UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the quarterly period ended June 30, 2020

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from _ to _
Commission File Number: 001-38753

Moderna, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**81-3467528**
(State or Other Jurisdiction of Incorporation or Organization)	(IRS Employer Identification No.)
200 Technology Square **Cambridge, Massachusetts**	**02139**
(Address of Principal Executive Offices)	(Zip Code)

(617) 714-6500
(Registrant's Telephone Number, Including Area Code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common stock, par value $0.0001 per share	MRNA	The NASDAQ Stock Market LLC

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, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer", "accelerated filer", "smaller reporting company", and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☒ Accelerated filer ☐ Non-accelerated filer ☐ Smaller reporting company ☐
Emerging growth company ☐

If an emerging growth company, 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 is a shell company (as defined in Rule 12b-2 of the Act). **Yes** ☐ **No** ☒

As of July 31, 2020, there were 394,586,852 shares of the registrant's common stock, par value $0.0001 per share, outstanding.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q ("Form 10-Q"), including the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations," contains express or implied forward-looking statements that are based on our management's belief and assumptions and on information currently available to our management. Although we believe that the expectations reflected in these forward-looking statements are reasonable, these statements relate to future events or our future operational or financial performance, and involve known and unknown risks, uncertainties, and other factors that may cause our actual results, performance, or achievements to be materially different from any future results, performance, or achievements expressed or implied by these forward-looking statements. Forward-looking statements in this Form 10-Q include, but are not limited to, statements about:

- the initiation, timing, progress, results, safety and efficacy, 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 ultimate impact of the current coronavirus pandemic, or the COVID-19 pandemic, or any other health epidemic, on our business, manufacturing, clinical trials, research programs, supply chain, regulatory review, healthcare systems or the global economy as a whole;
- risks related to the direct or indirect impact of the COVID-19 pandemic or any future large-scale adverse health event, such as the scope and duration of the outbreak, government actions and restrictive measures implemented in response, material delays in diagnoses, initiation or continuation of treatment for diseases that may be addressed by our development candidates and investigational medicines, or in patient enrollment in clinical trials, potential clinical trials, regulatory review or supply chain disruptions, and other potential impacts to our business, the effectiveness or timeliness of steps taken by us to mitigate the impact of the pandemic, and our ability to execute business continuity plans to address disruptions caused by the COVID-19 pandemic or future large-scale adverse health event;
- our activities with respect to mRNA-1273, our investigational vaccine against SARS-CoV-2, the novel strain of coronavirus that causes COVID-19, including our plans and expectations regarding clinical development, manufacturing, pricing, commercialization, if approved, regulatory matters and potential third-party arrangements;
- our anticipated next steps for our development candidates and investigational medicines that may be slowed down due to the impact of the COVID-19 pandemic, including our resources being significantly diverted towards mRNA-1273, including if the federal government seeks to require us to divert such resources;
- our ability to identify research priorities and apply a risk-mitigated strategy to efficiently discover and develop development candidates and investigational medicines, including by applying learnings from one program to our other programs and from one modality to our other modalities;
- our ability and the potential to successfully manufacture our drug substances, delivery vehicles, development candidates, and investigational medicines for preclinical use, for clinical trials and on a larger scale for commercial use, if approved;
- the ability and willingness of our third-party strategic collaborators to continue research, development and manufacturing activities relating to our development candidates and investigational medicines;
- our ability to obtain funding for our operations necessary to complete further development, manufacturing and commercialization of our investigational medicines;
- our ability to obtain and maintain regulatory approval of our investigational medicines;
- our ability to commercialize our products, if approved;
- the pricing and reimbursement of our investigational medicines, if approved;
- the implementation of our business model, and strategic plans for our business, investigational medicines, and technology;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our investigational medicines and technology;
- estimates of our future expenses, revenues, capital requirements, and our needs for additional financing;

- the potential benefits of strategic collaboration agreements, our ability to enter into strategic collaborations or arrangements, and our ability to attract collaborators with development, regulatory, manufacturing and commercialization expertise;
- future agreements with third parties in connection with the manufacturing and commercialization of our investigational medicines, if approved;
- the size and growth potential of the markets for our investigational medicines, and our ability to serve those markets;
- our financial performance;
- the rate and degree of market acceptance of our investigational medicines;
- regulatory developments in the United States and foreign countries;
- our ability to contract with third-party suppliers and manufacturers and their ability to perform adequately;
- our ability to produce our products or investigational medicines with advantages in turnaround times or manufacturing cost;
- the success of competing therapies that are or may become available;
- our ability to attract and retain key scientific or management personnel;
- the impact of laws and regulations;
- developments relating to our competitors and our industry; and
- other risks and uncertainties, including those discussed in Part II, Item 1A - Risk Factors in this Form 10-Q.

In some cases, forward-looking statements can be identified by terminology such as “will,” “may,” “should,” “could,” “expects,” “intends,” “plans,” “aims,” “anticipates,” “believes,” “estimates,” “predicts,” “potential,” “continue,” or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. These statements are only predictions. You should not place undue reliance on forward-looking statements because they involve known and unknown risks, uncertainties, and other factors, which are, in some cases, beyond our control and which could materially affect results. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under the section entitled “Risk Factors” and elsewhere in this Form 10-Q. If one or more of these risks or uncertainties occur, or if our underlying assumptions prove to be incorrect, actual events or results may vary significantly from those expressed or implied by the forward-looking statements. No forward-looking statement is a promise or a guarantee of future performance.

The forward-looking statements in this Form 10-Q represent our views as of the date of this Form 10-Q. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. You should therefore not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this Form 10-Q.

This Form 10-Q includes statistical and other industry and market data that we obtained from industry publications and research, surveys, and studies conducted by third parties. Industry publications and third-party research, surveys, and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. We have not independently verified the information contained in such sources.

NOTE REGARDING COMPANY REFERENCES

Unless the context otherwise requires, the terms “Moderna,” “the Company,” “we,” “us,” and “our” in this Form 10-Q refer to Moderna, Inc. and its consolidated subsidiaries.

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Item 1. Financial Statements

MODERNA, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited, in thousands, except share and per share data)

	June 30, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 1,761,629	$ 235,876
Investments	955,384	867,124
Accounts receivable	33,362	5,369
Prepaid expenses and other current assets	45,337	19,403
Restricted cash	1,032	1,032
Total current assets	2,796,744	1,128,804
Investments, non-current	354,916	159,987
Property and equipment, net	229,939	201,495
Right-of-use assets, operating leases	92,046	86,414
Restricted cash, non-current	10,791	10,791
Other non-current assets	1,570	1,931
Total assets	$ 3,486,006	$ 1,589,422
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 18,817	$ 7,090
Accrued liabilities	89,204	67,652
Deferred revenue	45,244	63,310
Other current liabilities	8,382	5,063
Total current liabilities	161,647	143,115
Deferred revenue, non-current	208,478	138,995
Operating lease liabilities, non-current	99,636	93,675
Financing lease liabilities, non-current	68,136	38,689
Other non-current liabilities	1,224	138
Total liabilities	539,121	414,612
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Preferred stock, par value $0.0001; 162,000,000 shares authorized as of June 30, 2020 and December 31, 2019; no shares issued or outstanding at June 30, 2020 and December 31, 2019	—	—
Common stock, par value $0.0001; 1,600,000,000 shares authorized as of June 30, 2020 and December 31, 2019; 393,277,267 and 336,536,985 shares issued and outstanding as of June 30, 2020 and December 31, 2019, respectively	39	34
Additional paid-in capital	4,675,987	2,669,426
Accumulated other comprehensive income	8,256	1,804
Accumulated deficit	(1,737,397)	(1,496,454)
Total stockholders' equity	2,946,885	1,174,810
Total liabilities and stockholders' equity	$ 3,486,006	$ 1,589,422

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

MODERNA, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited, in thousands, except share and per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019 [1]	2020	2019 [1]
Revenue:				
Collaboration revenue	$ 28,442	$ 10,030	$ 32,899	$ 24,145
Grant revenue	37,909	3,053	41,841	4,963
Total revenue	66,351	13,083	74,740	29,108
Operating expenses:				
Research and development	151,856	128,305	266,993	258,718
General and administrative	36,622	28,487	60,736	55,740
Total operating expenses	188,478	156,792	327,729	314,458
Loss from operations	(122,127)	(143,709)	(252,989)	(285,350)
Interest income	7,092	10,322	14,944	21,294
Other expense, net	(1,530)	(1,877)	(2,684)	(3,808)
Loss before income taxes	(116,565)	(135,264)	(240,729)	(267,864)
Provision for (benefit from) income taxes	148	(324)	214	(348)
Net loss	$ (116,713)	$ (134,940)	$ (240,943)	$ (267,516)
Net loss per share, basic and diluted	$ (0.31)	$ (0.41)	$ (0.66)	$ (0.81)
Weighted average common shares used in net loss per share, basic and diluted	380,531,488	329,176,107	366,818,254	328,994,058

[1] Restated to conform to ASC 842. See accompanying Note 2.

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

MODERNA, INC.
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(Unaudited, in thousands)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019 [1]	2020	2019 [1]
Net loss	$ (116,713)	$ (134,940)	$ (240,943)	$ (267,516)
Other comprehensive income:				
Unrealized gain on available-for-sale debt securities, net of tax of $0 and $608, for the three months ended June 30, 2020 and 2019, respectively, and net of tax of $0 and $1,148 for the six months ended June 30, 2020 and 2019, respectively	13,171	2,167	5,561	4,075
Less: amounts recognized for net realized loss (gain) included in net loss	1,212	(17)	891	(14)
Total other comprehensive income	14,383	2,150	6,452	4,061
Comprehensive loss	$ (102,330)	$ (132,790)	$ (234,491)	$ (263,455)

[1] Restated to conform to ASC 842. See accompanying Note 2.

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

MODERNA, INC.
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
FOR THE THREE MONTHS AND SIX MONTHS ENDED JUNE 30, 2020 AND 2019
(Unaudited, in thousands except share data)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at March 31, 2020	370,102,805	$ 37	$ 3,267,648	$ (6,127)	$ (1,620,684)	$ 1,640,874
Proceeds from public offering of common stock, net of issuance costs of $978	17,600,000	1	1,303,303	—	—	1,303,304
Vesting of restricted common stock units	46,123	—	—	—	—	—
Exercise of options to purchase common stock, net	5,354,601	1	78,196	—	—	78,197
Purchase of common stock under employee stock purchase plan	173,738	—	2,917	—	—	2,917
Stock-based compensation	—	—	23,923	—	—	23,923
Unrealized loss on marketable securities	—	—	—	14,383	—	14,383
Net loss	—	—	—	—	(116,713)	(116,713)
Balance at June 30, 2020	393,277,267	$ 39	$ 4,675,987	$ 8,256	$ (1,737,397)	$ 2,946,885

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit [1]	Total Stockholders' Equity [1]
	Shares	Amount				
Balance at March 31, 2019	328,853,340	$ 33	$ 2,556,709	$ 591	$ (1,115,008)	$ 1,442,325
Vesting of restricted common stock	58,564	—	—	—	—	—
Exercise of options to purchase common stock, net	1,046,268	—	3,930	—	—	3,930
Transition adjustment from adoption of ASC 606	—	—	—	—	—	—
Transition adjustment from adoption of ASC 842	—	—	—	—	—	—
Stock-based compensation	—	—	21,495	—	—	21,495
Unrealized gain on marketable securities	—	—	—	2,150	—	2,150
Net loss	—	—	—	—	(134,940)	(134,940)
Balance at June 30, 2019	329,958,172	$ 33	$ 2,582,134	$ 2,741	$ (1,249,948)	$ 1,334,960

[1] Restated to conform to ASC 842. See accompanying Note 2.

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2019	336,536,985	$ 34	$ 2,669,426	$ 1,804	$ (1,496,454)	$ 1,174,810
Proceeds from public offering of common stock, net of issuance costs of $2,086	47,863,158	4	1,852,755	—	—	1,852,759
Vesting of restricted common stock units	160,114	—	—	—	—	—
Exercise of options to purchase common stock, net	8,543,272	1	106,553	—	—	106,554
Purchase of common stock under employee stock purchase plan	173,738	—	2,917	—	—	2,917
Stock-based compensation	—	—	44,336	—	—	44,336
Unrealized loss on marketable securities	—	—	—	6,452	—	6,452
Net loss	—	—	—	—	(240,943)	(240,943)
Balance at June 30, 2020	393,277,267	$ 39	$ 4,675,987	$ 8,256	$ (1,737,397)	$ 2,946,885

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit [1]	Total Stockholders' Equity [1]
	Shares	Amount				
Balance at December 31, 2018	328,798,904	$ 33	$ 2,538,155	$ (1,320)	$ (1,006,627)	$ 1,530,241
Vesting of restricted common stock	107,475	—	—	—	—	—
Exercise of options to purchase common stock, net	1,051,793	—	3,987	—	—	3,987
Transition adjustment from adoption of ASC 606	—	—	—	—	27,984	27,984
Transition adjustment from adoption of ASC 842	—	—	—	—	(3,789)	(3,789)
Stock-based compensation	—	—	39,992	—	—	39,992
Unrealized gain on marketable securities	—	—	—	4,061	—	4,061
Net loss	—	—	—	—	(267,516)	(267,516)
Balance at June 30, 2019	329,958,172	$ 33	$ 2,582,134	$ 2,741	$ (1,249,948)	$ 1,334,960

[1] Restated to conform to ASC 842. See accompanying Note 2.

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

MODERNA, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited, in thousands)

	Six Months Ended June 30,	
	2020	**2019** [1]
Operating activities		
Net loss	$ (240,943)	$ (267,516)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	44,336	39,992
Depreciation and amortization	15,045	14,793
Amortization/accretion of investments	1,947	(2,360)
Loss on disposal of property and equipment	226	14
Changes in assets and liabilities:		
Accounts receivable	(27,993)	8,067
Prepaid expenses and other assets	(11,788)	6,035
Right-of-use assets, operating leases	(12,387)	(3,580)
Accounts payable	11,473	(1,471)
Accrued liabilities	20,189	(27,796)
Deferred revenue	51,417	(23,100)
Operating lease liabilities	14,007	3,395
Other liabilities	4,405	674
Net cash used in operating activities	(130,066)	(252,853)
Investing activities		
Purchases of marketable securities	(903,613)	(843,313)
Proceeds from maturities of marketable securities	516,913	563,634
Proceeds from sales of marketable securities	108,016	39,200
Purchases of property and equipment	(24,855)	(18,181)
Net cash used in investing activities	(303,539)	(258,660)
Financing activities		
Proceeds from public offering of common stock, net of issuance costs	1,852,759	—
Proceeds from issuance of common stock through equity plans, net	106,554	3,987
Charges to financing lease obligation	45	483
Net cash provided by financing activities	1,959,358	4,470
Net increase (decrease) in cash, cash equivalents and restricted cash	1,525,753	(507,043)
Cash, cash equivalents and restricted cash, beginning of year	247,699	670,491
Cash, cash equivalents and restricted cash, end of period	$ 1,773,452	$ 163,448
Non-cash investing and financing activities		
Purchases of property and equipment included in accounts payable and accrued liabilities	$ 9,210	$ 6,074

[1] Restated to conform to ASC 842. See accompanying Note 2.

