwise no later than 12 months before the end of an Extended Period. The date of receipt of the declaration by the **Lessor** will be the decisive date.

- (3) Tacit extension of the Lease pursuant to Section 545 of the German Civil Code is excluded.

**Section 4**  
**Uninterrupted Possession of the Leased Object, Handover of Additional Areas, Contractual Compliance**

- (1) As regards the areas described in more detail in **Annex 1.1**), the **Lessee** is already in possession of the **Leased Object**. The Parties confirm that the **Lessee's** possession will be maintained without interruption.
- (2) As regards the Additional Areas described in more detail in **Annex 1.2**), the Parties agree that these areas will be handed over to the **Lessee** by the **Lessor** in accordance with the start of the Lease, either on 01.01.2024 or 01.01.2025.
- (3) The **Lessee** acknowledges that the **Leased Object** is suitable for the purpose of the Lease.

**Section 5**  
**Rent**

- (1) The monthly net rent excluding utilities (graduated rent) owed by the **Lessee** is the net rent excluding utilities agreed in **Annex 4.1**) until the inclusion of the Additional Areas in the Lease.
- (2) As soon as the Additional Areas are included in the Lease pursuant to **Section 1 (2)**, the **Lessee** will owe the net rent excluding utilities for all leased areas depending on the Additional Areas are included in the Lease, as agreed in **Annex 4.2**) (from 01.01.2024) or **Annex 4.3**) (from 01.01.2025).  
  
If the Lease is extended beyond the end of the Fixed Lease Term by the exercise of the Option Right pursuant to Section 3 (2) of this Lease, the monthly rent excluding utilities will be adjusted pursuant to the provisions in Section 6 of this Lease.
- (3) With respect to the net rent excluding utilities and with respect to all operating costs pursuant to Section 7, the **Lessee** additionally pays value added tax at the valid rate during the performance period, i.e. currently 19%.
- (4) The monthly net rent excluding utilities, including the advance payment for operating costs pursuant to Section 7, must be paid to the Lessor, without charges and in advance, by the third working day of the relevant month at the latest, into the account at [\*\*\*].
- (5) The **Lessee** may only set off claims against the **Lessor's** payment and exercise a right of retention only if it has recognised or legally determined counterclaims.

**Section 6**  
**Rent Adjustment if Option is Exercised**

Only in the event that the Lease is extended beyond 31.12.2034 ("Fixed Lease Term") by the exercise of the option (Section 3 (2)), the following applies to the adjustment of the rent excluding utilities from 01.01.2035 onwards:

- (1) Starting on 01.01.2035, the minimum monthly rent will be adjusted automatically on 1 January of each year on a percentage basis, in accordance with the change to the Consumer Price Index for Germany (2010=100). The first adjustment will take place on 01.01.2035 based

on the change in the index for the month of December 2034 compared with the month of December 2033. The following adjustments will take place accordingly with effect from 1 January, in accordance with the change in the index for the December of the previous year compared with the December of the year preceding the previous year.

- (2) If the Consumer Price Index determined by the Official Statistics Office for the Federal Republic of Germany is discontinued, not replaced by another index or changed to another benchmark index, the amended index will replace the index referred to in paragraph (1). Moreover, the Parties mutually undertake to agree a corresponding provision that comes closest in economic terms to the provisions agreed herein.
- (3) In the event of a change to the index, which leads to an adjustment of the rent pursuant to paragraph (1), the **Lessor** will notify the **Lessee** of this immediately in writing, without the notification and obligation for the **Lessee** to pay the adjusted rent being a prerequisite for payment. However, until the notification, no late payment interest will be owed by the **Lessee** or **Lessor**. A failure to notify or a delayed notification does not entail a waiver of the right to adjust the rent.
- (4) The Parties jointly assume that pursuant to Section 3 (1) of the German Price Clause Act of 7 September 2007, the indexation clause agreed in this Lease is admissible and no Party within the meaning of Section 2 (1) of the German Price Clause Act is inappropriately disadvantaged.
- (5) If Section 3 (1) of the German Price Clause Act is inapplicable and/or the indexation clause is inadmissible, the Parties undertake to agree an admissible provision that comes closest in economic terms to the indexation clause agreed in this Lease.

#### **Section 7 Operating Costs**

- (1) As a general rule, the **Lessee** bears all operating costs in addition to the net rent excluding utilities. Operating costs are costs charged to the **Lessor** on an ongoing basis as a result of its ownership of the property or the intended use of the **Leased Object**, the building (comprising Building H028 North, Building H028 South and Building H030), its facilities and installations, and the property. The operating costs to be borne by the **Lessee** include the operating costs pursuant to **Annex 5.1** to this Lease, provided that the **Lessee** has not rented the Additional Areas. From the date of inclusion of the Additional Areas, **Annex 5.1** will apply instead of **Annex 5.2**, since from this date, the **Lessee** will no longer be supplied with energy and media in Building H028 South by the **Lessor** within the framework of this Lease, and the **Lessee** will enter into separate energy and media supply contracts in order also to supply Building H028 South and/or include the delivery point H028 South in any existing energy and media supply contracts. The operating costs to be borne by the **Lessee** also include the operating costs labelled as "**Basic Infrastructure Costs**" and "**Drainage Costs**" in **Annex 5.1** and **Annex 5.2**, charged to the **Lessor** on an ongoing basis as a result of the operation of the Behringwerke Site.
- (2) If public taxes are newly introduced or if the **Lessor** is charged new operating costs within the meaning of this Lease by fulfilling legal obligations in relation to the **Leased Object** arising after conclusion of the Lease, these may be allocated pursuant to this Lease and a corresponding adjustment made to the advance payment for operating costs. The adjustment of operating costs referred to in **Annex 5.1** and **Annex 5.2**, and the creation of new operating costs, which concern neither public taxes nor the fulfilment of legal obligations in relation to



the **Leased Object** arising after conclusion of the Lease, may only take place while taking the principle of sound financial management into account. The **Lessor** will inform the **Lessee** immediately of any adjustments to operating costs.

(3) If the **Lessor** provides services within its own business operations which, if performed by third parties, would be charged as part of the operating costs pursuant to this Lease, the **Lessor** may issue a cost estimate for these services in an amount which corresponds to appropriate consideration, plus the value added tax applicable to these services during the period of performance insofar as applicable (e.g., where agreed, supply of energy and media at the prices applicable to the site, lift maintenance)

(4) Unless precluded by mandatory provisions, the operating costs will be allocated according to the proportion of surface area held by the **Lessee** in relation to the total surface area of the building. The ratio between the **Lessee's** proportion of surface area and the total surface area of Building H028 before inclusion of the Additional Areas, agreed only for the purpose of allocating the operating costs, is agreed by the Parties with binding force in **Annex 3.1**) to this Lease. The ratio between the **Lessee's** proportion of surface area and the total surface area of Building H028 after inclusion of the Additional Areas, agreed only for the purpose of allocating the operating costs, is agreed by the Parties with binding force in **Annex 3.2**) to this Lease.