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

MODERNA, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

1. Description of the Business

Moderna, Inc. (collectively, with its consolidated subsidiaries, any of Moderna, we, us, or the Company) was incorporated in Delaware on July 22, 2016. We are the successor in interest to Moderna LLC, a limited liability company formed under the laws of the State of Delaware in 2013. Our principal executive office is located at 200 Technology Square, Cambridge, MA.

We are a biotechnology company creating a new generation of transformative medicines based on messenger RNA (mRNA), to improve the lives of patients. mRNA medicines are designed to direct the body's cells to produce intracellular, membrane, or secreted proteins that have a therapeutic or preventive benefit with the potential to address a broad spectrum of diseases. Our platform builds on continuous advances in basic and applied mRNA science, delivery technology, and manufacturing, providing us the capability to pursue in parallel a robust pipeline of new development candidates. We are developing therapeutics and vaccines for infectious diseases, immuno-oncology, rare diseases, autoimmune and cardiovascular diseases, independently and with our strategic collaborators.

Since inception, we have incurred significant net losses. As of June 30, 2020, we had an accumulated deficit of $1.74 billion. We may continue to incur significant expenses and operating losses for the foreseeable future. In addition, we anticipate that our expenses will increase significantly in connection with our ongoing activities to support our platform research, drug discovery and clinical development, infrastructure and Research Engine and Early Development Engine, digital infrastructure, creation of a portfolio of intellectual property, expansion into global markets, and administrative support.

We do not expect to recognize significant revenue from sales of potential mRNA medicines unless and until we successfully complete clinical development and obtain regulatory approval for one or more of our investigational medicines. If we seek to obtain regulatory approval for any of our investigational medicines, we expect to incur significant commercialization expenses. Our investigational vaccine against the novel coronavirus (mRNA-1273), which is currently in clinical trials, has been developed rapidly to respond to the global COVID-19 pandemic. We are expending significant efforts to further the rapid development of this potential vaccine and expect to continue to do so over the next 12 months. These efforts have required and will continue to require the expenditure of significant funds and the establishment of significant worldwide infrastructure and partnerships.

As a result, we expect we will need substantial additional funding to support our continued operations and pursue our growth strategy. Until we can generate significant revenue from potential mRNA medicines, if ever, we expect to finance our operations through a combination of public or private equity offerings, structured financings and debt financings, government funding arrangements, strategic alliances and marketing, manufacturing, distribution and licensing arrangements. We may be unable to raise additional funds or enter into such other agreements on favorable terms, or at all. If we fail to raise capital or enter into such agreements as, and when, needed, we may have to significantly delay, scale back or discontinue the development and commercialization of one or more of our programs. We believe that our cash, cash equivalents, and investments as of June 30, 2020 will be sufficient to enable us to fund our projected operations through at least the next 12 months from the issuance of our financial statements.

Because of the numerous risks and uncertainties associated with pharmaceutical development, we are unable to predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability. Even if we are able to generate revenues from the sale of our investigational medicines, including mRNA-1273, if approved, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce our operations.

2. Summary of Basis of Presentation and Recent Accounting Standards

Basis of Presentation and Principles of Consolidation

The accompanying unaudited condensed consolidated financial statements that accompany these notes have been prepared in accordance with U.S. generally accepted accounting principles (GAAP) and applicable rules and regulations of the Securities and Exchange Commission (SEC) for interim financial reporting, consistent in all material respects with those applied in our Annual Report on Form 10-K for the year ended December 31, 2019 (2019 Form 10-K). Any reference in these notes to applicable guidance is meant to refer to the authoritative accounting principles generally accepted in the United States as found in the Accounting Standard

Codification (ASC) and Accounting Standards Update (ASU) of the Financial Accounting Standards Board (FASB). This report should be read in conjunction with the consolidated financial statements in our 2019 Form 10-K.

The consolidated financial statements include the Company and its subsidiaries. All intercompany transactions and balances have been eliminated in consolidation.

Use of Estimates

We have made estimates and judgments affecting the amounts reported in our condensed consolidated financial statements and the accompanying notes. On an ongoing basis, we evaluate our estimates, including critical accounting policies or estimates related to revenue recognition, research and development expenses, income tax provisions, stock-based compensation, leases, and useful lives of long-lived assets. We base our estimates on historical experience and on various relevant assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. The actual results that we experience may differ materially from our estimates. Significant estimates relied upon in preparing these financial statements include, among others, those related to fair value of equity awards, revenue recognition, research and development expenses, leases, fair value instruments, useful lives of property and equipment, income taxes, and our valuation allowance on our deferred tax assets.

Significant Accounting Policies

The significant accounting policies used in preparation of these condensed consolidated financial statements for the three and six months ended June 30, 2020 are consistent with those described in our 2019 Form 10-K, except for "Pre-Launch Inventory" and as noted within the "*Recently Adopted Accounting Standards*" section below.

Effective on December 31, 2019, we lost our emerging growth company (EGC) status which accelerated the requirement of ASC 842 (Lease Accounting) adoption. As a result, we adjusted our previously reported consolidated financial statements effective January 1, 2019 in our 2019 Form 10-K, and amendments to previously filed Forms 10-Q were not required. Accordingly, our prior period condensed consolidated financial statements and information, as presented herein, have been restated to conform to the new standard.

The following tables summarize the effects of adopting ASC 842 on our condensed consolidated financial statements for the three and six months ended June 30, 2019 (in thousands, except per share data):

	Three Months Ended June 30, 2019 ASC 842			Six Months Ended June 30, 2019 ASC 842		
	Previously reported	Adjustments	As adjusted	Previously reported	Adjustments	As adjusted
Operating expenses:						
Research and development	$ 128,496	$ (191)	$ 128,305	$ 259,071	$ (353)	$ 258,718
General and administrative	28,523	(36)	28,487	55,806	(66)	55,740
Total operating expenses	157,019	(227)	156,792	314,877	(419)	314,458
Loss from operations	(143,936)	227	(143,709)	(285,769)	419	(285,350)
Other expense, net	(1,764)	(113)	(1,877)	(3,584)	(224)	(3,808)
Loss before benefit from income taxes	(135,378)	114	(135,264)	(268,059)	195	(267,864)
Net loss	(135,054)	114	(134,940)	(267,711)	195	(267,516)
Net loss per share attributable to common stockholders, basic and diluted	(0.41)	—	(0.41)	(0.81)	—	(0.81)

	Six Months Ended June 30, 2019		
	Previously reported	ASC 842 Adjustment during the period	As adjusted
Operating activities			
Net loss	$ (267,711)	$ 195	$ (267,516)
Depreciation and amortization	14,817	(24)	14,793
Prepaid expenses and other assets	2,315	3,720	6,035
Right-of-use assets, operating leases	—	(3,580)	(3,580)
Deferred lease obligation	1,033	(1,033)	—
Operating lease liabilities	—	3,395	3,395
Other liabilities	53	621	674
Net cash used in operating activities	(256,147)	3,294	(252,853)
Financing activities			
Reimbursement of assets under lease financing obligation	3,678	(3,678)	—
Charges to financing lease obligation	—	483	483
Payments on financing lease obligation	99	(99)	—
Net cash provided by financing activities	7,764	(3,294)	4,470

Comprehensive Loss

Comprehensive loss includes net loss and other comprehensive (loss) income for the period. Other comprehensive (loss) income consists of unrealized gains and losses on our investments. Total comprehensive loss for all periods presented has been disclosed in the condensed consolidated statements of comprehensive loss.

The components of accumulated other comprehensive (loss) income for the three and six months ended June 30, 2020 are as follows (in thousands):

	Unrealized (Loss) Gain on Available-for-Sale Debt Securities
Accumulated other comprehensive income, balance at December 31, 2019	$ 1,804
Other comprehensive loss	(7,931)
Accumulated other comprehensive loss, balance at March 31, 2020	(6,127)
Other comprehensive income	14,383
Accumulated other comprehensive income, balance at June 30, 2020	$ 8,256

Restricted Cash

We include our restricted cash balance in the cash, cash equivalents and restricted cash reconciliation of operating, investing and financing activities in the condensed consolidated statements of cash flows.

The following table provides a reconciliation of cash, cash equivalents and restricted cash in the condensed consolidated balance sheets that sum to the total of the same such amounts shown in the condensed consolidated statements of cash flows (in thousands):

	As of June 30,	
	2020	2019
Cash and cash equivalents	$ 1,761,629	$ 151,624
Restricted cash	1,032	62
Restricted cash, non-current	10,791	11,762
Total cash, cash equivalents and restricted cash shown in the condensed consolidated statements of cash flows	$ 1,773,452	$ 163,448

Pre-Launch Inventory

Prior to an initial regulatory approval for our investigational medicines, we expense costs relating to production of inventory as research and development expense in our condensed consolidated statements of operations, in the period incurred. When we believe regulatory approval and subsequent commercialization of our investigational medicines is probable, and we also expect future economic benefit from the sales of the investigational medicines to be realized, we will then capitalize the costs of production as inventory.

Recently Adopted Accounting Standards

In June 2016, the FASB issued ASU No. 2016-13, *Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments.* This standard changes how companies account for credit losses for most financial assets and certain other instruments. For trade receivables, loans and held-to-maturity debt securities, companies will be required to recognize an allowance for credit losses rather than reducing the carrying value of the asset. The amendments in this standard should be applied on a modified retrospective basis to all periods presented. We adopted this standard in the first quarter of 2020. Based on the composition of our investment portfolio and investment policy, the adoption of this standard did not have a material impact on our consolidated financial statements and disclosures.

In August 2018, the FASB issued ASU 2018-15, *Intangibles—Goodwill and Other—Internal-Use Software (Topic 350): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract.* This standard requires capitalizing implementation costs incurred to develop or obtain internal-use software (and hosting arrangements that include an internal-use software license). We adopted this standard in the first quarter of 2020 using the prospective method. The adoption of this standard did not have a material impact on our consolidated financial statements and disclosures.

In December 2019, the FASB issued ASU 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*. This standard removes certain exceptions for investments, intraperiod allocations and interim calculations, and adds guidance to reduce complexity in accounting for income taxes. We early adopted this standard in the second quarter of 2020. The adoption of this standard did not have a material impact on our consolidated financial statements and disclosures.

Recently Issued Accounting Standards

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies and adopted by us as of the specified effective date. Unless otherwise discussed, we believe that the impact of recently issued standards that are not yet effective will not have a material impact on our consolidated financial statements and disclosures.

3. Collaboration Revenue

The following table summarizes our total consolidated net revenue from our strategic collaborators for the periods presented (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
Collaboration Revenue by Strategic Collaborator:	**2020**	**2019**	**2020**	**2019**
AstraZeneca	$ 15,884	$ 188	$ 17,154	$ 1,002
Merck	10,366	8,659	11,342	19,346
Vertex	2,192	1,183	4,248	3,797
Other	—	—	155	—
Total collaboration revenue	$ 28,442	$ 10,030	$ 32,899	$ 24,145

The following table presents changes in the balances of our receivables and contract liabilities related to our strategic collaboration agreements during the six months ended June 30, 2020 (in thousands):

	December 31, 2019	Additions	Deductions	June 30, 2020
Contract Assets:				
Accounts receivable	$ 1,972	$ 10,497	$ (8,120)	$ 4,349
Contract Liabilities:				
Deferred revenue	$ 199,528	$ 10,493	$ (37,057)	$ 172,964

During the three and six months ended June 30, 2020, we recognized the following revenue as a result of the change in the contract liability balances related to our collaboration agreements (in thousands):

Revenue recognized in the period from:	Three Months Ended June 30, 2020	Six Months Ended June 30, 2020
Amounts included in contract liabilities at the beginning of the period [1]	$ 30,753	$ 37,057
Performance obligations satisfied (or partially satisfied) in previous reporting periods [2]	—	1,262

[1] We first allocate revenue to the individual contract liability balance outstanding at the beginning of the period until the revenue exceeds that balance. If additional consideration is received on those contracts in subsequent periods, we assume all revenue recognized in the reporting period is first applied to the beginning contract liability.

[2] Related to changes in estimated costs for our future performance obligations and estimated variable considerations.

As of June 30, 2020, the aggregated amount of the transaction price allocated to performance obligations under our collaboration agreements that are unsatisfied or partially unsatisfied was $249.9 million.

AstraZeneca – Strategic Alliances in Cardiovascular and Oncology

2013 Option Agreement and Services and Collaboration Agreement

In March 2013, we entered into an Option Agreement, the AZ Option Agreement, and a related Services and Collaboration Agreement, the AZ Services Agreement, with AstraZeneca, which were amended and restated in June 2018. We refer to these agreements in the forms that existed prior to the 2018 amendment and restatement as the 2013 AZ Agreements. Under the 2013 AZ Agreements, we granted AstraZeneca certain exclusive rights and licenses, and options to obtain exclusive rights to develop and commercialize potential therapeutic mRNA medicines directed at certain targets for the treatment of cardiovascular and cardiometabolic diseases and cancer, and agreed to provide related services to AstraZeneca. Pursuant to the 2013 AZ Agreements, AstraZeneca was responsible for all research, development and commercialization activities, while we provided specified research and manufacturing services during a research and evaluation period, as described below, to further AstraZeneca's activities pursuant to an agreed upon services plan. Under the 2013 AZ Agreements, AstraZeneca could have requested we provide additional services, at AstraZeneca's expense. Subject to customary "back-up" supply rights granted to AstraZeneca, we exclusively manufactured (or had manufactured) mRNA for all research, development and commercialization purposes under the 2013 AZ Agreements until, on a product-by-product basis, the expiration of the time period for which we are entitled to receive earn-out payments with respect to such product pursuant to the 2013 AZ Agreements.

As of the effective date of the 2013 AZ Agreements, AstraZeneca acquired forty options that it may exercise to obtain exclusive rights to clinically develop and commercialize identified development candidates (and related back-up candidates) directed to specified targets that arise during the research and evaluation period. During the research and evaluation period for research candidates under the 2013 AZ Agreements, AstraZeneca could have elected to designate a limited number of research candidates as development candidates in order to continue preclinical development on such development candidates (and related back-up candidates). From such pool of development candidates designated by AstraZeneca, during a specified option exercise period, AstraZeneca could have then exercised one of its options to obtain exclusive rights to clinically develop and commercialize an identified development candidate (and related back-up candidates). If AstraZeneca did not exercise one of its options to acquire exclusive rights to clinically develop and commercialize a particular development candidate during the defined option exercise period for such development candidate, AstraZeneca's rights to exercise an option and other rights granted under the 2013 AZ Agreements with respect to such development candidate (and related back-up candidates) would terminate, all rights to exploit such development candidate (and related back-up candidates) would be returned to us and all data and results generated by AstraZeneca with respect to such development candidate (and related back-up candidates) would be either assigned or licensed to us. Upon the earlier of termination of the 2013 AZ Agreements for any reason and a specified anniversary of the effective date of the 2013 AZ Agreements, all unexercised options, and the right to exercise any and all options if not previously exercised by AstraZeneca, would automatically terminate. On a target-by-target basis, we and AstraZeneca agreed to certain defined exclusivity obligations under the 2013 AZ Agreements with respect to the research, development and commercialization of mRNA medicines for such target.

As of the effective date of the 2013 AZ Agreements, AstraZeneca made upfront cash payments to us totaling $240.0 million. Under the 2013 AZ Agreements, we were entitled to receive payments that are not related to any specific program of up to $180.0 million in the aggregate for the achievement of three technical milestones relating to toxicity, delivery, and competition criteria. We achieved the toxicity and competition milestones in the year ended December 31, 2015. The delivery milestone has expired. Under the 2013 AZ Agreements, AstraZeneca was obligated to pay us a $10.0 million option exercise fee with respect to each development candidate (and related back-up candidates) for which it exercised an option. In addition, upon AstraZeneca's exercise of each option, we were eligible to receive certain payments contingent upon the achievement of specified clinical, regulatory, and commercial events. For any product candidate optioned by AstraZeneca, we were eligible to receive, per product candidate, up to $100.0 million in payments for achievement of development milestones, up to $100.0 million payments for achievement of regulatory milestones, and up to $200.0 million payments for achievement of commercial milestones. Additionally, under the 2013 AZ Agreements, we were entitled to receive, on a product-by-product basis, earn-out payments on worldwide net sales of products ranging from a high-single digit percentage to 12%, subject to certain reductions, with an aggregate minimum floor.

We received from AstraZeneca under the 2013 AZ Agreements an option exercise payment of $10.0 million (the 2016 VEGF Exercise) in the year ended December 31, 2016, and a clinical milestone payment of $30.0 million with respect to AstraZeneca's VEGF-A product (AZD8601) during the year ended December 31, 2018, that is currently being developed in a Phase 2 clinical trial in certain fields. Unless earlier terminated, the 2013 AZ Agreements would have continued until the expiration of AstraZeneca's earn-out and contingent option exercise payment obligations for optioned product candidates. Either party had the right to terminate the 2013 AZ Agreements upon the other party's material breach, either in its entirety or in certain circumstances, with respect to relevant candidates, subject to a defined materiality threshold and specified notice and cure provisions. If AstraZeneca had the right to terminate the 2013 AZ Agreements for our material breach, then AstraZeneca could have elected, in lieu of terminating the 2013 AZ

Agreements, in their entirety or with respect to such candidates, to have the 2013 AZ Agreements remain in effect, subject to reductions in certain payments we were eligible to receive and certain adjustments to AstraZeneca's obligations under the 2013 AZ Agreements. AstraZeneca had the right to terminate the 2013 AZ Agreements in full, without cause, upon 90-days' prior notice to us.

2016 Strategic Alliance with AstraZeneca – IL-12

In January 2016, we entered into a new Strategic Drug Development Collaboration and License Agreement, which we refer to as the 2016 AZ Agreement, with AstraZeneca to discover, develop and commercialize potential mRNA medicines for the treatment of a range of cancers.

Under the terms of the 2016 AZ Agreement, we and AstraZeneca have agreed to work together on an immuno-oncology program focused on the intratumoral delivery of a potential mRNA medicine to make the IL-12 protein. The 2016 AZ Agreement initially included research activities with respect to a second discovery program. During a limited period of time, each party had an opportunity to propose additional discovery programs to be conducted under the 2016 AZ Agreement. We are responsible for conducting and funding all discovery and preclinical development activities under the 2016 AZ Agreement in accordance with an agreed upon discovery program plan for the IL-12 program and any other discovery program the parties agree to conduct under the 2016 AZ Agreement. For the IL-12 program and any other discovery program the parties agree to conduct under the 2016 AZ Agreement, during a defined election period that commenced as of the effective date of the 2016 AZ Agreement (for the IL-12 program) and otherwise will commence on initiation of any such new discovery program, AstraZeneca may elect to participate in the clinical development of a development candidate arising under the 2016 AZ Agreement from such program. If AstraZeneca so elects (as it has for the IL-12 program), AstraZeneca will lead clinical development activities worldwide and we will be responsible for certain activities, including being solely responsible for manufacturing activities, all in accordance with an agreed upon development plan. AstraZeneca will be responsible for funding all Phase 1 clinical development activities (including costs associated with our manufacture of clinical materials in accordance with the development plan), and Phase 2 clinical development activities (including costs associated with our manufacture of clinical materials in accordance with the development plan) up to a defined dollar threshold. We and AstraZeneca will equally share the costs of Phase 2 clinical development activities in excess of such dollar threshold, all Phase 3 clinical development activities and certain other costs of late-stage clinical development activities, unless we elect not to participate in further development and commercialization activities and instead receive tiered royalties, as described below.

We and AstraZeneca will co-commercialize products in the United States in accordance with an agreed upon commercialization plan and budget, and on a product-by-product basis will equally share the U.S. profits or losses arising from such commercialization. Notwithstanding, on a product-by-product basis, prior to a specified stage of development of a given product, we have the right to elect not to participate in the further development and commercialization activities for such product. If we make such election, instead of participating in the U.S. profits and losses share with respect to such product, we are obligated to discuss future financial terms with AstraZeneca. If we are unable to agree on future financial terms within a short, defined period of time, we are entitled to receive tiered royalties at default rates set forth in the 2016 AZ Agreement, ranging from percentages in the mid-single digits to 20% on worldwide net sales of products, subject to certain reductions with an aggregate minimum floor. AstraZeneca has sole and exclusive responsibility for all ex-U.S. commercialization efforts. Unless we have elected to not to participate in further development (in which case royalties on ex-U.S. net sales will be at the default rates as described above, unless otherwise agreed by the parties), we are entitled to tiered royalties at rates ranging from 10% to 30% on ex-U.S. net sales of the products, subject to certain reductions with an aggregate minimum floor. Subject to customary "back-up" supply rights granted to AstraZeneca, we exclusively manufacture (or have manufactured) products for all development and commercialization purposes. We and AstraZeneca have agreed to certain defined exclusivity obligations with each other under the 2016 AZ Agreement with respect to the development and commercialization of mRNA medicines for IL-12.

Unless earlier terminated, our strategic alliance under the 2016 AZ Agreement will continue on a product-by-product basis (i) until both parties cease developing and commercializing such product without the intention to resume, if we have not elected our right not to participate in further development and commercialization of such product or (ii) on a country-by-country basis, until the end of the applicable royalty term for such product in such country, if we have elected our right not to participate in further development and commercialization of such product.

Either party may terminate the 2016 AZ Agreement upon the other party's material breach, subject to specified notice and cure provisions. Each party may also terminate the 2016 AZ Agreement in the event the other party challenges such party's patent rights, subject to certain defined exceptions. AstraZeneca has the right to terminate the 2016 AZ Agreement in full or with respect to any program for scientific, technical, regulatory or commercial reasons at any time upon 90 days' prior written notice to us. On a product-by-product basis, we have the right to terminate the 2016 AZ Agreement in certain cases if AstraZeneca has suspended or is no longer proceeding with the development or commercialization of such product for a period of twelve consecutive months, subject to specified

exceptions, including tolling for events outside of AstraZeneca's control. On a product-by-product basis, if the 2016 AZ Agreement is terminated with respect to a given product, AstraZeneca's rights in such product will terminate and, to the extent we terminated for AstraZeneca's breach, patent challenge or cessation of development or AstraZeneca terminated in its discretion, AstraZeneca will grant us reversion licenses and take certain other actions so as to enable us to continue developing and commercializing such product in the oncology field.

If we continue developing and commercializing a given product following termination of the 2016 AZ Agreement by AstraZeneca in its discretion with respect to such product, AstraZeneca is entitled to receive a mid-single digit royalty on our worldwide net sales of such product and a high-single digit percentage of the amounts received by us from a third party in consideration of a license to such third party to exploit such product, in each case, until AstraZeneca recovers an amount equal to specified development costs incurred by AstraZeneca under the 2016 AZ Agreement with respect to such product prior to such termination. Such percentages increase by a low to mid-single digit amount to the extent such termination occurs after such product achieves a specified stage of development.

2017 Strategic Alliance with AstraZeneca – Relaxin

In October 2017, we entered a new Collaboration and License Agreement, which we refer to as the 2017 AZ Agreement, under which AstraZeneca may clinically develop and commercialize a development candidate, now known as AZD7970, which is comprised of an mRNA construct for the relaxin protein designed by us and encapsulated in one of our proprietary lipid nanoparticles (LNP). We discovered and performed preclinical development activities for AZD7970 prior to the initiation of the strategic alliance with AstraZeneca under the 2017 AZ Agreement.

Under the terms of the 2017 AZ Agreement, we will fund and be responsible for conducting preclinical development activities for AZD7970 through completion of IND-enabling GLP toxicology studies and AstraZeneca will lead pharmacological studies, each in accordance with an agreed upon discovery program plan. During a defined election period that commences as of the effective date of the 2017 AZ Agreement, AstraZeneca may elect to participate in further development and commercialization of AZD7970. Upon such election, AstraZeneca will lead clinical development activities for AZD7970 worldwide and we will be responsible for manufacturing AZD7970, certain regulatory matters and any other development activities that we agree to perform and that are set forth in an agreed upon development plan. AstraZeneca will be responsible for funding Phase 1 clinical development activities (including costs associated with our manufacture of clinical materials in accordance with the development plan, up to a cap above which such costs are shared), and Phase 2 clinical development activities (including costs associated with our manufacture of clinical materials in accordance with the development plan, up to a cap above which such costs are shared) up to a defined dollar threshold. Thereafter, we and AstraZeneca will equally share the costs of Phase 2 clinical development activities in excess of such defined dollar threshold, all Phase 3 clinical development activities and certain other costs of late-stage clinical development activities, unless we elect not to participate in further development and co-commercialization activities and instead receive tiered royalties as described below. If the development candidate is determined to be IND-ready, and AstraZeneca does not timely elect to participate in the clinical development of AZD7970, AstraZeneca is obligated to reimburse us for certain costs we incurred in the manufacture and development of AZD7970, since execution of the 2017 AZ Agreement.

We and AstraZeneca will co-commercialize AZD7970 in the United States in accordance with an agreed upon commercialization plan and budget, and will equally share U.S. profits or losses arising from such commercialization. Notwithstanding, prior to a specified stage of development of AZD7970, we have the right to elect not to participate in the further development and commercialization activities for AZD7970. If we make such election, instead of participating in the U.S. profits and losses share with respect to AZD7970, we are obligated to discuss future financial terms with AstraZeneca. If we are unable to agree on future financial terms within a short, defined period of time, we are entitled to receive tiered royalties at default rates set forth in the 2017 AZ Agreement, ranging from percentages in the mid-single digits to the low 20s on worldwide net sales by AstraZeneca of AZD7970, subject to certain reductions, with an aggregate minimum floor. AstraZeneca has sole and exclusive responsibility for all ex-U.S. commercialization efforts. Unless we have elected not to participate in further development (in which case royalties on ex-U.S. net sales will be at the default rates as described above, unless otherwise agreed by the parties), we are entitled to receive tiered royalties at rates ranging from 10% to 30% on annual ex-U.S. net sales of AZD7970, subject to certain reductions with an aggregate minimum floor. Subject to customary "back-up" supply rights granted to AstraZeneca, we exclusively manufacture (or have manufactured) products for all development and commercialization purposes. Additionally, we and AstraZeneca have agreed to certain defined exclusivity obligations under the 2017 AZ Agreement with respect to the development and commercialization of mRNA medicines for Relaxin.

Unless earlier terminated, our strategic alliance under the 2017 AZ Agreement will continue (i) until the expiration of AstraZeneca's election period, if it does not elect to participate in the clinical development of AZD7970, (ii) until both parties cease developing and commercializing AZD7970 without the intention to resume, if we have not elected our right not to participate in further development

and commercialization of AZD7970, (iii) on a country-by-country basis, until the end of the applicable royalty term for AZD7970 in such country, if we have elected our right not to participate in further development and commercialization of AZD7970 or (iv) following completion of IND-enabling studies with respect to AZD7970, if we provide AstraZeneca with written notice that we do not reasonably believe that the product is IND-ready.

Either party may terminate the 2017 AZ Agreement upon the other party's material breach, subject to specified notice and cure provisions. Each party may also terminate the 2017 AZ Agreement in the event the other party challenges the validity or enforceability of such party's patent rights, subject to certain defined exceptions. AstraZeneca has the right to terminate the 2017 AZ Agreement in full for scientific, technical, regulatory or commercial reasons at any time upon 90 days' prior written notice to us. We have the right to terminate the 2017 AZ Agreement in certain cases if AstraZeneca has suspended or is no longer proceeding with the development or commercialization of AZD7970 for a period of twelve consecutive months, subject to specified exceptions, including tolling for events outside of AstraZeneca's control. If AstraZeneca does not timely elect to participate in clinical development of AZD7970, or the Agreement is terminated, AstraZeneca's rights in AZD7970 will terminate and, to the extent we terminated for AstraZeneca's breach, patent challenge or cessation of development or AstraZeneca terminated in its discretion, AstraZeneca will grant us reversion licenses and take certain other actions so as to enable us to continue developing and commercializing AZD7970 in the cardiovascular and cardiometabolic fields.

If we continue developing and commercializing AZD7970 following a termination of the 2017 AZ Agreement by AstraZeneca in its discretion, AstraZeneca is entitled to receive a mid-single digit royalty on our worldwide net sales of AZD7970 and a high-single digit percentage of the amounts received by us from a third party in consideration for a license to such third party to exploit AZD7970, in each case until AstraZeneca recovers an amount equal to specified development costs incurred by AstraZeneca under the 2017 AZ Agreement with respect to AZD7970 prior to such termination. Such percentages increase by a low to mid-single digit amount to the extent such termination occurs after such product achieves a specified stage of development.

2013 Agreements with AstraZeneca, amended and restated in 2018

In June 2018, we entered into an Amended and Restated Option Agreement and a related Amended and Restated Services and Collaboration Agreement with AstraZeneca, or the 2018 A&R Agreements, which amended and restated the 2013 AZ Agreements. Under the 2018 A&R Agreements, we granted AstraZeneca certain exclusive rights and licenses to research, develop and commercialize potential therapeutic mRNA medicines directed at certain targets for the treatment of cardiovascular and cardiometabolic diseases and cancer, and agreed to provide related services to AstraZeneca. The activities to be performed by the parties under the 2018 A&R Agreements are limited to defined biological targets in the cardiovascular and cardiometabolic fields and one defined target in the cancer field.

Pursuant to the 2018 A&R Agreements, AstraZeneca is responsible for all research, development and commercialization activities and associated costs, while we provide specified research and manufacturing services during a research and evaluation period, as described below, to further AstraZeneca's activities conducted pursuant to an agreed upon services plan. During this research and evaluation period, these research services, and manufacturing services in excess of a specified threshold, are provided at AstraZeneca's expense, and manufacturing services below the specified threshold are provided at no additional expense to AstraZeneca. AstraZeneca may request we provide additional research and manufacturing services, at AstraZeneca's expense, following the end of the research and evaluation period. Subject to customary "back-up" supply rights granted to AstraZeneca, we exclusively manufacture (or have manufactured) mRNA for all research, development and commercialization purposes under the 2018 A&R Agreements until, on a product-by-product basis, the expiration of the time period for which we are entitled to receive earn-out payments with respect to such product pursuant to the 2018 A&R Agreements.