(5) The areas described in more detail in **Annex 1.1**) and located in Building H028 North are supplied with energy and media not within the framework of this Lease, but instead on the basis of the supply contracts to be entered into by the **Lessee** outside of this Lease.

The areas described in more detail in **Annex 1.1**) and located in Building H028 South are supplied with energy and media within the framework of this Lease only until the inclusion of the Additional Areas in the Lease. From the time of inclusion of the

Additional Areas, the **Lessor's** obligation under this Lease to supply the **Lessee** with energy and media in Building H028 South will end.

The Parties agree that the supply limit/transfer point for all energy and media supplied is the outlet of the relevant shut-off devices and/or output terminals of the **Lessor's** main distributor in the central energy room. The distribution/onward transfer of energy and media in Building H028 South to the areas rented by the **Lessee** will be agreed between the **Lessee** and [\*\*\*] outside of this Lease.

Until the time of inclusion of the Additional Areas in the Lease, the costs for supplying H028 South with energy and media will be billed based on consumption, as follows:

For each type of energy and media, an assessment of the total energy and media quantities supplied to Building H028 South will be drawn up based on information from the **Lessor's** metering points.

[\*\*\*]

[\*\*\*]

According to the **Lessee's** share in the relevant energy and media consumption determined in this manner, the supply costs will be allocated within the framework of the operating costs billing.

As soon as H028 South is fully rented by the **Lessee**, the following applies:

For each type of energy and media, an assessment for the total energy and media quantities supplied to Building H028 will be drawn up based on information from the **Lessor's** metering points. The **Lessee** will enter into energy and media supply contracts with the **Lessor** or third parties in order to supply the **Leased Object**, if this has not been done already. If and to the extent that energy and media supply agreements are already in place between the **Lessor** and **Lessee**, these may be extended to include the delivery points in Building H028 South.

- (6) For the future, the **Lessor** may change the allocation criteria at its discretion in agreement with the **Lessee**.
- (7) The operating costs labelled as "Basic Infrastructure Costs" and "Drainage Costs" in **Annex 5.1/Annex 5.2** will be determined for the billing year pursuant to the agreement set out in **Annex 5.1/Annex 5.2**, and allocated to the **Lessee** in accordance with the arrangements described and agreed in **Annex 5.1/Annex 5.2**. The Basic Infrastructure Costs and Drainage Costs are not subject to the monthly advance payment for operating costs (**Annex 5.3**); instead, they are billed for separately by the **Lessor** and reimbursed by the **Lessee**.
- (8) If there are fire alarms and fault indication systems or any other technical fittings required for the operation of the building – except for access control installations – located in areas used jointly with other lessees of Building H028, the costs of these installations will be borne by the **Lessee** in proportion to the spaces used exclusively by it compared with the total surface area of Building H028 (**Annexes 3.1 and 3.2**). The same applies to lightning protection.
- (9) The **Lessee** will pay monthly advance payments for operating costs, which will be determined as follows if they are not those operating costs labelled as "Basic Infrastructure Costs" and "Drainage Costs":  
  
For each calendar year, the **Lessor** will estimate a planned amount of the operating costs, adjusted to account for the operating costs actually incurred for the previous year, and invoice the **Lessee** on a monthly basis for 1/12 of this amount, plus value added tax, as an advance payment for the operating costs.
- (10) Energy and media consumption will be invoiced for on a monthly basis. No advance payment has been agreed.
- (11) After expiry of the billing period (calendar year), when invoicing for operating costs, the **Lessor** will determine all operating costs incurred during the billing period. The **Lessor** will compare the operating costs actually incurred with the advance payment for operating costs paid by the **Lessee** and will notify the **Lessee** of the result when invoicing for the operating costs.
- (12) Any difference between the amount of the advance payment and the amount of the invoice in the **Lessor/Lessee's** favour must be settled by the **Lessor/Lessee** within three (3) months after receipt of the invoice by the **Lessee**, plus the value added tax applicable at the time of payment.
- (13) The **Lessee** must notify any objections to an invoice in writing to the **Lessor** within three (3) months after receipt of the invoice; otherwise, any objections to the accuracy of the invoice will be excluded unless (i) the **Lessee** is not responsible for the delay in asserting the

objections, or (ii) the **Lessor** did not specifically refer to the cut-off point and the consequences of its expiry in the invoice letter.

At the **Lessee's** request, the **Lessor** will grant the **Lessee** access to the invoicing documents in the **Lessor's** business premises during usual business hours, by prior appointment within four weeks after receipt of the invoice.

- (14) If the **Lessee** moves out during the invoicing period, in the event of doubt, the apportionment for the next invoice due will take place in proportion to the leasing period compared with the invoicing period.
- (15) The current advance payment amounts as at the start date of the Lease are appended to this Lease as **Annex 5.3**). The Parties agree that in the event of an amendment to the advance payment amounts, **Annex 5.3**) will not be adjusted and no new annex to the Lease will be created; instead, a simple notification of the amendment (e.g. in the form of a bill) by the **Lessor** will be sufficient.
- (16) The **Lessor** must provide the **Lessee** with the invoice no later than by the end of the 12<sup>th</sup> (twelfth) month after the end of the invoicing period. After expiry of this period, any subsequent claim by the **Lessor** is excluded, unless the **Lessor** is not responsible for the delay in asserting such claim.

**Section 8**  
**Operator Liability**

- (1) The **Lessee** must create and maintain all the conditions required to operate its business at its own expense (operator liability).  
  
Requirements of the trade inspectorate or other authorities must be fulfilled by the **Lessee** at its own expense, to the extent that corresponding requirements are specifically associated with the business of the **Lessee** or its activities in the **Leased Object**, even if they are directed at the **Lessor**. Section 2 (6) of this Lease is not affected by this.  
  
The **Lessee** will conduct its business in the **Leased Object** in accordance with applicable laws and in accordance with the requirements of national and international authorities.
- (2) The **Lessee** shall hold the **Lessor** harmless against all claims asserted against the **Lessor** by third parties as a result of a breach of the operator liability requirements that apply to the **Lessee**.

**Section 9**  
**Warranties, Liability**

- (1) The **Lessee** is aware that the **Leased Object** is located on an industrial site, and that annoyances typical of industrial sites may be caused during the term of the Lease, such as emissions from neighbouring users, works on supply lines, roads, neighbouring buildings and plots.
- (2) The strict liability of the **Lessor** to compensate for initial defects is excluded.
- The exclusion of liability for initial defects also applies to rights and entitlements in relation to rectification of defects, deterioration, termination and rights of retention of the **Lessee**, unless the **Lessee** was not aware of the defect at the start of the Lease or it is not responsible for it and the **Lessee** can prove its unawareness or lack of responsibility.
- (3) If a defect occurs in the **Leased Object** after the start of the Lease and the **Lessee**, as a general rule, is entitled to warranty claims in relation to this defect, the provisions laid down by Sections 536 et seqq. of the German Civil Code will apply in accordance with this Lease.
- (4) If the **Lessor** delays rectifying the defect, the **Lessee** may rectify the defect itself and demand compensation for the expenditure incurred in this regard.
- (5) The **Lessee** will only be entitled to a rent reduction if the appropriate timeframe set for the **Lessor** by the **Lessee** within which to rectify defects has expired without action. Section 9 (2) of this Lease remains unaffected.
- (6) Claims for compensation by the **Lessee**, to the extent not excluded by this Lease, including claims arising from pre-contractual obligations and unlawful acts, can only be asserted if they are based on the intent or gross negligence of the **Lessor** or its vicarious agents.
- (7) All liability exclusions and limitations contained in this Lease also apply to the benefit of the organs, representatives and vicarious agents of the **Lessor**.
- (8) If the **Lessor** supplies energy and media within the framework of this Lease that are to be invoiced as operating costs, the following liability provision will apply regardless of the item supplied:
- [\*\*\*]
- If the causes of an interruption or erratic supply are due to the electricity supply network operated by the **Lessor** as the operator of the electricity supply network for the Behringwerke Site, the **Lessor** is liable vis-à-vis the **Lessee** in accordance with Section 18 of the German Network Connection Ordinance.

**Section 10**  
**Maintenance, Cosmetic Repairs,**  
**Structural and Technical Amendments**

- (1) The allocation of obligations set out below is based on the circumstance that the **Lessee** is entitled to organise the internal fittings in the **Leased Object** at its own risk to the greatest extent in accordance with its operational requirements, and to take over the fixtures and

conversions of the previous lessees under its own responsibility. The allocation of obligations was also taken into consideration when calculating the rent excluding utilities.

The **Lessor** is only responsible for the maintenance, repair, upkeep, and inspection (hereinafter referred to as "Maintenance") of the **Leased Object** within the defined limits pursuant to Section 1 of the Lease, namely the building envelope and the load-carrying components ("Roof and Structures"), and the installations, facilities, and fittings of the **Leased Object** described in more detail in **Annex 2.1), Annex 2.2)** (Additional Areas), and **Annex 2.3)**, as well as for maintaining and repairing the circulation and ancillary use areas not included in the Lease (marked in "grey" in **Annex 1.1), Annex 1.2)**, and **Annex 1.3)**) and any other communal technical installations, facilities and areas. This does not affect the exclusion of liability for initial defects pursuant to Section 9 of this Lease. Major maintenance and repair measures to be taken by the **Lessor**, i.e. such measures that may significantly affect the operations of the **Lessee**, will be agreed in good time with the **Lessee** beforehand. Prior agreement will not be required in the event of imminent danger.

Except in relation to the house connection, there is no obligation to maintain energy and media distribution infrastructure located within the building, as this infrastructure is not owned by the **Lessor** and does not form part of the **Leased Object**.

At its own expense, the **Lessee** is responsible for the maintenance, repair, upkeep and inspection of the facilities, installations, and fittings within Building H028, to the extent that these are not listed in **Annex 2.1), 2.2), and 2.3)** as part of the **Leased Object** but are located in the areas provided to the **Lessee**/in the spaces used by the **Lessee**. The **Lessee** is more specifically responsible for the maintenance, repair, upkeep and inspection of the fixtures and conversions carried out by the previous lessees and by the **Lessee** itself at its own expense. All works to maintain the operational readiness and operational safety of these facilities, installations, and fittings that are required by law and/or necessary according to the manufacturer's instructions are the responsibility of the **Lessee** and must be carried out at its own expense.

Cosmetic repairs (e.g. replacing the wallpaper, paint and cleaning the carpets) in the **Leased Object** are the responsibility of the **Lessee**.

(2) The **Lessor** is responsible for maintaining an appropriate physical appearance of the façade of the **Leased Object**. The **Lessor** will carry out modernisation work on the façade of Building H028, as described in **Annex 9)** to this Lease.

(3) The **Lessee** is authorised to carry out structural or technical amendments to the **Leased Object** with the prior consent of the **Lessor**, to the extent not already acknowledged in Section 2 (2). For the **Lessor** to provide its consent, questions on the effects of the planned measures in terms of planning permission (including statics, fire protection, construction physics) and significance in terms of site development (including effects on the neighbourhood, environment and infrastructure) must be answered and a realistic assessment of the operational significance of the measures must be obtained. A joint approach is required in this regard.

If the **Lessor** approves structural and/or technical amendments, before the measures are implemented, by means of follow-up management, the type and extent of the amendments must be documented in a manner that complies with the written form requirement, as well as – where agreed – a waiver by the **Lessor** of the right to demand, at the end of the Lease,

restoration by the **Lessee** of the condition of the **Leased Object** prior to the structural and/or technical amendment and the obligation to maintain it.

- (4) In accordance with the areas key agreed pursuant to **Annex 3.1) and 3.2)**, the **Lessee** will bear the costs of the adaptation of the technical building equipment of Building H028 by the **Lessor**, if and to the extent that adaptation is necessary, in order to allow simultaneous use of the building by the **Lessee** and other companies based in the building, regardless of which part of Building H028 the adaptation is carried out in.

#### **Section 11 Company Sign**

- (1) Taking the conditions on site into account, after agreement with the **Lessor**, the **Lessee** may affix its own company signs at its own expense only to the buildings or parts of buildings for which it has sole use. These costs will be at its own expense. If official permits are required for the affixing of these signs, the **Lessee** will obtain these and bear the associated costs.

The **Lessee** is responsible for fulfilling the public safety obligation for signs affixed by it.

- (2) (Hanging) internal communication and information boxes or boards installed outside of the areas for which the **Lessee** has sole use are subject to agreement between the **Lessee** and **Lessor** depending on the type of design, size and installation site.

- (3) If it is necessary to remove company signs pursuant to paragraphs (1) or (2) for works at the site or on the **Leased Object**, the **Lessee** will bear the costs of the removal, storage and reinstallation, including the resulting repairs to the facility required. At the end of the Lease, the **Lessee** must remove the company sign at its own expense and rectify any damage caused by the affixing, operation and removal.

- (4) If the **Lessor** installs standardised company signs, the **Lessee** may participate in the costs for affixing and maintaining these installations on a proportionate basis.

#### **Section 12 Technical Building Services, Supply and Disposal**

- (1) The **Lessor** is responsible for ensuring the proper technical connection of the **Leased Object** to the currently existing supply and disposal systems at the site. Except as provided for in Section 7 (5) concerning the supply of H028 South, the **Lessee** will be responsible for the supply of the **Leased Object** with the energy and media required for its use at its own expense by entering into separate energy supply contracts with the **Lessor** or third parties. The **Lessee** will be responsible for sufficiently heating the **Leased Object** using the air conditioning installations installed by it in the **Leased Object** for the purposes of production. Irrespective of their invoicing as operating costs or their supply within the framework of energy supply agreements, the delivery of energy and media takes place from the output terminal of the main distributor and from the first shut-off valve in the central energy room.

The Lease does not cover the infrastructure required for the onward transfer of energy and media in the building, such as electricity and water supply lines and these are not, therefore, included in **Annex 2.1), Annex 2.2)**, and **Annex 2.3)**.