As of the effective date of the 2013 AZ Agreements, and as further reflected in the 2018 A&R Agreements, AstraZeneca acquired forty options that it may exercise to obtain exclusive rights to clinically develop and commercialize identified development candidates (and related back-up candidates) directed to specified targets that arise during the research and evaluation period. During the research and evaluation period for research candidates, AstraZeneca may elect to designate a limited number of research candidates as development candidates in order to continue preclinical development on such development candidates (and related back-up candidates). From such pool of development candidates designated by AstraZeneca, during a specified option exercise period, AstraZeneca may then exercise one of its options to obtain exclusive rights to clinically develop and commercialize an identified development candidate (and related back-up candidates) in certain fields. If AstraZeneca does not exercise one of its options to acquire exclusive rights to clinically develop and commercialize a particular development candidate during the defined option exercise period for such development candidate, AstraZeneca's rights to exercise an option and other rights granted under the 2018 A&R Agreements with respect to such development candidate (and related back-up candidates) will terminate, all rights to exploit such development candidate (and related back-up candidates) will be returned to us and all data and results generated by AstraZeneca with respect to

such development candidate (and related back-up candidates) will be either assigned or licensed to us. Upon the earlier of termination of the 2018 A&R Agreements for any reason and a specified anniversary of the effective date of the 2013 AZ Agreements, all unexercised options, and the right to exercise any and all options if not previously exercised by AstraZeneca, will automatically terminate.

On a target-by-target basis, we and AstraZeneca have agreed to certain defined exclusivity obligations under the 2018 A&R Agreements with respect to the research, development and commercialization of mRNA medicines for such target in certain fields. In addition, we and AstraZeneca have agreed to certain defined exclusivity obligations with respect to the research, development and commercialization of mRNA medicines coding for the same polypeptide as any development candidate being developed under the 2018 A&R Agreements.

Unless earlier terminated, the 2018 A&R Agreements will continue until the expiration of AstraZeneca's earn-out and contingent option exercise payment obligations for optioned product candidates. Either party may terminate the 2018 A&R Agreements upon the other party's material breach, either in its entirety or in certain circumstances, with respect to relevant candidates, subject to a defined materiality threshold and specified notice and cure provisions. If AstraZeneca has the right to terminate the 2018 A&R Agreements for our material breach, then AstraZeneca may elect, in lieu of terminating the 2018 A&R Agreements, in their entirety or with respect to such candidates, to have the 2018 A&R Agreements remain in effect, subject to reductions in certain payments we are eligible to receive and certain adjustments to AstraZeneca's obligations under the 2018 A&R Agreements. AstraZeneca may terminate the 2018 A&R Agreements in full, without cause, upon 90 days' prior notice to us.

Accounting Treatment

We applied the provisions of ASC 606 (Revenue from Contracts with Customers) in accounting for these arrangements, except for the 2017 AZ Agreement which was accounted for under ASC 808 (Collaborative Arrangements). In August 2016, AstraZeneca exercised a product option available pursuant to the 2013 AZ Agreements to obtain exclusive rights to clinically develop and commercialize the VEGF-A product (AZD8601). This option exercise is referred to as the 2016 VEGF Exercise. Pursuant to ASC 606, we determined that the 2016 VEGF Exercise and the 2017 AZ Agreement should be accounted for as separate transactions as the agreements are not interrelated or interdependent. Conversely, the 2013 Agreements, as amended by the 2018 A&R Agreements, and the 2016 AZ Agreement, were combined for accounting purposes and treated as a single agreement, as these agreements were negotiated in contemplation of each other. We refer to this combined transaction as the Combined 2018 AZ Agreements. We determined that all aspects of Combined 2018 AZ Agreements and the 2016 VEGF Exercise represent a transaction with a customer and therefore is accounted for in accordance with ASC 606.

Combined 2018 AZ Agreements

We identified the following performance obligations in the Combined 2018 AZ Agreements: (i) a combined performance obligation that includes a research license, research and development pool services, and manufacturing obligations related to the 2013 AZ Agreements, as amended by the 2018 A&R Agreements, collectively referred to as the Combined 2018 AZ Agreement Performance Obligation, (ii) preclinical development services for IL-12, (iii) preclinical development services for an oncology development target, (iv) a combined performance obligation for a development and commercialization license and manufacturing obligations for IL-12, and (v) a material right to receive development and commercialization rights and manufacturing services for an oncology development target.

We concluded that the research license is not distinct from the research and development pool services or the manufacturing obligations related to the 2018 A&R Agreements, as AstraZeneca cannot fully exploit the value of the research license without receipt of such services and supply. Our services and supply involve specialized expertise, particularly as it relates to mRNA technology that is not available in the marketplace. Any supply requested by AstraZeneca in excess of the minimum quantities specified in the agreement are considered customer options and treated as separate contracts for accounting purposes. Further, we concluded that AstraZeneca cannot exploit the value of the development and commercialization license for IL-12 without receipt of supply as the development and commercialization license does not convey to AstraZeneca the right to manufacture and therefore combined the development and commercialization license and the manufacturing obligations for IL-12 into one performance obligation.

The following table summarizes the composition of the total transaction price for the periods presented (in thousands):

	Transaction Price	
Combined 2018 AZ Agreements:	June 30, 2020	December 31, 2019
Upfront payments	$ 240,000	$ 240,000
Sublicense reimbursement	1,000	1,000
Toxicity milestone payment	60,000	60,000
Competition milestone payment	60,000	60,000
Estimated reimbursement for IL-12 manufacturing obligations	38,089	40,782
Total	$ 399,089	$ 401,782

We utilize the most likely amount method to determine the amount of reimbursement for IL-12 manufacturing obligations to be received. We determined that any sales-based royalties related to IL-12 will be recognized when the related sales occur as they were determined to relate predominately to the license granted and therefore have been excluded from the transaction price. In addition, we are eligible to receive future milestones and royalties on future commercial sales for optioned product candidates under the 2018 A&R Agreements and future royalties under the 2016 Agreement; however, these amounts are not considered variable consideration under the Combined 2018 Agreements as we are only eligible to receive such amounts if AstraZeneca exercises its options (including certain options that are deemed to be material rights). We have concluded that the exercise of an optioned product candidate represents a separate transaction under ASC 606. We re-evaluate the transaction price at the end of each reporting period. There was a $2.7 million decrease to the transaction price during the six months ended June 30, 2020, resulting from a change in estimate of variable consideration.

The transaction price was allocated to the performance obligations based on the relative estimated standalone selling prices of each performance obligation. We developed the estimated standalone selling price for the licenses included in the Combined 2018 AZ Agreement Performance Obligation and the combined performance obligation for a development and commercialization license and manufacturing obligations for IL-12 primarily based on the probability-weighted present value of expected future cash flows associated with each license related to each specific program. In developing such estimate, we also considered applicable market conditions and relevant entity-specific factors, including those factors contemplated in negotiating the agreement, probability of success and the time needed to commercialize a product candidate pursuant to the associated license. We developed the estimated standalone selling price for the services and/or manufacturing and supply included in each of the performance obligation, as applicable, primarily based on the nature of the services to be performed and/or goods to be manufactured and estimates of the associated costs, adjusted for a reasonable profit margin that would be expected to be realized under similar contracts. The estimated standalone selling price of the material right to receive development and commercialization rights and manufacturing services for an oncology development target was developed by estimating the amount of discount that AstraZeneca would receive when exercising the option and adjusting such amount by the likelihood that the option will be exercised.

The following table summarizes the allocation of the total transaction price to the identified performance obligations under the arrangement, and the amount of the transaction price unsatisfied as of June 30, 2020 (in thousands):

	Transaction Price
Combined 2018 AZ Agreements:	June 30, 2020
Combined 2018 AZ Agreement performance obligation	$ 293,223
Preclinical development service - IL-12	8,133
Preclinical development service - oncology development target	8,133
Development and commercialization license and manufacturing obligation	88,009
Material right to receive development and commercialization rights	1,591
Total	$ 399,089
Remaining unsatisfied performance obligation	$ 104,945

As of June 30, 2020, $95.2 million of the remaining performance obligations that are unsatisfied is expected to be recognized as revenue through December 31, 2029 and $9.7 million is expected to be recognized as revenue at the earlier of expiration or modification of the Combined 2018 AZ Agreement.

We measure proportional performance over time using an input method based on cost incurred relative to the total estimated costs for the Combined 2018 AZ Agreement Performance Obligation and the preclinical development services for IL-12 and the other oncology target performance obligations. We recognize revenue related to the amounts allocated to the combined performance obligation for a development and commercialization license and manufacturing obligations for IL-12 based on the point in time upon which control of supply is transferred to AstraZeneca for each delivery of the associated supply.

We recognize revenue for the Combined 2018 AZ Agreement Performance Obligation, on a quarterly basis, by determining the proportion of effort incurred as a percentage of total effort we expect to expend. This ratio is applied to the transaction price allocated to this combined performance obligation. We also estimate the development plan, including expected demand from AstraZeneca, and the associated costs for this combined performance obligation, as we will satisfy this combined performance obligation as the manufacturing services are performed. Management has applied significant judgment in the process of developing our budget estimates. Any changes to these estimates will be recognized in the period in which they change as a cumulative catch up.

The following table summarizes the revenue recognized for the periods presented (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Combined AZ Agreements	$ 1,218	$ 214	$ 2,901	$ 1,028

The revenue recognized for the three and six months ended June 30, 2020 includes the amortization of deferred revenue due to the satisfaction of our performance obligation during the period, offset by a cumulative catch-up adjustment of $1.4 million in the first quarter due to changes in estimated costs for our future performance obligations.

The following table summarizes the balances of deferred revenue at period end, which is classified as current or non-current in the condensed consolidated balance sheets based on the period the services are expected to be performed or control of the supply is expected to be transferred (in thousands):

	June 30, 2020	December 31, 2019
Combined AZ Agreements	$ 71,398	$ 73,669

2016 VEGF Exercise

We concluded that the 2016 VEGF Exercise should be treated as a separate transaction for accounting purposes. We identified one performance obligation in this arrangement which is comprised of the exclusive license to develop and commercialize VEGF and the manufacturing of clinical supply. We concluded that the VEGF license is not distinct from the manufacturing obligations because AstraZeneca cannot fully exploit the value of the license without receipt of such supply. This is due to limitations inherent in the licenses conveyed wherein AstraZeneca does not have the contractual right to manufacture during the term of the agreement.

The following table summarizes the composition of the total transaction price for the periods presented (in thousands):

	Transaction Price	
	June 30, 2020	December 31, 2019
2016 VEGF Exercise:		
Option exercise fee	$ 10,000	$ 10,000
Milestone payment	$ 30,000	$ 30,000
Sublicense reimbursement	2,250	2,250
Estimated reimbursement for clinical supply	18,062	15,621
Total	$ 60,312	$ 57,871

We are eligible to receive future milestones and royalties on future commercial sales under this arrangement. We utilize the most likely amount method to estimate any development and regulatory milestone payments to be received and the amount of estimated reimbursement for clinical supply. As of June 30, 2020, there were no milestones that had not been achieved included in the transaction price. We considered the stage of development and the risks associated with the remaining development required to

achieve each milestone, as well as whether the achievement of the milestone is outside of our or AstraZeneca's control. The outstanding milestone payments were fully constrained, as a result of the uncertainty whether any of the milestones would be achieved. We determined that any commercial milestones and sales-based royalties will be recognized when the related sales occur as they were determined to relate predominantly to the license granted and therefore have also been excluded from the transaction price. We re-evaluate the transaction price at the end of each reporting period and as uncertain events are resolved or other changes in circumstances occur. When a milestone payment is included in the transaction price in the future, it is recognized as revenue based on the relative completion of the underlying performance obligation. There was a $2.4 million increase to the transaction price during the six months ended June 30, 2020, resulting from a change in estimate of variable consideration.

The following table summarizes the total transaction price allocated to the single identified performance obligation under the arrangement, and the amount of the transaction price unsatisfied as of June 30, 2020 (in thousands):

	Transaction Price June 30, 2020
2016 VEGF Exercise combined performance obligation	$ 60,312
Remaining unsatisfied performance obligation	41,877

As of June 30, 2020, the aggregate amount of the transaction price allocated to the remaining performance obligation that is unsatisfied is expected to be recognized as revenue through December 31, 2025.

We recognize revenue related to the amount of the transaction price allocated to the VEGF Exercise performance obligation based on the point in time upon which control of supply is transferred to AstraZeneca for each delivery of the associated supply.

The following table summarizes the revenue recognized for the periods presented (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
2016 VEGF Exercise	$ 14,666	$ (26)	$ 14,253	$ (26)

The revenue recognized for the three and six months ended June 30, 2020 includes the amortization of deferred revenue due to the satisfaction of our performance obligation during the period, offset by a cumulative catch-up adjustment in the first quarter of $0.4 million as a reduction of revenue due to changes in estimated costs for our future performance obligation associated with the 2016 VEGF Exercise.

The following table summarizes the balances of deferred revenue at period end, which is classified as current or non-current in the condensed consolidated balance sheets based on the period the control of the supply is expected to be transferred for the periods presented (in thousands):

	June 30, 2020	December 31, 2019
2016 VEGF Exercise	$ 29,319	$ 41,166

2017 AZ Agreement

We concluded the 2017 AZ Agreement is under the scope of ASC 808 as we and AstraZeneca are both active participants in the development, manufacturing and commercialization activities and are exposed to significant risks and rewards that are dependent on commercial success of the activities of the arrangement. Additionally, we determined the development, manufacturing and commercialization activities are not deliverables under ASC 606. As a result, the activities conducted pursuant to the development, manufacturing and commercialization activities are accounted for as a component of the related expense in the period incurred. We considered the guidance in ASC 606 by analogy in determining the appropriate treatment for the transactions between us and AstraZeneca and concluded that reimbursement for transactions in which we are considered to be principal because we control a promised good or service before transferring that good or service to the customer, are accounted for as gross revenue.

We did not recognize any revenue from the 2017 AZ Agreement for either of the three or six month periods ended June 30, 2020 and 2019.

Merck – Strategic Alliances in Infectious Diseases and Cancer Vaccines

2015 Strategic Alliance with Merck – Infectious Disease

In January 2015, we entered into a Master Collaboration and License Agreement with Merck, which was amended in each of January 2016, June 2016, and May 2019, and which we refer to, as amended, as the 2015 Merck Agreement. Pursuant to the 2015 Merck Agreement, we and Merck have agreed to research, develop, and commercialize potential mRNA medicines for the prevention of infections by RSV. As a part of the May 2019 amendment of the 2015 Merck Agreement, we and Merck agreed to conclude the collaboration as it relates to development of potential mRNA medicines for other viruses, including mRNA-1278 for the prevention of VZV infection. Pursuant to the 2015 Merck Agreement, Merck is primarily responsible for research, development, and commercialization activities and associated costs of such research and commercialization. We are responsible for designing and manufacturing all mRNA constructs for preclinical and Phase 1 and Phase 2 clinical development purposes, and Merck pays us for such manufacture, and we are responsible for certain costs associated with the conduct of a Phase 1 clinical trial for an RSV vaccine product candidate (mRNA-1172). Responsibility for manufacturing mRNA constructs for late stage clinical development and commercialization purposes is to be determined.

The 2015 Merck Agreement includes a three-year period, expected to end on January 12, 2022, during which Merck may continue to preclinically and clinically develop RSV vaccine product candidates using mRNA constructs that were initially developed during an initial four-year research period which terminated in January 2019. Merck may, prior to January 12, 2022, elect to exclusively develop and commercialize up to five RSV vaccine product candidates.

We and Merck have agreed to certain defined exclusivity obligations during the term of the 2015 Merck Agreement with respect to mRNA investigational medicines against RSV. As part of the May 2019 amendment of the 2015 Merck Agreement, we and Merck agreed to certain expectations to the existing exclusivity obligations, pursuant to which we will no longer be restricted from researching, developing, and commercializing an mRNA investigational medicine for the prevention of a specific set of respiratory infections, including RSV, for the pediatric population.

Under the terms of the 2015 Merck Agreement, we received a $50.0 million upfront payment. We are eligible to receive, on a product-by-product basis, up to $300.0 million in aggregate milestone payments upon the achievement of certain development, regulatory, and commercial milestone events. To date, we have received from Merck a clinical milestone payment of $5.0 million with respect to the initiation of a Phase 1 clinical trial for a Merck RSV vaccine product candidate. In addition, under the terms of the 2015 Merck Agreement, we are eligible to receive an additional milestone payment unless Merck elects not to continue with further clinical development of mRNA-1172. On a product-by-product basis, we are also entitled to receive royalties on Merck's net sales of products at rates ranging from the mid-single digits to low teens, subject to certain reductions, with an aggregate minimum floor. Additionally, concurrent with entering into the 2015 Merck Agreement in 2015, Merck made a $50.0 million equity investment in us, and concurrent with amending the 2015 Merck Agreement in January 2016, we received an upfront payment of $10.0 million from Merck.

Unless earlier terminated, the 2015 Merck Agreement will continue on a product-by-product and country-by-country basis for so long as royalties are payable by Merck on a given product in a given country. Either party may terminate the 2015 Merck Agreement upon the other party's material breach, either in its entirety or with respect to a particular program, product candidate, product or country, subject to specified notice and cure provisions. Merck may terminate the 2015 Merck Agreement in full or with respect to a particular product candidate or product upon certain advance notice to us for any reason, or earlier if Merck determines the alliance or product is no longer commercially practicable. If Merck has the right to terminate the 2015 Merck Agreement, in its entirety or with respect to a program, product candidate or product, for our material breach, then Merck may elect, in lieu of terminating the 2015 Merck Agreement, to have the 2015 Merck Agreement remain in effect, subject to reductions in certain payments we are eligible to receive with respect to the terminable rights. Upon a termination of the 2015 Merck Agreement with respect to a program, all licenses and other rights granted to Merck with respect to such program will terminate and the continued development and commercialization of product candidates and products will revert to us. If the 2015 Merck Agreement is terminated with respect to a given product candidate or product, all licenses and other rights granted to Merck with respect to such product candidate or product will terminate and, to the extent we terminated for Merck's breach, Merck will grant us licenses under select Merck technology for our continued development and commercialization of such product candidate or product.

Accounting Treatment

We determined that all aspects of amended 2015 Merck Agreement represent a transaction with a customer and therefore the amended 2015 Merck Agreement is accounted for in accordance with ASC 606. The four-year research period was complete as of December 31, 2018 and we recognized the total transaction price of $65.0 million (the $60.0 million in aggregate upfront payments and a $5.0 million payment pertaining to achievement of a development milestone) in full as we concluded there were no unsatisfied performance obligations pertaining to the amended 2015 Merck Agreement. Additionally, we concluded the following customer options are marketing offers as such options did not provide any discounts or other rights that would be considered a material right in the arrangement: (i) research services during the three-year period following the initial four-year research period during which Merck may continue to preclinically and clinically develop product candidates and (ii) clinical mRNA supply for Phase 1 and Phase 2 and/or non-cGMP mRNA supply beyond the initial four-year research period. Therefore, such options will be accounted for as a separate contract upon the customer's election. We utilize the most likely amount method to estimate any development and regulatory milestone payments to be received. As of June 30, 2020, there were no milestones that had not been achieved included in the transaction price. We considered the stage of development and the risks associated with the remaining development required to achieve each milestone, as well as whether the achievement of the milestone is outside of our or Merck's control. The outstanding milestone payments were fully constrained, as a result of the uncertainty whether any of the milestones would be achieved. We determined that any commercial milestones and sales-based royalties will be recognized when the related sales occur as they were determined to relate predominantly to the license granted and therefore have also been excluded from the transaction price. When a milestone payment is included in the transaction price in the future, it will be recognized as revenue based on the relative completion of the underlying performance obligation.

After completion of the initial four-year research period, and as part of the May 2019 amendment of the 2015 Merck Agreement, Merck elected to establish a new RSV vaccine product candidate and elected to conduct a Phase 1 clinical trial. We are responsible for certain costs associated with the conduct of the Phase 1 clinical trial. We determined that our obligation under the May 2019 amendment to reimburse Merck for certain costs associated with the RSV vaccine Phase 1 clinical trial represents consideration payable to a customer and is accounted for as a reduction of the transaction price. The consideration amount is determined based on the most likely method and recorded as contra-revenue as costs are incurred. The one-time payment upon election by Merck to continue developing RSV is fully constrained as it is contingent upon completion of the RSV Phase 1 clinical trial and upon decisions to be made by Merck to continue development thereafter.

The following table summarizes the composition of the total transaction price for the periods presented (in thousands):

	Transaction Price	
	June 30, 2020	December 31, 2019
2015 Merck Agreement:		
Upfront payments	$ 60,000	$ 60,000
Development milestones	5,000	5,000
Reduction of reimbursements paid to Merck	(9,704)	(5,265)
Total	$ 55,296	$ 59,735

We re-evaluate the transaction price at the end of each reporting period and as uncertain events are resolved or other changes in circumstances occur. For the six months ended June 30, 2020, there was a $4.4 million deduction to the transaction price related to reimbursements paid to Merck for RSV vaccine Phase I clinical trial costs.

The following table summarizes the total transaction price allocated to the combined performance obligation under the arrangement, and the amount of the transaction price unsatisfied as of June 30, 2020 (in thousands):

	Transaction Price June 30, 2020
2015 Merck Agreement	$ 55,296
Remaining unsatisfied performance obligation	—

We utilize the most likely amount method to estimate any development and regulatory milestone payments to be received. As of June 30, 2020, there were no milestones that had not been achieved included in the transaction price. We considered the stage of development and the risks associated with the remaining development required to achieve each milestone, as well as whether the achievement of the milestone is outside of our or Merck's control. The outstanding milestone payments were fully constrained, as a result of the uncertainty whether any of the milestones would be achieved. We determined that any commercial milestones and sales-

based royalties will be recognized when the related sales occur as they were determined to relate predominantly to the license granted and therefore have also been excluded from the transaction price. When a milestone payment is included in the transaction price in the future, it will be recognized as revenue based on the relative completion of the underlying performance obligation.

The following table summarizes the revenue and contra-revenue recognized for the periods presented (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Contra-revenue under the May 2019 Amendment	$ (2,350)	$ (2,139)	$ (4,439)	$ (2,139)
Collaboration revenue under the 2015 Merck Agreement	—	372	12	854
Total contra-revenue	$ (2,350)	$ (1,767)	$ (4,427)	$ (1,285)

Contra-revenue recognized was related to consideration payable to Merck under the May 2019 Amendment. Collaboration revenue recognized was pursuant to separate agreements with Merck related to the exercise of customer options to purchase clinical mRNA supply to further develop a product candidate after the initial four-year research period. Clinical mRNA supply is recognized as collaboration revenue at a point in time upon which control of supply is transferred to Merck for each delivery of the associated supply. We had no deferred revenue as of June 30, 2020 or December 31, 2019 from the amended 2015 Merck Agreement as all performance obligations under the amended 2015 Merck Agreement were completed as of December 31, 2018.

2016 Cancer Vaccine Strategic Alliance—Personalized mRNA Cancer Vaccines

In June 2016, we entered into a personalized mRNA cancer vaccines (PCV) Collaboration and License Agreement with Merck, which we refer to as the PCV Agreement, to develop and commercialize PCVs for individual patients using our mRNA vaccine and formulation technology. Under the strategic alliance, we identify genetic mutations present in a particular patient's tumor cells, synthesize mRNA for these mutations, encapsulate the mRNA in one of our proprietary LNPs and administer to each patient a unique mRNA cancer vaccine designed to specifically activate the patient's immune system against her or his own cancer cells.

Pursuant to the PCV Agreement, we are responsible for designing and researching PCVs, providing manufacturing capacity and manufacturing PCVs, and conducting Phase 1 and Phase 2 clinical trials for PCVs, alone and in combination with KEYTRUDA (pembrolizumab), Merck's anti-PD-1 therapy, all in accordance with an agreed upon development plan and budget and under the oversight of a committee comprised of equal representatives of each party. The parties have entered into a clinical quality agreement with respect to Moderna's manufacture and supply activities. We received an upfront payment of $200.0 million from Merck. In November 2017, we and Merck announced the achievement of a key milestone for the first-in-human dosing of a PCV (mRNA-4157) as a part of the alliance. The Phase 1 open-label, dose escalation, multicenter clinical trial in the United States (KEYNOTE-603) is designed to assess the safety, tolerability and immunogenicity of mRNA-4157 alone in subjects with resected solid tumors and in combination with KEYTRUDA, in subjects with unresectable solid tumors.

Until the expiration of a defined period of time following our completion of Phase 1 and Phase 2 clinical trials for PCVs under the PCV Agreement and delivery of an associated data package to Merck, Merck has the right to elect to participate in future development and commercialization of PCVs by making a $250.0 million participation payment to us. If Merck exercises its election and pays the participation payment, then the parties will equally co-fund subsequent clinical development of PCVs, with Merck primarily responsible for conducting clinical development activities under a jointly agreed development plan and budget. Each party may also conduct additional clinical trials for PCVs that are not included in the jointly agreed development plan and budget, in which case the non-conducting party will reimburse the conducting party for half of the total costs for such trials, plus interest, from its share of future profits resulting from sales of such PCVs, if any. Merck will lead worldwide commercialization of PCVs, subject to Moderna's option to co-promote PCVs in the United States, and the parties will equally share the profits or losses arising from worldwide commercialization. Until a PCV becomes profitable, we may elect to defer payment of our share of the commercialization and related manufacturing costs and instead reimburse Merck for such costs, plus interest, from our share of future profits resulting from sales of such PCV, if any. Subject to customary "back-up" supply rights granted to Merck, we will manufacture (or have manufactured) PCVs for preclinical and clinical purposes. Manufacture of PCVs for commercial purposes will be determined by the parties in accordance with the terms of the PCV Agreement. Under the PCV Agreement, we grant certain licenses to Merck to perform its collaboration activities.

If Merck does not exercise its right to participate in future development and commercialization of PCVs, then Moderna will retain the exclusive right to develop and commercialize PCVs developed during the strategic alliance, subject to Merck's rights to receive a

percentage in the high teens to the low 20s, subject to reductions of our net profits on sales of such PCVs. During a limited period following such non-exercise, Merck has the right to perform clinical studies of such PCVs in combination with KEYTRUDA, for which we agree to use reasonable efforts to supply such PCVs. During such limited period, we also have the right to perform clinical studies of PCVs in combination with KEYTRUDA, for which Merck agrees to use reasonable efforts to supply KEYTRUDA. In addition, following its non-exercise, Merck is also entitled to receive a percentage in the high teens to the low 20s, subject to reductions, of our net profits on sales of certain PCVs first developed by us following such non-exercise and reaching a specified development stage within a defined period of time.

We and Merck have agreed to certain defined, limited exclusivity obligations with respect to the development and commercialization of PCVs.

2018 Expansion of the Cancer Vaccine Strategic Alliance—Shared Neoepitope Cancer Vaccines

In April 2018, we and Merck agreed to expand our cancer vaccine strategic alliance to include the development and commercialization of our KRAS vaccine development candidate, mRNA-5671 or V941, and potentially other shared neoantigen mRNA cancer vaccines (SAVs). We preclinically developed mRNA-5671 prior to its inclusion in the cancer vaccine strategic alliance and it is comprised of a novel mRNA construct designed by us and encapsulated in one of our proprietary LNPs. The PCV Agreement was amended and restated to include the new SAV strategic alliance (PCV/SAV Agreement).

We have granted Merck certain licenses and we and Merck have agreed to certain exclusivity obligations with respect to SAVs and particular SAV programs, which obligations are subject to termination or expiration upon certain triggering events. Under the PCV/SAV Agreement, Merck will be responsible for conducting Phase 1 and Phase 2 clinical trials for mRNA-5671 and for all costs associated with such activities, in accordance with a jointly agreed development plan and budget, and we will be responsible for manufacturing and supplying all mRNA-5671 required to conduct such trials and for all costs and expenses associated with such manufacture and supply. Under the PCV/SAV Agreement, our budgeted commitment for PCV increased to $243.0 million. Until the expiration of a defined period of time following the completion of Phase 1 and Phase 2 clinical trials for mRNA-5671 under the PCV/SAV Agreement and our delivery of an associated data package to Merck, Merck has the right to elect to participate in future development and commercialization of mRNA-5671 by making a participation payment to us. If Merck exercises its participation rights, then the parties will equally co-fund subsequent clinical development of mRNA-5671, with Merck primarily responsible for conducting clinical development activities under a jointly agreed development plan and budget. If Merck declines to participate in future development and commercialization activities following the initial Phase 1 and Phase 2 clinical trials for mRNA-5671, then we will retain the rights to develop and commercialize mRNA-5671. If Merck elects to participate in future development and commercialization of mRNA-5671, Merck may also conduct additional clinical trials for mRNA-5671 that are not included in the jointly agreed development plan and budget, in which case we will reimburse Merck for half of the total development costs for such clinical trials, plus interest, from our share of future profits resulting from sales of mRNA-5671, if any. If Merck does conduct additional clinical trials for mRNA-5671, we will be responsible for manufacturing and supplying all mRNA-5671 required to conduct such trials. Merck will lead worldwide commercialization of mRNA-5671, subject to our option to co-promote mRNA-5671 in the United States, and the parties will equally share the operating profits or losses arising from worldwide commercialization. Until mRNA-5671 becomes profitable, we may elect to defer payment of our share of the commercialization and related manufacturing costs and instead reimburse Merck for such costs, plus interest, from our share of future profits resulting from sales of mRNA-5671, if any. Subject to “back-up” supply rights granted to Merck, we will manufacture (or have manufactured) mRNA-5671 and other SAVs for preclinical and clinical purposes. After Merck exercises its right to participate in future development and commercialization of mRNA-5671 and other SAVs, we will grant the applicable development and commercialization licenses and the parties are obligated to discuss responsibility for future manufacturing, giving consideration to applicable criteria.