This infrastructure is in the possession of [\*\*\*] and the **Lessee** will agree with [\*\*\*] on the usage and – if it rents all floors of Building H028 - transfer of this infrastructure outside the scope of this Lease. If this is not successful or if the infrastructure is not made available, this circumstance does not entitle the **Lessee** to terminate this Lease.

- (2) The **Lessee** will use the supply and disposal lines, e.g. for electricity, gas, nitrogen, compressed air, and water/wastewater only to the extent that no overload is caused. Any additional needs can be covered by the **Lessee** by extending the lines and necessary technical installations at its own expense after obtaining the **Lessor's** prior written consent, which may only be refused for an important reason.
- (3) If it is necessary to convert devices or equipment, equipment parts and auxiliary equipment belonging to the **Lessee** because of a legally required change to the way energy is obtained, the costs of converting these devices or equipment, equipment parts and auxiliary equipment will be borne by the **Lessee**. Any claims for compensation by the **Lessee** and entitlements to rent reduction are excluded in this case.

### **Section 13 Insurance Policies**

- (1) As at the handover date, the **Lessor** holds all risks property insurance, including building fire cover, as well as business liability insurance with a minimum coverage amount of EUR 10 million. The costs of these insurance policies are included (proportionately where necessary) in the operating costs pursuant to Section 7 of this Lease.
- (2) From the commencement of the Lease, the **Lessee** is obliged to take out a liability insurance policy which provides cover for rental damage with a minimum coverage amount of EUR 10 million, as well as all insurance policies necessary for the operations pursuant to Section 2 of this Lease. Comprehensive insurance coverage or policies that provide for an excess to be paid by the **Lessee** fulfil this requirement.  
  
In the event of an increase to the previously insured risk, the **Lessee** must extend its insurance coverage without being requested to do so. The same applies to the **Lessor's** insurance obligation under paragraph (1).
- (3) All insurance coverage must be maintained throughout the entire term of the Lease, either by continuing the relevant insurance policy or by taking out new comparable insurance policies. The determining factor is whether insurance coverage exists throughout the entire term of the Lease.
- (4) At the request of the other Party, each Party must produce certificates for the insurance policies to be taken out by it, which also state the amount of the excess and, when requested to do so at any time, provide evidence of payment of the premium where required.
- (5) Each Party undertakes to notify the other Party immediately if it becomes aware of missing or insufficient general or special insurance protection. This applies in particular in circumstances whereby the risk may be changed or increased, particularly where installations, structural amendments or changes of use take place.
- (6) The **Lessee** will notify the insurer and the **Lessor** immediately of any damage event and ensure that, to the extent possible and reasonable, no changes are made to the damage site before

the insurer's inspection. Nevertheless, the Parties are obliged to take any measures required in order to reduce the damage or reduce consequential damage. The Parties will take these measures in agreement with each other and with the relevant insurer.



**Section 14**  
**End of the Lease, Handover Obligation,**  
**Restoration to the original condition**

- (1) At the end of the Lease, the **Lessee** must return the **Leased Object** in accordance with the provisions of this Lease, swept clean and free from materials which may cause danger, significant disadvantages or significant pollution for individuals or the general public within the meaning of Section 3 of the German Federal Emissions Act (hereinafter referred to as "Contamination"), unless the Contamination was not caused by the **Lessee** or by previous lessees.
- (2) If there is Contamination in the **Leased Object** or in the parts of the building made available for use free of charge, the **Lessee** must also indemnify the **Lessor** fully during the term of the Lease if claims are made against the **Lessor** for investigations, decontamination or any other measures in relation to the Contamination, and it must also indemnify the **Lessor** against any claims from third parties in connection with such Contamination, unless the relevant Contamination was caused before 01.01.2005.
- (3) The **Lessee** is obliged to do the following at the end of the Lease:
- have all facilities, installations, and fittings (even those installed in the **Leased Object** by previous lessees) located in Building H028 (including H030) in the areas used by the **Lessee**/in the spaces used by the **Lessee** professionally removed at its own expense, unless these are identified in **Annex 2.1), Annex 2.2), and Annex 2.3)** to the Lease as part of the **Leased Object**, including their connections to the **Leased Object**;
  - remove its movable fixtures at its own expense;
  - have all structural and technical amendments to the **Leased Object** (also to the extent carried out by previous lessees) professionally removed at its own expense and restore the structural and technical condition of the **Leased Object** identified in **Annexes 1.1), 1.2), and 1.3)** and in **Annex 2.1), Annex 2.2), and Annex 2.3),**
- unless the **Lessor** has waived this obligation in writing in an amendment to this Lease.
- (4) If the **Lessee** does not fulfil its obligation to return the **Leased Object** pursuant to Section 14 of this Lease within the requisite period, then for each day of the delayed handover, it must pay the **Lessor** 1/30 of the most recently paid monthly advance payment for operating costs, plus the value added tax applicable at the time of payment.
- The **Lessor's** right to claim for compensation due to additional damage is not excluded.
- (5) The Parties will draw up a written handover report concerning the return of the **Leased Object**.

**Section 15**  
**Force majeure**

If and to the extent that a Party is prevented from fulfilling its contractual obligations due to force majeure, it will be released from such obligations. It will notify the other Party immediately of the circumstances of the force majeure and make efforts to remedy these circumstances. If necessary and possible, the Parties will agree on the required adaptive measures.

**Section 16**  
**Confidentiality**

(1) The Parties mutually undertake to maintain confidentiality in relation to all information that they obtain in relation to the conclusion of this Lease and its performance, including all economic framework conditions and the provisions laid down in this Lease, as well as any business and operational secrets that may become known. This means that the relevant information must not be disclosed to third parties without prior written consent of the other Party.

Excluded from this is the disclosure of information to third parties appointed by a Party for the implementation of the Lease, however only to the extent strictly necessary for the implementation of the Lease.

However, it is a requirement that such third parties (e.g. lawyers, tax advisors, brokers, experts, tradesmen, group companies, etc.) either are subject to professional secrecy obligations or are required in turn to maintain confidentiality.

The foregoing confidentiality obligation applies for a period of up to ten (10) years after the end of the Lease.

(2) Excluded from the confidentiality obligation under paragraph (1) is information which the Parties have obtained prior to conclusion of the Lease and independent of the implementation of the Lease, and information that can be obtained by one of the Parties from generally accessible sources, without either Party having caused such information to be accessible through a breach of the confidentiality obligation.

The confidentiality obligation does not apply if one of the Parties discloses the necessary information as a result of a legal or official order or in legal proceedings to safeguard its legitimate interests.

**Section 17**  
**Guarantees**

(1) Within 14 days after the signing of this Lease, in order to guarantee all claims of the **Lessor** against the **Lessee** under this Lease, the **Lessee** will provide a guarantee that is directly enforceable on first request, issued by a German bank or public savings bank [*Sparkasse*] in accordance with the appended template (**Annex 6**), for an amount equal to three times the monthly rent excluding utilities at the start of the Lease, plus the advance payment for operating costs at the start of the Lease, plus value added tax.

(2) If the **Lessee** does not provide a rental guarantee in the due and proper form within the agreed timeframe and after a deadline extension has been granted, the **Lessor** is authorised to extraordinarily terminate the Lease without notice.

(3) Six months after the end of the Lease, the **Lessor** will return the guarantee to the **Lessee** if and to the extent that the **Lessor** does not assert against the **Lessee** or the guarantor any claims arising from the Lease and secured by the guarantee.

**Section 18**  
**Subletting, Transfer of Use**

- (1) The **Lessee** may only transfer the use of the **Leased Object** to a third party and/or sublet it with the consent of the **Lessor**. The **Lessor** is obliged to permit a transfer of use to third parties if the third party is not a competitor of the **Lessor** and there is no other important reason for refusing permission.

**Section 19**  
**Consideration, Averting Dangers**

- (1) The Parties agree that the foregoing provisions are only viable if they act considerately at the request of the other Party, taking into account other companies operating on the site and more specifically, undertake to seek amicable solutions to issues that cannot be foreseen and are not contractually provided for in detail.
- (2) This applies in particular to measures implemented by the Parties in accordance with the provisions laid down in this Lease under their own responsibility and at their own expense, and for official and other orders, which can only be complied with by mutual agreement.
- (3) In the event of imminent danger, the **Lessee** must comply with the instructions from the site security and fire services. It will also impose this obligation on its staff and on third parties appointed by it.
- (4) The attachment, placement or storage of items of any kind (boxes, goods, etc.) outside of the **Leased Object**, particularly on the shared traffic routes, is only permitted in the designated storage/parking areas.
- (5) The **Lessee** will receive a copy of the parking rules (**Annex 7**) and ensure that its employees and visitors comply with the parking rules and support the **Lessor** as far as possible in enforcing the parking rules.

**Section 20**  
**Entire Agreement, Written Form**

- (1) This Lease contains all agreements made between the Parties. There are no additional agreements, ancillary agreements, or undertakings. If, contrary to the previous sentence, additional agreements, ancillary agreements, or undertakings do exist, these are hereby rescinded.
- (2) Amendments and supplements to this agreement and its annexes, and all declarations of intent under this Lease, must be made in writing in order to be valid. This also applies in the event of an amendment to this written form clause.
- (3) The Parties undertake not to terminate this Lease early by invoking any non-compliance with the written form requirement. This applies not only to the conclusion of this Lease, but also to any addenda, amendments or supplements hereto. If the written form requirement is not complied with for amendments and supplements, the Parties further undertake to rectify this immediately.
- (4) The Lease is drawn up in two counterparts; each Party receives one copy thereof.

**Section 21**  
**Entry to the Leased Object, Public Safety Obligation, Annexes,**  
**Partial Invalidity, Place of Jurisdiction, Competition Clause**

- (1) The **Lessor**, its representatives, experts, and interested parties may enter the **Leased Object** after providing sufficient notice and during business hours in order to check its condition for re-letting or sale purposes or for another important reason, subject to agreement and taking the legitimate interests of the **Lessee** into consideration.
- If regulatory requirements apply to parts of the **Leased Object** (for example GMP rules), entry by the **Lessor** is only authorised if these requirements are complied with. The **Lessee** will provide the **Lessor** with comprehensive information on the rules to be complied with and the necessary measures in good time.
- In the event of imminent danger, they must be granted access at any time of day or night. In this case, in the event of absence, the **Lessee** must provide the corresponding access options or leave keys in an accessible place known to the **Lessor**.
- If required, the **Lessor** and its appointed parties are also authorised to enter the **Leased Object** at any time of day or night in agreement with the **Lessee** (the agreement must be documented for example by providing a corresponding access authorisation card) in order to access energy rooms, communications hubs, main and single-floor distribution boards for telephones, main and single-floor fire alarm distribution boards, battery facilities and electroacoustic installations, as well as any other premises used to supply the **Leased Object**.
- When entering the **Leased Object**, the **Lessor** must give the necessary and requested consideration to the **Lessee**'s operations.
- (2) The **Lessee** is subject to the public safety obligation within the leased areas and technical areas used by it alone, to the extent that these are indeed used by the **Lessee** alone. If technical areas are used by both the **Lessee** and **Lessor** (Section 1 (3) of the Lease), both parties are equally bound by the public safety obligation and are jointly and severally liable vis-à-vis third parties in the event of a breach of the public safety obligation.
- (3) All annexes constitute a component of this Lease.
- (4) On the date on which it comes into force, this Lease replaces all existing oral and/or written ancillary agreements between the parties concerning the leasing of areas and spaces in Building H028, therefore also the Lease concerning H028 North of 25.06.2016, together with its amendments.
- (5) This Lease is independent of further leases entered into between the contractual parties.
- (6) The laws of the Federal Republic of Germany apply to this Lease and the tenancy provided for therein. If any translations of the Lease are created, the German version will prevail.
- (7) In relation to any disputes resulting from this Lease, the courts of Marburg will have jurisdiction, as far as legally permitted.

(8) If a provision of this agreement or a future new provision is fully or partially ineffective or unenforceable, or loses its validity or enforceability at a later date, or if a loophole is discovered in this agreement, this will not affect the validity of the other provisions. To replace the ineffective or unenforceable provisions or to close the loophole, an appropriate provision will be agreed on in the proper form, which, as far as legally permissible, comes closest to what the Parties intended when entering into the Lease, or to what they would have wanted in accordance with the purpose of the agreement if they had considered the matter.

(9) There is no competition clause.

(10) The following are annexes to this agreement:

<u>Annex 1.1)</u>	Plans for the Leased Object, (H028 North, H030 and H028 South <u>without</u> Additional Areas, i.e. only floors 1 - 2)
<u>Annex 1.2)</u>	Plans for the Leased Object (only Additional Areas, i.e. only H028 South, floors 1 - 2)
<u>Annex 1.3)</u>	Plans for the Leased Object after leasing of the Additional Areas (H028 North, H030 and H028 South <u>including</u> Additional Areas)
<u>Annex 1.4)</u>	Site plan
<u>Annex 2.1)</u>	List of installations, facilities, and fittings for the Leased Premises (H028 North, H030, and H028 South without Additional Areas, i.e. without floors 1 - 2)
<u>Annex 2.2)</u>	List of installations, facilities, and fittings for the Leased Premises (only Additional Areas, i.e. only H028 South, floors 1 - 2)
<u>Annex 2.3)</u>	List of installations, facilities, and fittings for the Leased Premises (H028 North, H030, H028 South, floors 1 - 6)
<u>Annex 3.1)</u>	Lessee's share of the total area for the building, without Additional Areas
<u>Annex 3.2)</u>	Lessee's share of the total area for the building, with Additional Areas
<u>Annex 4.1)</u>	Net rent excluding utilities, without Additional Areas, from 01.01.2020
<u>Annex 4.2)</u>	Net rent excluding utilities, with Additional Areas, from 01.01.2024
<u>Annex 4.3)</u>	Net rent excluding utilities, with Additional Areas, from 01.01.2025
<u>Annex 5.1)</u>	Services covered by operating expenses H028 North, H028 South (without floors 1-2 H028 South), and H030, i.e. including energy and media supply
<u>Annex 5.2)</u>	Services covered by operating expenses H028 North, H028 South (with floors 1-2 H028 South), and H030, i.e. without energy and media supply
<u>Annex 5.3)</u>	Initial advance payment for operating expenses
<u>Annex 6)</u>	Rental guarantee template
<u>Annex 7)</u>	General entrance and parking rules for the Behringwerke Site
<u>Annex 8)</u>	List of the goods only to be stored in Building H030
<u>Annex 9)</u>	Description of the façade renovation