Pursuant to the PCV/SAV Agreement, for a defined period of time, either party may propose that the parties conduct additional programs for the research and development of SAVs directed to different shared neoantigens. If the parties agree to conduct any such programs, then we will be responsible for conducting and funding preclinical discovery and research activities for such SAVs, and otherwise the programs would be conducted on substantially the same terms as mRNA-5671 program. If we or Merck propose a new SAV program and the other party does not agree to conduct such program, then the PCV/SAV Agreement includes provisions allowing the proposing party to proceed with such development, at the proposing party’s expense. If Merck is the proposing party, we will be responsible for manufacturing and supplying material for such program at Merck’s expense. In such case, the non-proposing party will have the right to opt-in to such SAV program any time before the proposing party commits to performing Good Laboratory Practice (GLP)-toxicity studies. Until the expiration of a defined period of time following our completion of Phase 1 and Phase 2 clinical trials for any SAV program mutually agreed by the parties under the PCV/SAV Agreement and our delivery of an associated data package to Merck, Merck has the right to elect to participate in future development and commercialization of such SAV by making a participation payment to us.

Unless earlier terminated, the PCV/SAV Agreement will continue on a program-by-program basis until Merck terminates its participation in such program. Following any such termination, we will retain the exclusive right to develop and commercialize PCVs or SAVs developed as a part of such program, subject to restrictions and certain limited rights retained by Merck.

In connection with the amendment of the PCV Agreement to include the development and commercialization of mRNA-5671 and potentially other SAVs, Merck made a contemporaneous equity investment in our Series H redeemable convertible preferred stock, resulting in gross proceeds of $125.0 million, of which $13.0 million is determined to be a premium and recorded to deferred revenue.

Accounting Treatment

We determined that the PCV/SAV Agreement should be accounted for separately from the amended 2015 Merck Agreement, as the agreements were not negotiated in contemplation of one another and the elements within each of the agreements are not closely interrelated or interdependent on each other. We determined that all aspects of the PCV/SAV Agreement represent a transaction with a customer and therefore the PCV/SAV Agreement is accounted for in accordance with ASC 606. In addition, the equity investment in our Series H redeemable convertible preferred stock was considered together with the PCV/SAV Agreement as the transactions were executed contemporaneously in contemplation of one another. Further, the purchase price paid by Merck with respect to the investment in the Series H redeemable convertible preferred stock was not representative of fair value on the date of such purchase. As such, the incremental proceeds received in excess of the fair value of the underlying stock related to the equity investment were included in the transaction price related to the PCV/SAV Agreement and the shares of Series H redeemable convertible preferred stock purchased by Merck were recorded at their respective fair value on the date of issuance.

We identified the following performance obligations in the PCV/SAV Agreement: (i) a research license and research and development services, including manufacturing and supply of PCVs, during the proof of concept (POC) term for the PCV program, referred to as the PCV Performance Obligation, and (ii) research license and manufacturing and supply of mRNA-5671 during the POC term for the KRAS program, referred to as the KRAS Performance Obligation. We concluded that the research license is not distinct from the research and development services, including manufacturing and supply of PCVs, during the POC term for the PCV program, as Merck cannot fully exploit the value of the license without receipt of such services and supply. Our services and supply involve specialized expertise, particularly as it relates to mRNA technology that is not available in the marketplace. Therefore, the research license has been combined with the research and development services, including manufacturing and supply of PCVs, during the POC term for the PCV program, into a single performance obligation. Similarly, we concluded that the research license is not distinct from the manufacturing and supply of mRNA-5671 during the POC term for the KRAS program, as Merck cannot fully exploit the value of the license without receipt of such supply which must be provided by us. This is due to limitations inherent in the licenses conveyed wherein Merck does not have the contractual right to manufacture during the POC term. Therefore, the research license has been combined with the manufacturing and supply of mRNA-5671, during the POC term for the KRAS program, into a single performance obligation. Conversely, we concluded that the PCV Performance Obligation and the KRAS Performance Obligation are distinct from each other because Merck can fully exploit the value of each program for its intended purpose without the promises associated with the other program. Additionally, we concluded the following customer options are marketing offers as such options did not provide any discounts or other rights that would be considered a material right in the arrangement: (i) Merck participation election license related to future joint development and commercialization on a program-by-program basis, (ii) manufacturing and supply in support of certain SAV programs and/or the PCV program upon Merck election to not participate in future development and commercialization of that program and (iii) research and development services associated with certain SAV programs. Therefore, such options will be accounted for as a separate contract upon the customer's election.

The following table summarizes the composition of the total transaction price for the periods presented (in thousands):

	Transaction Price	
PCV/SAV Agreement:	June 30, 2020	December 31, 2019
Upfront payment	$ 200,000	$ 200,000
Premium associated with the contemporaneous sale of Series H redeemable convertible preferred stock	13,050	13,050
Reimbursement for clinical supply	310	—
Total	$ 213,360	$ 213,050

We determined there are no other components of variable consideration that should be included in the transaction price as of June 30, 2020, as additional consideration to which we could be entitled is subject to Merck's election to exercise a customer option that

was deemed to be a marketing offer. We re-evaluate the transaction price at the end of each reporting period. During the six months ended June 30, 2020, there was a $0.3 million increase to the transaction price from a reimbursement for clinical supply.

The transaction price was allocated to the performance obligations based on the relative estimated standalone selling price of each performance obligation. We developed the estimated standalone selling price for the license included in each of the PCV Performance Obligation and the KRAS Performance Obligation primarily based on the probability-weighted present value of expected future cash flows associated with each license related to each specific program. In developing such estimate, we also considered applicable market conditions and relevant entity-specific factors, including those factors contemplated in negotiating the agreement, probability of success and the time needed to commercialize a development candidate pursuant to the associated license. We developed the estimated standalone selling price for the services and/or manufacturing and supply included in each of the PCV Performance Obligation and the KRAS Performance Obligation, as applicable, primarily based on the nature of the services to be performed and/or goods to be manufactured and estimates of the associated cost, adjusted for a reasonable profit margin that would be expected to be realized under similar contracts.

The following tables summarize the allocation of the total transaction price to the identified performance obligations under the arrangement, and the amount of the transaction price unsatisfied as of June 30, 2020 (in thousands):

	Transaction Price
PCV/SAV Agreement:	June 30, 2020
PCV performance obligation	$ 206,356
KRAS performance obligation	7,004
Total	$ 213,360
Remaining unsatisfied performance obligation	$ 68,340

We will recognize revenue related to amounts allocated to the PCV Performance Obligation over time as the underlying services are performed using a proportional performance model. We measure proportional performance using an input method based on the costs incurred relative to the total estimated costs of research and development efforts. We recognize revenue related to the amounts allocated to the KRAS Performance Obligation based on the point in time upon which control of supply is transferred to Merck for each delivery of the associated supply. As of June 30, 2020, the remaining performance obligations that are unsatisfied is expected to be recognized as revenue through December 31, 2024.

The following table summarizes the revenue recognized for the periods presented (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
PCV/SAV Agreement	$ 12,716	$ 10,426	$ 15,769	$ 20,631

The revenue recognized during the three and six months ended June 30, 2020 includes the amortization of deferred revenue due to the satisfaction of our performance during the period, offset by a cumulative catch-up adjustment of $3.5 million in the first quarter due to changes in estimated costs for our future performance obligations.

The following table summarizes the balances of deferred revenue, which is classified as current or non-current in the condensed consolidated balance sheets based on the period the services are expected to be performed or control of the supply is expected to be transferred for the periods presented (in thousands):

	June 30, 2020	December 31, 2019
PCV/SAV Agreement	$ 68,340	$ 83,799

Vertex – 2016 Strategic Alliance in Cystic Fibrosis

In July 2016, we entered into a Strategic Collaboration and License Agreement, with Vertex Pharmaceuticals Incorporated, and Vertex Pharmaceuticals (Europe) Limited, together, Vertex, which we refer to as the Vertex Agreement. The Vertex Agreement, which was amended in July 2019, which we refer to as the 2019 Vertex Amendment, is aimed at the discovery and development of potential mRNA medicines for the treatment of cystic fibrosis (CF) by enabling cells in the lungs of people with CF to produce functional CFTR proteins.

Pursuant to the Vertex Agreement, we led discovery efforts during an initial research period that was extended through March 2020, leveraging our Platform technology and mRNA delivery expertise along with Vertex's scientific experience in CF biology and the functional understanding of CFTR. Vertex is responsible for conducting development and commercialization activities for candidates and products that arise from the strategic alliance, including the costs associated with such activities. Subject to customary "back-up" supply rights granted to Vertex, we exclusively manufacture (or have manufactured) mRNA for preclinical, clinical and commercialization purposes. The parties established a joint steering committee to oversee and coordinate activities under the Vertex Agreement. We and Vertex have granted each other certain licenses under the Vertex Agreement.

Under the terms of the Vertex Agreement, we received a $20.0 million upfront payment from Vertex. In July 2019, Vertex elected to extend the initial three-year research period by six months pursuant to the 2019 Vertex Amendment. In March 2020, based on the promising preclinical data generated to date, Vertex extended the conduct of the initial Research Plan through the First Extended Research Term (an additional 18-month term) by making an additional payment to us. Vertex has rights to further extend the research period for two additional one-year periods by making an additional payment to us for each one-year extension. We are eligible to receive up to $55.0 million in payments for achievement of development milestones, up to $220.0 million in payments for achievement of regulatory milestones and potentially could receive an additional $3.0 million milestone payment for achievement of a regulatory milestone for a second and each subsequent product under the Vertex Agreement. Vertex will also pay us tiered royalties at rates ranging from the low- to high teens on worldwide net sales of products arising from the strategic alliance, subject to certain reductions, with an aggregate minimum floor. In connection with the strategic alliance, Vertex also made a $20.0 million equity investment in us. During the term of the Vertex Agreement, we and Vertex have agreed to certain defined exclusivity obligations under the Vertex Agreement with respect to the development and commercialization of certain mRNA medicines.

Unless earlier terminated, the Vertex Agreement will continue until the expiration of all royalty terms. Vertex may terminate the Vertex Agreement for convenience upon 90 days' prior written notice, except if termination relates to a product in a country where Vertex has received marketing approval, which, in such case, Vertex must provide 180 days' prior written notice. Either party may terminate the Vertex Agreement upon the other party's material breach, subject to specified notice and cure provisions. Each party may also terminate the Vertex Agreement in the event that the other party challenges the validity or enforceability of such party's patent rights, subject to certain exceptions, or if the other party becomes insolvent.

Accounting Treatment

As of June 30, 2020, all performance obligations under the 2019 Vertex Amendment were completed and the total transaction price of $4.5 million, comprised of the $2.0 million upfront payment and $2.5 million in research and development funding related to the research and development services and supply of non-cGMP mRNA, was fully recognized.

The First Extended Research Term represents a contract modification and is accounted for as a separate contract. Pursuant to the 2019 Vertex Amendment, we identified one performance obligation comprised of: (i) a research, development and commercialization license and (ii) research and development services, including manufacturing and supply of non-cGMP mRNA, during the 18-month First Extended Research Term. We concluded that the license is not distinct from the research and development services, including manufacturing and supply of non-cGMP mRNA. Additionally, we concluded that the following customer options are marketing offers as such options did not provide any discounts or other rights that would be considered a material right in the arrangement: (i) Vertex's rights to extend the extended initial research period and (ii) clinical mRNA supply and/or non-cGMP mRNA supply beyond the extended initial research period. Therefore, such options will be accounted for as a separate contract upon the customer's election.

The following table summarizes the composition of the total transaction price for the First Extended Research Term at June 30, 2020 (in thousands):

Vertex Agreement - First Extended Research Term:	June 30, 2020
Upfront payment	$ 4,000
Research and development	32,983
Total	$ 36,983

We utilize the most likely amount method to determine the amount of research and development funding to be received. As of June 30, 2020, there were no milestones included in the transaction price. We considered the stage of development and the risks associated with the remaining development required to achieve each milestone, as well as whether the achievement of the milestone is outside of our or Vertex's control. The outstanding milestone payments were fully constrained, as a result of the uncertainty whether any of the milestones would be achieved. We determined that any sales-based royalties will be recognized when the related sales occur as they were determined to relate predominantly to the license granted and therefore have also been excluded from the transaction price. We re-evaluate the transaction price at the end of each reporting period and as uncertain events are resolved or other changes in circumstances occur.

The following table summarizes the total transaction price allocated to the single performance obligation under the arrangement, and the amount of the transaction price unsatisfied as of June 30, 2020 (in thousands):

	June 30, 2020
First Extended Research Term transaction price	$ 36,983
Remaining unsatisfied performance obligation	34,787

As of June 30, 2020 the aggregate amount of transaction price allocated to the remaining performance obligations that are unsatisfied is expected to be recognized as revenue through the fourth quarter of 2021.

We recognize revenue related to amounts allocated to the single performance obligation over time as the underlying services are performed using a proportional performance model. We measure proportional performance using an input method based on the costs incurred relative to the total estimated costs of the research and development efforts.

The following table summarizes the revenue recognized for the periods presented (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Vertex First Extended Research Term	$ 2,196	$ —	$ 2,196	$ —
Vertex Agreement/2019 Amendment	(4)	1,183	2,052	3,797
Total	$ 2,192	$ 1,183	$ 4,248	$ 3,797

The revenue recognized during the three and six months ended June 30, 2020 includes the amortization of the deferred revenue due to the satisfaction of our performance during the period.

The following table summarizes the balances of deferred revenue, classified as current and non-current in the condensed consolidated balance sheets based on the term of the research period for the periods presented (in thousands):

	June 30, 2020	December 31, 2019
Vertex Agreement[1]	$ 3,888	$ 793

(1) Balance as of December 31, 2019 represents deferred revenue related to the Vertex 2019 Amendment

4. Grant Revenue

In April 2020, we entered into an agreement with the Biomedical Advanced Research and Development Authority (BARDA), a division of the Office of the Assistant Secretary for Preparedness and Response (ASPR) within the U.S. Department of Health and Human Services (HHS), for an award of up to $483.3 million to accelerate development of our mRNA vaccine candidate (mRNA-1273) against the novel coronavirus (SARS-CoV-2). Under the terms of the agreement, BARDA will fund the advancement of mRNA-1273 to FDA licensure. All contract options have been exercised. As of June 30, 2020, the remaining available funding net of revenue earned was $449.3 million.

In September 2016, we received an award of up to $125.8 million from BARDA, to help fund our Zika vaccine program. Three of the four contract options have been exercised. As of June 30, 2020, the remaining available funding net of revenue earned was $76.0 million, with an additional $8.4 million available if the final contract option is exercised.

In January 2016, we entered a global health project framework agreement with the Gates Foundation to advance mRNA-based development projects for various infectious diseases, including human immunodeficiency virus, or HIV. As of June 30, 2020, the available funding net of revenue earned was $12.7 million, with up to an additional $80.0 million available if additional follow-on projects are approved.