Marburg, 25.07.19

Marburg, 25.07.2019

Pharmaserv GmbH

Novartis Manufacturing GmbH







































BILINGUAL KEY	
DE	EN
<b>Anlage 1.4)</b> zum Mietvertrag über Flächen und Räume in Gebäude H028 zwischen Pharnaserv GmbH und Novartis Manufacturing GmbH	<b>Appendix 1.4)</b> to the lease concerning areas and spaces in building H028 between Pharnaserv GmbH and Novartis Manufacturing GmbH
Gebäude H034	Building H034
Gebäude H030	Building H030
Gebäude H033	Building H033
Lageplan	Site plan
Abstellfläche für Abfallcontainer H028 Nord	Storage area for waste container(s) H028 north
H028 Nord	H028 north
Gebäude H028 gesamt	Building H028 entire
H028 Süd	H028 south
Abstellfläche für Abfallcontainer H028 Süd	Storage area for waste container(s) H028 south
Gebäude H021	Building H021
Stand: 26.06.2019	As of: 26.06.2019
Seite 1 von 1	Page 1 of 1























**Annex 3.1)**

to the Lease of Space and Premises in the H028 and H030 Buildings  
between Pharmaserv GmbH  
and Novartis Manufacturing GmbH

**Proportion of the total area allocated to the Lessee  
H030 Building**

1. The total area of the H030 Building is	13,217.08 m <sup>2</sup>
2. The proportion of the total area of the H028 Building (H028 North entire building and H028 South 3rd - 6th floors) allocated to the Lessee is	10,267.65 m <sup>2</sup>

to the Lease of Space and Premises in the H028 and H030 Buildings  
between Pharnaserv GmbH  
and Novartis Manufacturing GmbH

**Proportion of the total area allocated to the Lessee  
H030 Building**

1. The total area of the H030 Building is	86.54 m <sup>2</sup>
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2. The proportion of the total area of the H030 Building allocated to the Lessee is	86.54 m <sup>2</sup>
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**Annex 3.2)**

to the Lease of Space and Premises in the H028 and H030 Buildings  
between Pharmaserv GmbH  
and Novartis Manufacturing GmbH

**Proportion of the total area allocated to the Lessee  
H028 Building**

1. The total area of the H028 Building is	13,217.08 m <sup>2</sup>
2. The proportion of the total area of the H028 Building (H028 North entire building and H028 South entire building) allocated to the Lessee is	13,217.08 m <sup>2</sup>

to the Lease of Space and Premises in the H028 and H030 Buildings  
between Pharnaserv GmbH  
and Novartis Manufacturing GmbH

**Proportion of the total area allocated to the Lessee  
H030 Building**

1. The total area of the H030 Building is	86.54 m <sup>2</sup>
2. The proportion of the total area of the H030 Building allocated to the Lessee is	86.54 m <sup>2</sup>

**Annex 4.1)**

to the Lease of Space and Premises in the H028 and H030 Buildings  
between Pharmaserv GmbH  
and Novartis Manufacturing GmbH

**Basic rent (graduated rent) euros/month net  
H028 Building excluding additional space with effect from 01.07.2019  
(H028 North, H028 South 3rd – 6th Floors)**

<b>Lease period</b>	<b>Euros/month</b>
01.07.2019 – 31.12.2019	€ [***]
01.01.2020 - 31.12.2020	€ [***]
01.01.2021 - 31.12.2021	€ [***]
01.01.2022 - 31.12.2022	€ [***]
01.01.2023 - 31.12.2023	€ [***]
01.01.2024 – 31.12.2024	€ [***]
01.01.2025 - 31.12.2025	€ [***]
01.01.2026 - 31.12.2026	€ [***]
01.01.2027 - 31.12.2027	€ [***]
01.01.2028 - 31.12.2028	€ [***]
01.01.2029 -31.12.2029	€ [***]
01.01.2030 - 31.12.2030	€ [***]
01.01.2031 - 31.12.2031	€ [***]
01.01.2032 - 31.12.2032	€ [***]
01.01.2033 - 31.12.2033	€ [***]
01.01.2034 - 31.12.2034	€ [***]

**Annex 4.1)**

to the Lease of Space and Premises in the H028 and H030 Buildings  
between Pharmaserv GmbH  
and Novartis Manufacturing GmbH

**Basic rent (graduated rent) euros/month net  
H030 Building with effect from 01.07.2019**

<b>Lease period</b>	<b>Euros/month</b>
01.07.2019 – 31.12.2019	€ [***]
01.01.2020 - 31.12.2020	€ [***]
01.01.2021 - 31.12.2021	€ [***]
01.01.2022 - 31.12.2022	€ [***]
01.01.2023 - 31.12.2023	€ [***]
01.01.2024 – 31.12.2024	€ [***]
01.01.2025 - 31.12.2025	€ [***]
01.01.2026 - 31.12.2026	€ [***]
01.01.2027 - 31.12.2027	€ [***]
01.01.2028 - 31.12.2028	€ [***]
01.01.2029 -31.12.2029	€ [***]
01.01.2030 - 31.12.2030	€ [***]
01.01.2031 - 31.12.2031	€ [***]
01.01.2032 - 31.12.2032	€ [***]
01.01.2033 - 31.12.2033	€ [***]
01.01.2034 - 31.12.2034	€ [***]

**Annex 4.2)**

to the Lease of Space and Premises in the H028 and H030 Buildings  
between Pharnaserv GmbH  
and Novartis Manufacturing GmbH

**Basic rent (graduated rent) euros/month net  
H028 Building excluding additional space with effect from 01.01.2024  
(H028 North, H028 South 3rd – 6th Floors, entire H028 South with effect from 01.01.2024)**

Lease period	Euros/month
01.07.2019 – 31.12.2019	€ [***]
01.01.2020 - 31.12.2020	€ [***]
01.01.2021 - 31.12.2021	€ [***]
01.01.2022 - 31.12.2022	€ [***]
01.01.2023 - 31.12.2023	€ [***]
01.01.2024 – 31.12.2024	€ [***]
01.01.2025 - 31.12.2025	€ [***]
01.01.2026 - 31.12.2026	€ [***]
01.01.2027 - 31.12.2027	€ [***]
01.01.2028 - 31.12.2028	€ [***]
01.01.2029 -31.12.2029	€ [***]
01.01.2030 - 31.12.2030	€ [***]
01.01.2031 - 31.12.2031	€ [***]
01.01.2032 - 31.12.2032	€ [***]
01.01.2033 - 31.12.2033	€ [***]
01.01.2034 - 31.12.2034	€ [***]