The following tables summarize grant revenue and deferred grant revenue as of and for the periods presented (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
BARDA	$ 37,048	$ 1,876	$ 39,816	$ 3,365
Other grant revenue	861	1,177	2,025	1,598
Total grant revenue	$ 37,909	$ 3,053	$ 41,841	$ 4,963

	June 30, 2020	December 31, 2019
Deferred grant revenue	$ 5,758	$ 1,496

5. Financial Instruments

Cash and Cash Equivalents and Investments

The following tables summarize our cash and available-for-sale securities by significant investment category at June 30, 2020 and December 31, 2019 (in thousands):

	June 30, 2020						
	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value	Cash and Cash Equivalents	Current Marketable Securities	Non-Current Marketable Securities
Cash and cash equivalents	$ 1,761,629	$ —	$ —	$ 1,761,629	$ 1,761,629	$ —	$ —
Available-for-sale:							
Level 2:							
Certificates of deposit	35,909	91	(3)	35,997	—	27,506	8,491
U.S. treasury securities	174,634	777	—	175,411	—	105,592	69,819
Debt securities of U.S. government agencies and corporate entities	1,090,314	8,669	(91)	1,098,892	—	822,286	276,606
	$ 3,062,486	$ 9,537	$ (94)	$ 3,071,929	$ 1,761,629	$ 955,384	$ 354,916

	December 31, 2019						
	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value	Cash and Cash Equivalents	Current Marketable Securities	Non-Current Marketable Securities
Cash and cash equivalents	$ 225,874	$ —	$ —	$ 225,874	$ 225,874	$ —	$ —
Available-for-sale:							
Level 2:							
Certificates of deposit	82,028	79	(6)	82,101	10,002	69,197	2,902
U.S. treasury securities	117,891	260	(2)	118,149	—	110,186	7,963
Debt securities of U.S. government agencies and corporate entities	834,187	2,708	(32)	836,863	—	687,741	149,122
	$ 1,259,980	$ 3,047	$ (40)	$ 1,262,987	$ 235,876	$ 867,124	$ 159,987

The amortized cost and estimated fair value of marketable securities by contractual maturity at June 30, 2020 are as follows (in thousands):

	June 30, 2020	
	Amortized Cost	Estimated Fair Value
Due in one year or less	$ 950,151	$ 955,384
Due after one year through five years	350,706	354,916
Total	$ 1,300,857	$ 1,310,300

In accordance with our investment policy, we place investments in investment grade securities with high credit quality issuers, and generally limit the amount of credit exposure to any one issuer. We evaluate securities for impairment at the end of each reporting period. Impairment is evaluated considering numerous factors, and their relative significance varies depending on the situation. Factors considered include whether a decline in fair value below the amortized cost basis is due to credit-related factors or noncredit-related factors, the financial condition and near-term prospects of the issuer, and our intent and ability to hold the investment to allow for an anticipated recovery in fair value. Any impairment that is not credit related is recognized in other comprehensive (loss) income,

net of applicable taxes. A credit-related impairment is recognized as an allowance on the balance sheet with a corresponding adjustment to earnings. We did not recognize any credit losses related to available-for-sale securities for the three and six months ended June 30, 2020 and 2019.

The following table summarizes the amount of gross unrealized losses and the estimated fair value for our available-for-sale securities in an unrealized loss position by length of time the securities have been in an unrealized loss position at June 30, 2020 and December 31, 2019 (in thousands):

	Less than 12 months		12 months or more		Total	
	Gross Unrealized Losses	Estimated Fair Value	Gross Unrealized Losses	Estimated Fair Value	Gross Unrealized Losses	Estimated Fair Value
As of June 30, 2020:						
Certificates of deposit	$ (3)	$ 8,490	$ —	$ —	$ (3)	$ 8,490
U.S. treasury securities	(3)	24,970	—	—	(3)	24,970
Debt securities of U.S. government agencies and corporate entities	(88)	28,435	—	—	(88)	28,435
Total	$ (94)	$ 61,895	$ —	$ —	$ (94)	$ 61,895
As of December 31, 2019:						
Certificates of deposit	$ (6)	$ 12,822	$ —	$ —	$ (6)	$ 12,822
U.S. treasury securities	(2)	9,979	—	—	(2)	9,979
Debt securities of U.S. government agencies and corporate entities	(32)	62,360	—	—	(32)	62,360
Total	$ (40)	$ 85,161	$ —	$ —	$ (40)	$ 85,161

At June 30, 2020 and December 31, 2019, we held zero and 19 available-for-sale securities, respectively, out of our total investment portfolio that were in a continuous unrealized loss position. We neither intend to sell these investments nor conclude that we are more-likely-than-not that we will have to sell them before recovery of their carrying values. We also believe that we will be able to collect both principal and interest amounts due to us at maturity.

6. Balance Sheet Components

Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets, as of June 30, 2020 and December 31, 2019 consists of the following (in thousands):

	June 30, 2020	December 31, 2019
Prepaid expenses	$ 20,849	$ 8,475
Tenant incentives receivables	16,982	4,093
Interest receivable on marketable securities	7,506	6,835
Prepaid expenses and other current assets	$ 45,337	$ 19,403

Property and Equipment, Net

Property and equipment, net, as of June 30, 2020 and December 31, 2019 consists of the following (in thousands):

	June 30, 2020	December 31, 2019
Laboratory equipment	$ 111,541	$ 108,257
Leasehold improvements	161,411	152,426
Furniture, fixtures and other	4,451	3,316
Computer equipment and software	12,275	11,985
Internally developed software	7,020	7,020
Right-of-use asset, financing	24,179	9,853
Construction in progress	12,922	3,222
	333,799	296,079
Less: Accumulated depreciation	(103,860)	(94,584)
Property and equipment, net	$ 229,939	$ 201,495

Depreciation and amortization expense for the three months ended June 30, 2020 and 2019 was $7.6 million and $7.5 million, respectively. Depreciation and amortization expense for the six months ended June 30, 2020 and 2019 was $15.0 million and $14.8 million, respectively.

Accrued Liabilities

Accrued liabilities, as of June 30, 2020 and December 31, 2019 consists of the following (in thousands):

	June 30, 2020	December 31, 2019
Property and equipment	$ 8,309	$ 4,029
Compensation-related	25,012	27,428
External goods and services	55,883	36,195
Accrued liabilities	$ 89,204	$ 67,652

Deferred Revenue

The following table summarizes the activities in deferred revenue for the six months ended June 30, 2020 (in thousands):

	Deferred Revenue June 30, 2020
Balance at December 31, 2019	$ 202,305
Additions	91,467
Deductions	(40,050)
Balance at June 30, 2020	$ 253,722

In the second quarter of 2020, we received deposits of $75.0 million for our future mRNA-1273 vaccine supply based on preliminary agreements with certain of our potential customers. We may enter into definitive supply agreements with these potential customers in the third quarter of 2020. The $75.0 million deposits were recorded to deferred revenue as of June 30, 2020. Our remaining deferred revenue was related to our collaboration agreements and grants (see Note 3 and Note 4).

7. Leases

We have entered into various long-term non-cancelable lease arrangements for our facilities and equipment expiring at various times through 2032. Certain of these arrangements have free rent periods or escalating rent payment provisions. We recognize lease cost under such arrangements on a straight-line basis over the life of the leases. We have two campuses in Massachusetts, our Cambridge facility and our Moderna Technology Center, or MTC, located in Norwood.

Operating Leases

Cambridge facility

We occupy a multi-building campus in Technology Square in Cambridge, MA with a mix of offices and research laboratory space totaling approximately 175,000 square feet. Our Cambridge facility leases have expiry ranges from 2020 to 2029.

In August 2019, we entered into an amendment to our lease agreements to consolidate our Technology Square space in Cambridge, MA. This included entering into a forward-starting lease agreement starting in January 2020 to acquire approximately 50,000 square feet of additional space at 200 Technology Square including space previously occupied under a sublease which expired on December 31, 2019. In addition, our current 200 Technology Square lease has been extended for two years to 2029. The lease amendment provides an additional aggregated tenant improvement allowance of $3.5 million for the design and construction of improvements at 200 Technology Square. As part of the lease amendment, we completely exited our leased space of approximately 60,000 square feet at 500 Technology Square in May 2020.

In May 2016, we entered into a lease agreement for 125,000 square feet of office and laboratory space at 200 Technology Square in Cambridge, Massachusetts. The lease commenced on September 1, 2016, with the base rent subject to increases over an 11-year term. We have occupied the premises in six phases from September 2016 to January 2020. We have the option to extend the lease term for two extension periods of five years each, at market-based rates. In addition to rent payments, the lease also provides that we pay our proportionate share of operating expenses and taxes during the term of the lease. As the amount of square footage that we lease increases over the term of the lease, we have recognized each phase's total rent payments on a straight-line basis over the respective lease term. The lease provides us with an initial tenant allowance of $10.00 per square foot against which costs incurred are capitalized as leasehold improvements.

We record operating lease cost for each of our operating leases on a straight-line basis from lease commencement date through the end of the lease term. Operating lease cost is recorded to operating expenses in our consolidated statements of operations.

Finance Leases

Moderna Technology Center manufacturing facility (MTC South)

In August 2016, we entered into a lease agreement for approximately 200,000 square feet of office, laboratory, and light manufacturing space, MTC South, in Massachusetts. The lease commencement date for accounting purposes was October 1, 2016. In connection with this lease, the landlord provided a tenant improvement allowance of approximately $24.2 million for costs associated with the design, engineering, and construction of tenant improvements for the building. The lease will expire in September 2032. We have the option to extend the term for two extension periods of ten years each at market-based rents. The base rent is subject to increases over the term of the lease.

Pursuant to ASC 842, the MTC South lease is bifurcated into a building lease and a land lease using an estimated incremental borrowing rate as of the lease commencement date. The building lease is classified as a financing lease and the land lease is classified as an operating lease. For accounting purposes, the lease term is determined to be 35 years, which is the non-cancelable period of the lease and includes the optional extension periods as we are reasonably certain that we will exercise the options to extend the lease term. Upon the adoption of ASC 842 at January 1, 2019, we derecognized the assets and liabilities recorded as a result of historical build-to-suit accounting under ASC 840 and recorded financing lease liabilities and financing right-of-use asset associated with the building lease. The financing right-of-use asset is amortized on a straight-line basis to depreciation expense over the remaining lease term. We record interest expense related to the financing lease liabilities in the consolidated statements of operations.

Moderna Technology Center North (MTC North)

In February 2019, we entered into a new lease agreement for office and laboratory space of approximately 200,000 square feet, MTC North, located in Massachusetts. The lease commenced in the second quarter of 2019 and had an initial expiration date of 2031. We have the option to extend the lease for up to four additional five-year terms. Contemporaneously, we entered into an agreement to sublease approximately 64 percent of the leased space to a third party. We have no rent obligations to the landlord for the space

occupied by the third party. All sublease payments from the third party are paid directly to the landlord. In May 2020, we entered into an amendment to the lease whereby we exercised an option available in the original lease to receive a tenant improvement allowance in the amount of $22.2 million to be paid back over the term of the lease with interest and extend the term of the lease to 2035. In May 2020, we also amended our MTC North sublease agreement. As the result of that amendment, effective June 1, 2020, we obtained an additional, approximately 28,000 square feet, or 12 percent of the leased space in MTC North and confirmed the sublease will expire in July 2020. The two lease modifications to MTC North in the second quarter of 2020 resulted in a change in lease classification, from operating to finance.

Operating and financing lease right-of-use assets and lease liabilities as of June 30, 2020 and December 31, 2019 were as follows (in thousands):

	June 30, 2020	December 31, 2019
Assets:		
Right-of-use assets, operating, net [1] [2]	$ 92,046	$ 86,414
Right-of-use assets, financing, net [3] [4]	23,702	9,544
Total	$ 115,748	$ 95,958
Liabilities:		
Current:		
Operating lease liabilities [5]	$ 4,193	$ 3,584
Non-current:		
Operating lease liabilities, non-current	99,636	93,675
Financing lease liabilities, non-current	68,136	38,689
Total non-current lease liabilities	167,772	132,364
Total	$ 171,965	$ 135,948

[1] These assets are real estate related assets, which include land, office and laboratory spaces.
[2] Net of accumulated depreciation.
[3] These assets are real estate assets related to the MTC North and MTC South leases.
[4] Included in property and equipment in the condensed consolidated balance sheets, net of accumulated depreciation.
[5] Included in other current liabilities in the condensed consolidated balance sheets.

The components of the lease costs for three and six months June 30, 2020 and 2019 were as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Operating lease costs	4,379	3,872	9,015	7,742
Financing lease costs:				
Amortization of right-of-use assets, financing leases	112	73	185	146
Interest expense for financing lease liabilities	1,877	1,634	3,542	3,257
Total financing lease costs	1,989	1,707	3,727	3,403
Variable lease costs	1,091	1,171	2,498	2,065

Supplemental cash flow information relating to our leases for the six months ended June 30, 2020 and 2019 was as follows (in thousands):

	Six Months Ended June 30, 2020	
	2020	2019
Cash paid for amounts included in measurement of lease liabilities:		
Operating cash flows used in operating leases	$ (7,576)	$ (7,529)
Operating cash flows used in financing leases	(2,954)	(2,774)
Operating lease non-cash items:		
Right-of-use assets reduced through lease modifications and reassessments	6,755	219
Right-of-use assets obtained in exchange for operating lease liabilities	16,015	17,416
Finance lease non-cash items:		
Right-of-use assets obtained through lease modifications and reassessments	14,326	—
Charges to financing lease obligation	45	483

Future minimum lease payments under non-cancelable operating lease agreements at June 30, 2020, are as follows (in thousands):

Fiscal Year	Operating Leases [1]	Financing Leases [1]
2020 (remainder of the year)	$ 6,361	$ 3,453
2021	15,117	8,314
2022	15,466	8,497
2023	15,779	8,679
2024	16,168	8,871
Thereafter	110,167	338,525
Total minimum lease payments	179,058	376,339
Less amounts representing interest or imputed interest	(75,228)	(308,203) [2]
Present value of lease liabilities	$ 103,830	$ 68,136

[1] Include the optional extensions in the MTC South lease term which represent a total of $10.3 million and $208.5 million un-discounted future lease payments in operating leases and financing leases, respectively. Include the optional extensions in the MTC North lease term which represent a total of $46.3 million un-discounted future lease payments in the financing leases.
[2] MTC South interest is based on an imputed interest rate of 17.2%. MTC North interest is based upon an incremental borrowing rate of 8.2%.

8. Commitments and Contingencies

Strategic Collaborations

Under our strategic collaboration agreements, we are committed to perform certain research, development, and manufacturing activities. As part of our PCV Agreement and PCV/SAV Agreement with Merck, we are committed to perform certain research, development and manufacturing activities related to PCV products through an initial Phase 2 clinical trial up to a budgeted amount of $243.0 million for both periods as of June 30, 2020 and December 31, 2019 (see Note 3).

Legal Proceedings

We are not currently a party to any material legal proceedings.