**Annex 4.2)**

to the Lease of Space and Premises in the H028 and H030 Buildings  
between Pharnaserv GmbH  
and Novartis Manufacturing GmbH

**Basic rent (graduated rent) euros/month net  
H030 Building with effect from 01.07.2019**

<b>Lease period</b>	<b>Euros/month</b>
01.07.2019 – 31.12.2019	€ [***]
01.01.2020 - 31.12.2020	€ [***]
01.01.2021 - 31.12.2021	€ [***]
01.01.2022 - 31.12.2022	€ [***]
01.01.2023 - 31.12.2023	€ [***]
01.01.2024 – 31.12.2024	€ [***]
01.01.2025 - 31.12.2025	€ [***]
01.01.2026 - 31.12.2026	€ [***]
01.01.2027 - 31.12.2027	€ [***]
01.01.2028 - 31.12.2028	€ [***]
01.01.2029 -31.12.2029	€ [***]
01.01.2030 - 31.12.2030	€ [***]
01.01.2031 - 31.12.2031	€ [***]
01.01.2032 - 31.12.2032	€ [***]
01.01.2033 - 31.12.2033	€ [***]
01.01.2034 - 31.12.2034	€ [***]



**Annex 4.3)**

to the Lease of Space and Premises in the H028 and H030 Buildings  
between Pharmaserv GmbH  
and Novartis Manufacturing GmbH

**Basic rent (graduated rent) euros/month net  
H028 Building excluding additional space with effect from 01.01.2025  
(H028 North, H028 South 3rd – 6th Floors, entire H028 South with effect from 01.01.2025)**

Lease period	Euros/month
01.07.2019 – 31.12.2019	€ [***]
01.01.2020 - 31.12.2020	€ [***]
01.01.2021 - 31.12.2021	€ [***]
01.01.2022 - 31.12.2022	€ [***]
01.01.2023 - 31.12.2023	€ [***]
01.01.2024 – 31.12.2024	€ [***]
01.01.2025 - 31.12.2025	€ [***]
01.01.2026 - 31.12.2026	€ [***]
01.01.2027 - 31.12.2027	€ [***]
01.01.2028 - 31.12.2028	€ [***]
01.01.2029 -31.12.2029	€ [***]
01.01.2030 - 31.12.2030	€ [***]
01.01.2031 - 31.12.2031	€ [***]
01.01.2032 - 31.12.2032	€ [***]
01.01.2033 - 31.12.2033	€ [***]
01.01.2034 - 31.12.2034	€ [***]

**Annex 4.3)**

to the Lease of Space and Premises in the H028 and H030 Buildings  
between Pharnaserv GmbH  
and Novartis Manufacturing GmbH

**Basic rent (graduated rent) euros/month net  
H030 Building with effect from 01.07.2019**

Lease period	Euros/month
01.07.2019 – 31.12.2019	€ [***]
01.01.2020 - 31.12.2020	€ [***]
01.01.2021 - 31.12.2021	€ [***]
01.01.2022 - 31.12.2022	€ [***]
01.01.2023 - 31.12.2023	€ [***]
01.01.2024 – 31.12.2024	€ [***]
01.01.2025 - 31.12.2025	€ [***]
01.01.2026 - 31.12.2026	€ [***]
01.01.2027 - 31.12.2027	€ [***]
01.01.2028 - 31.12.2028	€ [***]
01.01.2029 -31.12.2029	€ [***]
01.01.2030 - 31.12.2030	€ [***]
01.01.2031 - 31.12.2031	€ [***]
01.01.2032 - 31.12.2032	€ [***]
01.01.2033 - 31.12.2033	€ [***]
01.01.2034 - 31.12.2034	€ [***]

**Annex 5.1)**

to the Lease of Space and Premises in the H028 and H030 Buildings  
between Pharnaserv GmbH  
and Novartis Manufacturing GmbH

Service charges as defined in Article 7 of the Lease are		Notes
1.	***	
2.	***	
3.	***	
4.	***	
5.	***	
6.	***	
7.	***	

to the Lease of Space and Premises in the H028 and H030 Buildings  
 between Pharnaserv GmbH  
 and Novartis Manufacturing GmbH

Service charges as defined in Article 7 of the Lease are	Notes
---	-------

8.	[***]	[***]	
9.	[***]		
	[***]	[***]	
	[***]	[***]	
	[***]	[***]	
	[***]	[***]	
	[***]	[***]	
	[***]	[***]	

to the Lease of Space and Premises in the H028 and H030 Buildings  
between Pharnaserv GmbH  
and Novartis Manufacturing GmbH

Service charges as defined in Article 7 of the Lease are	Notes
---	-------

	[***]
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to the Lease of Space and Premises in the H028 and H030 Buildings  
between Pharnaserv GmbH  
and Novartis Manufacturing GmbH

Service charges as defined in Article 7 of the Lease are	Notes
---	-------

10.	[***]
	[***]
11.	[***]
12.	[***]
13.	[***]

**Annex 5.2)**

to the Lease of Space and Premises in the H028 and H030 Buildings  
between Pharmaserv GmbH  
and Novartis Manufacturing GmbH

Service charges as defined in Article 7 of the Lease are	Notes
---	-------

1.	[***]	
2.	[***]	
3.	[***]	
4.	[***]	
5.	[***]	
	[***]	[***]
	[***]	[***]
	[***]	[***]
	[***]	[***]

**Annex 5.2)**

to the Lease of Space and Premises in the H028 and H030 Buildings  
between Pharnaserv GmbH  
and Novartis Manufacturing GmbH

Service charges as defined in Article 7 of the Lease are	Notes
---	-------

	5.5	[***]
	5.6	[***]
	[***]	



to the Lease of Space and Premises in the H028 and H030 Buildings  
between Pharnaserv GmbH  
and Novartis Manufacturing GmbH

Service charges as defined in Article 7 of the Lease are	Notes
---	-------

6.	[***]
	[***]
7.	[***]
8.	[***]
9.	[***]

**Annex 5.3)**

to the Lease of Space and Premises in the H028 and H030 Buildings  
between Pharmaserv GmbH  
and Novartis Manufacturing GmbH

Advance payment of service charges euros/month net  
H028 Building

€ [\*\*\*]

to the Lease of Space and Premises in the H028 and H030 Buildings  
between Pharnaserv GmbH  
and Novartis Manufacturing GmbH

Advance payment of service charges euros/month net  
H030 Building

€ [\*\*\*]

**Annex 6)**  
to the Lease of Space and Premises in the H028 and H030 Buildings  
between Pharmaserv GmbH  
and Novartis Manufacturing GmbH

**STANDARD**

**RENT GUARANTEE**

**Novartis Manufacturing GmbH**  
Emil-von-Behring-Strasse 76  
35041 Marburg

- hereinafter called "**Lessee**" -

and

**Pharmaserv GmbH**  
Emil-von-Behring-Strasse 76  
35041 Marburg

- hereinafter called "**Lessor**" -

concluded on \_\_\_\_\_ a Lease for Commercial Premises on the site in Emil-von-Behring-Strasse 76 in 35041 Marburg (leased premises: space and premises in the H028 Building). The provision of a guarantee by the **Lessee** from a bank approved for business transactions in the EU had been agreed to ensure the performance of the contractual obligations of the **Lessee**.

With this proviso, we

\_\_\_\_\_ [Bank],

herewith assume with regard to the **Lessor**, including its successors (hereinafter **Beneficiary** in each case) all existing and future claims, including conditional and/or limited claims, which the **Beneficiary** has or will have against the **Lessee** under or in connection with the aforementioned Lease (including claims for damages for breach of duty, non-performance or in lieu of performance,

claims in respect of delay or unjust enrichment), with the unconditional, unlimited and irrevocable guarantee up to an amount that corresponds to three times the applicable monthly rent inclusive of service charges plus value added tax ("maximum amount"). The aforementioned basis of calculation currently establishes a maximum amount of

€ [\*\*\*]  
(in words:  
[\*\*\*]).

The assumption of claims entails waiving the pleas of contestability and set-off, unless the counterclaim for set-off made by the Lessee is either undisputed or expressly acknowledged or legally binding, and waiving the plea that the creditor first proceeds against the debtor (Section 771 German Civil Code). This guarantee applies regardless of any other guarantees and other collateral, which are provided by a third party as additional security for claims by the **Beneficiary**. The creation of a collective guarantee (joint and several liability) pursuant to Section 769 German Code is thus excluded.

We will make a payment to the **Beneficiary** on receipt of the first written request from the **Beneficiary** and may only be called upon to make payment of money. The guarantee expires when this document is returned to us by the **Beneficiary**.

The laws of the Federal Republic of Germany shall apply to this guarantee. If this guarantee is translated, the German version shall prevail. The courts in Marburg shall have exclusive jurisdiction to hear any legal disputes that may arise out of this guarantee.

\_\_\_\_\_, on \_\_\_\_\_  
\_\_\_\_\_



[\*\*\*]

\*\*\*



**Annex 8)**

to the Lease of Space and Premises in the H028 and H030 Buildings  
between Pharmaserv GmbH  
and Novartis Manufacturing GmbH

**Inventory H030 Building**

Material	Substances
***	***
***	***
***	***
***	***
***	***
***	***
***	***
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***	***
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***	***
***	***

**Annex 9)**

to the Lease of Space and Premises in the H028 and H030 Buildings  
between Pharnaserv GmbH  
and Novartis Manufacturing GmbH

**Scheduled works on the leased premises  
excluding the H030 Building**

**Objectives**

[\*\*\*]



**Annex 9)**

[\*\*\*]

[\*\*\*]

[\*\*\*]



Subsidiary	Jurisdiction of Incorporation
BioNTech Cell & Gene Therapies GmbH	Germany
BioNTech Delivery Technologies GmbH	Germany
BioNTech Diagnostics GmbH	Germany
BioNTech Europe GmbH	Germany
BioNTech Innovative Manufacturing Services GmbH	Germany
BioNTech Manufacturing GmbH	Germany
BioNTech Manufacturing Marburg GmbH	Germany
BioNTech RNA Pharmaceuticals GmbH	Germany
resano GmbH	Germany
JPT Peptide Technologies GmbH	Germany
BioNTech Real Estate Verwaltungs GmbH	Germany
BioNTech Real Estate Holdings GmbH	Germany
BioNTech Real Estate GmbH & Co. KG	Germany
BioNTech Real Estate An der Goldgrube GmbH & Co. KG	Germany
BioNTech Real Estate Adam Opel Strasse GmbH & Co. KG	Germany
BioNTech Real Estate Haus Vier GmbH & Co. KG	Germany
BioNTech Austria Beteiligungen GmbH	Austria
BioNTech Pharmaceuticals Asia Pacific Pte. Ltd.	Singapore
BioNTech UK Limited	United Kingdom
BioNTech USA Holding LLC	Delaware
BioNTech Research and Development, Inc.	Delaware
BioNTech US Inc.	Delaware
JPT Peptide Technologies, Inc.	Delaware
BioNTech Turkey Tibbi Ürünler Ve Klinik Araştırma Ticaret Anonim Şirketi	Turkey

**CERTIFICATION PURSUANT TO  
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,  
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Ugur Sahin, certify that:

1. I have reviewed this annual report on Form 20-F of BioNTech SE;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;
4. The company's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the company and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and
5. The company's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: March 30, 2021

By: \_\_\_\_\_ /s/ Prof. Dr. Ugur Sahin  
**Prof. Dr. Ugur Sahin**  
**Chief Executive Officer**

**CERTIFICATION PURSUANT TO  
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,  
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Sierk Poetting, certify that:

1. I have reviewed this annual report on Form 20-F of BioNTech SE;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;
4. The company's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the company and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and
5. The company's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: March 30, 2021

By: \_\_\_\_\_ /s/ Dr. Sierk Poetting  
**Dr. Sierk Poetting**  
**Chief Financial Officer**



CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

The certification set forth below is being submitted in connection with the Annual Report on Form 20-F for the year ended 2019 (the "Report") for the purpose of complying with Rule 13a-14(b) or Rule 15d-14(b) of the Securities Exchange Act of 1934 (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code.

I, Ugur Sahin, certify that:

1. the Report fully complies with the requirements of Section 13(a) or 15(d) of the Exchange Act; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 30, 2021

By: \_\_\_\_\_  
/s/ Prof. Dr. Ugur Sahin  
**Prof. Dr. Ugur Sahin**  
**Chief Executive Officer**

**CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

The certification set forth below is being submitted in connection with the Annual Report on Form 20-F for the year ended 2019 (the "Report") for the purpose of complying with Rule 13a-14(b) or Rule 15d-14(b) of the Securities Exchange Act of 1934 (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code.

I, Sierk Poetting, certify that:

1. the Report fully complies with the requirements of Section 13(a) or 15(d) of the Exchange Act; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 30, 2021

By: \_\_\_\_\_  
/s/ Dr. Sierk Poetting  
**Dr. Sierk Poetting**  
**Chief Financial Officer**

**Consent of Independent Registered Public Accounting Firm**

We consent to the incorporation by reference in the Registration Statement (Form F-3) of BioNTech SE and in the related Prospectus of our report dated March 30, 2021, with respect to the consolidated financial statements of BioNTech SE, and the effectiveness of internal control over financial reporting of BioNTech SE, incorporated by reference in this Annual Report (Form 20-F) for the year ended December 31, 2020.

/s/ Ernst & Young GmbH Wirtschaftsprüfungsgesellschaft

Cologne, Germany

March 30, 2021