Indemnification Obligations

As permitted under Delaware law, we indemnify our officers, directors, and employees for certain events, occurrences while the officer, or director is, or was, serving at our request in such capacity. The term of the indemnification is for the officer's or director's lifetime.

We have standard indemnification arrangements in our leases for laboratory and office space that require us to indemnify the landlord against any liability for injury, loss, accident, or damage from any claims, actions, proceedings, or costs resulting from certain acts, breaches, violations, or non-performance under our leases.

We enter into indemnification provisions under our agreements with other companies in the ordinary course of business, typically with business partners, contractors, clinical sites and customers. Under these provisions, we generally indemnify and hold harmless the indemnified party for losses suffered or incurred by the indemnified party as a result of our activities. These indemnification provisions generally survive termination of the underlying agreement. The maximum potential amount of future payments we could be required to make under these indemnification provisions is unlimited.

Through the three months ended June 30, 2020 and the year ended December 31, 2019, we had not experienced any losses related to these indemnification obligations, and no material claims were outstanding. We do not expect significant claims related to these indemnification obligations and, consequently, concluded that the fair value of these obligations is negligible, and no related reserves were established.

Purchase Commitments and Purchase Orders

In May 2020, we entered into a 10-year strategic collaboration agreement with Lonza Ltd. to enable larger scale manufacture for our mRNA vaccine candidate (mRNA-1273) against the SARS-CoV-2 and additional Moderna products in the future. Under the terms of the agreement, we plan to establish dedicated manufacturing suites at Lonza's facilities in the United States and Switzerland for the manufacture of mRNA-1273 at both sites. Certain arrangements under this strategic collaboration agreement are within the scope of lease accounting (Lonza leases). However, we did not recognize any right-of-use assets or lease liabilities related to Lonza leases as of June 30, 2020, as the leases had not yet commenced. The non-cancelable contractual obligations related to the Lonza agreement, including the early termination fees, are included in our non-cancelable purchase commitments related to supply and manufacturing agreements of $201.2 million below.

We enter into agreements in the normal course of business with vendors for preclinical research studies and clinical trials and with contract manufacturing organizations (CMOs) for supply and manufacturing. As of June 30, 2020, we had $5.4 million of non-cancelable purchase commitments for clinical services which are expected to be paid from 2020 to 2023. As of June 30, 2020, we had $201.2 million of non-cancelable purchase commitments related to supply and manufacturing agreements which are expected to be paid through 2021. These amounts represent our minimum contractual obligations, including termination fees.

In addition to purchase commitments, we have agreements with third parties for various services, including services related to clinical operations and support and contract manufacturing, for which we are not contractually able to terminate for convenience and avoid any and all future obligations to the vendors. Certain agreements provide for termination rights subject to termination fees or wind down costs. Under such agreements, we are contractually obligated to make certain payments to vendors, mainly, to reimburse them for their unrecoverable outlays incurred prior to cancellation. At June 30, 2020 and December 31, 2019, we had cancelable open purchase orders of $264.5 million and $105.9 million, respectively, in total under such agreements for our significant clinical operations and support and contract manufacturing. These amounts represent only our estimate of those items for which we had a contractual commitment to pay at June 30, 2020 and December 31, 2019, assuming we would not cancel these agreements. The actual amounts we pay in the future to the vendors under such agreements may differ from the purchase order amounts.

9. Shareholders' Equity

On February 28, 2018 and May 7, 2018, the Board of Directors approved an amendment to our Certificate of Incorporation resulting in a total of 775,000,000 shares of common stock and a total of 509,352,795 shares of redeemable convertible preferred stock being authorized, respectively. Upon completion of our initial public offering (IPO), our authorized capital stock consists of 1,600,000,000 shares of common stock, par value $0.0001 per share, and 162,000,000 shares of preferred stock, par value $0.0001 per share, all of which shares of preferred stock are undesignated.

On December 11, 2018, we completed our IPO, whereby we sold 26,275,993 shares of common stock at a price of $23.00 per share. The aggregate net proceeds received by us from the IPO were $563.0 million, net of underwriting discounts and commissions of $33.2 million and offering expenses of $8.1 million payable by us. Upon the closing of the IPO, all outstanding shares of our redeemable convertible preferred stock were converted into 236,012,913 shares of the common stock.

On February 14, 2020, we sold 26,315,790 shares of common stock at a price of $19.00 per share through a public equity offering. The aggregate net proceeds from the offering were $477.7 million, net of underwriting discounts, commissions and offering expenses. In addition, the underwriters exercised their option to purchase an additional 3,947,368 shares of common stock at the public offering price less the underwriting discount, resulting in additional net proceeds of $71.8 million.

On May 21, 2020, we sold 17,600,000 shares of common stock at a price of $76.00 per share through a public equity offering. The aggregate net proceeds from the offering were $1.30 billion, net of underwriting discount, commission and offering expenses.

10. Stock-Based Compensation

Equity Plans

In October 2013, we adopted the 2013 Equity Incentive Plan (the 2013 Incentive Plan) and the 2013 Unit Option and Grant Plan (the 2013 Option Plan), which provided for the grant of incentive units, non-qualified unit options, and restricted and unrestricted unit awards to our employees, officers, directors, advisors, and outside consultants. Historically, we also granted restricted stock to founders, officers, directors, and advisors outside any of the Plans.

In August 2016, we adopted the 2016 Stock Option and Grant Plan (the 2016 Equity Plan), which replaced the 2013 Option Plan and the 2013 Incentive Plan. The 2016 Equity Plan and provided for the grant of incentive stock options, non-qualified stock options, restricted stock, unrestricted stock, and restricted stock units to our employees, officers, directors, consultants, and other key persons.

In connection with the IPO, we adopted the 2018 Stock Option and Incentive Plan (the 2018 Equity Plan) in November 2018. The 2018 Equity Plan became effective on the date immediately prior to the effective date of the IPO and replaced our 2016 Plan. The 2018 Equity Plan provides flexibility to our compensation committee to use various equity-based incentive awards as compensation tools to motivate our workforce. We have initially reserved 13,000,000 shares of our common stock for the issuance of awards under the 2018 Equity Plan. The 2018 Equity Plan provides that the number of shares reserved and available for issuance under the plan will automatically increase each January 1, beginning on January 1, 2019, by 4% of the outstanding number of our common stock on the immediately preceding December 31, or such lesser number of shares as determined by our compensation committee. The shares of common stock underlying any awards that are forfeited, canceled, held back upon exercise or settlement of an award to satisfy the exercise price or tax withholding, reacquired by us prior to vesting, satisfied without any issuance of stock, expire or are otherwise terminated (other than by exercise) under the 2018 Equity Plan and the 2016 Plan will be added back to the shares of common stock available for issuance under the 2018 Equity Plan.

The terms and conditions of stock-based awards are defined at the sole discretion of our Board of Directors. We issue service-based awards, vesting over a defined period of service, and performance-based awards, vesting upon achievement of defined conditions. Service based awards generally vest over a four-year period, with the first 25% of such awards vesting following twelve months of continued employment or service. The remaining awards vests in twelve quarterly installments over the following twelve quarters. Stock options granted under the 2016 Equity Plan expire ten years from the date of grant and the exercise price must be at least equal to the fair market value of common stock on the grant date.

As of June 30, 2020, we had a total of 69.6 million shares reserved for future issuance under our Equity Plans, of which 41.7 million shares were reserved for equity awards previously granted, and 27.9 million shares were available for future grants under the 2018 Equity Plan. No additional awards will be granted under the 2016 Equity Plan as it was replaced by the 2018 Equity Plan.

Options

We have granted options generally through the 2018 Equity Plan and 2016 Equity Plan. The following table summarizes our option activity during the six months ended June 30, 2020:

	Number of Options	Weighted-Average Exercise Price per Share	Weighted-Average Grant Date Fair Value per Share	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value[(1)] (in thousands)
Outstanding at Outstanding at December 31, 2019	45,536,915	$ 13.82	$ 7.35	7.2 years	$ 286,310
Granted	4,078,743	28.66	15.38		
Exercised	(8,543,272)	12.47	6.18		
Canceled/forfeited	(1,347,643)	17.24	10.28		
Outstanding at June 30, 2020	39,724,743	15.52	8.32	7.1 years	1,934,410
Exercisable at June 30, 2020	19,040,306	10.80	5.48	5.8 years	1,017,013
Expected to vest at June 30, 2020	20,684,437	19.86	10.94	8.4 years	917,397

[(1)]Aggregate intrinsic value is calculated as the difference between the exercise price of the underlying options and the fair value of common stock for those options in the money as of June 30, 2020.

For the six months ended June 30, 2020, 8.5 million stock options were exercised. The total intrinsic value of options exercised was $304.9 million for the six months ended June 30, 2020. The aggregate intrinsic value represents the difference between the exercise price and the selling price received by option holders upon the exercise of stock options during the period. The total consideration recorded as a result of stock option exercises was approximately $106.6 million for the six months ended June 30, 2020.

Restricted Common Stock Units

We have granted restricted stock unit awards generally through the 2018 Equity Plan and 2016 Equity Plan. The following table summarizes our restricted stock unit activity during the six months ended June 30, 2020:

	Units	Weighted-Average Fair Value per Unit
Outstanding, non-vested at December 31, 2019	1,177,249	$ 19.01
Issued	1,119,204	26.89
Vested	(160,114)	20.87
Canceled/forfeited	(156,206)	22.36
Outstanding, non-vested at June 30, 2020	1,980,133	23.10

2018 Employee Stock Purchase Plan

In November 2018, we adopted our 2018 Employee Stock Purchase Plan (ESPP), which became effective on December 5, 2018. The ESPP initially reserved and authorized the issuance of up to a total of 810,000 shares of common stock to participating employees. We make one or more offerings, consisting of one or more purchase periods, each year to our employees to purchase shares under the ESPP. Offerings usually begin every six months and will continue for six-month periods, referred to as offering periods. The purchase price at which shares are sold under the ESPP is equal to 85% of the lower of the fair market value of the shares on the first business day of the offering period or the last business day of the purchase period. Employees are generally eligible to participate through payroll deductions of between 1% to 50% of their compensation and may not purchase more than 3,000 shares of common stock during each purchase period or $25,000 worth of shares of common stock in any calendar year. We began our first ESPP offering on June 1, 2019. There were 173,738 shares sold at an average price of $16.80 per share under the ESPP during the six months ended June 30, 2020. As of June 30, 2020, 3.7 million shares were available for future issuance under the ESPP.

Valuation and Stock-Based Compensation Expense

Stock-based compensation for options granted under our Equity Plans is determined using the Black-Scholes option pricing model. The weighted-average assumptions used to estimate the fair value of options and ESPP granted for the six months ended June 30, 2020 and 2019 are as follows:

	Weighted Average Six Months Ended June 30,	
	2020	2019
Options:		
Risk-free interest rate	0.93 %	2.42 %
Expected term	6.11 years	6.07 years
Expected volatility	57.74 %	62 %
Expected dividends	— %	— %
Weighted average fair value per share	$ 15.38	$ 11.87
ESPP:		
Risk-free interest rate	0.18 %	2.31 %
Expected term	0.50 years	0.50 years
Expected volatility	65 %	50 %
Expected dividends	— %	— %
Weighted average fair value per share	$ 20.64	$ 19.85

The following table presents the components and classification of stock-based compensation expense for the three and six months ended June 30, 2020 and 2019 as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Options	$ 20,423	$ 19,994	$ 38,441	$ 37,481
Restricted common stock units	2,861	1,327	4,694	2,337
ESPP	639	174	1,201	174
Total	$ 23,923	$ 21,495	$ 44,336	$ 39,992
Research and development	$ 14,703	$ 12,869	$ 26,739	$ 23,652
General and administrative	9,220	8,626	17,597	16,340
Total	$ 23,923	$ 21,495	$ 44,336	$ 39,992

As of June 30, 2020, there was $230.0 million of total unrecognized compensation cost related to unvested stock-based compensation with respect to options and restricted stock granted. That cost is expected to be recognized over a weighted-average period of 3.01 years at June 30, 2020.

11. Income Taxes

We recognize deferred tax assets and liabilities for the expected future tax consequences of temporary differences between the financial reporting and tax bases of assets and liabilities. These differences are measured using the enacted statutory tax rates that are expected to be in effect for the years in which differences are expected to reverse. Valuation allowances are provided when the expected realization of deferred tax assets does not meet a “more likely than not” criterion. Realization of our deferred tax assets is dependent upon the generation of future taxable income, the amount and timing of which are uncertain. We continued to maintain a full valuation allowance against all of our deferred tax assets based on management’s evaluation of all available evidence.

There were no significant income tax provisions or benefits for the three and six months ended June 30, 2020 and 2019.

12. Net Loss per Share

Basic and diluted net loss per share for the three and six months ended June 30, 2020 and 2019 are calculated as follows (in thousands, except share and per share data):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Numerator:				
Net loss	$ (116,713)	$ (134,940)	$ (240,943)	$ (267,516)
Denominator:				
Weighted average common shares used in net loss per share, basic and diluted	380,531,488	329,176,107	366,818,254	328,994,058
Net loss per share, basic and diluted	$ (0.31)	$ (0.41)	$ (0.66)	$ (0.81)

The following common stock equivalents, presented based on amounts outstanding as of June 30, 2020 and 2019, were excluded from the calculation of diluted net loss per share attributable to common stockholders for the periods indicated because their inclusion would have been anti-dilutive:

	June 30,	
	2020	2019
Stock options	39,724,743	51,982,687
Restricted common stock	—	90,808
Restricted common stock units	1,980,133	1,073,894
	41,704,876	53,147,389

13. Subsequent Events

On July 26, 2020, we amended our contract with BARDA to provide for an additional commitment of up to $471.6 million to support late-stage clinical development of mRNA-1273, including the execution of a 30,000 participant Phase 3 study in the U.S. The amendment increased the maximum award from BARDA from $483.3 million to $954.9 million.

Subsequent to June 30, 2020, we have entered into several supply agreements with customers to supply filled and finished mRNA-1273. Based on the initial confirmed volume, subject to modifications, we have received upfront deposits of $383.0 million, of which $75.0 million was received and recorded in the second quarter of 2020. These deposits will be recorded as deferred revenue. We will recognize revenue when revenue recognition criteria have been met.

Subsequent to June 30, 2020, we have entered into additional binding purchase commitments with third-party contractual manufacturing organizations for our mRNA-1273 under existing agreements. We are currently committed to minimum non-cancelable purchase obligations of $299.0 million related to these agreements, which are expected to be paid through 2021.

Item 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with our unaudited financial information and related notes included in this Form 10-Q and our consolidated financial statements and related notes and other financial information in our Annual Report on Form 10-K for the year ended December 31, 2019, which was filed with the SEC on February 27, 2020 (the "2019 Form 10-K"). Some of the information contained in this discussion and analysis or set forth elsewhere in this Form 10-Q, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in Part II, Item 1A - Risk Factors in this Form 10-Q, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a biotechnology company pioneering messenger RNA (mRNA) therapeutics and vaccines to create a new generation of transformative medicines to improve the lives of patients. mRNA medicines are designed to direct the body's cells to produce intracellular, membrane, or secreted proteins that have a therapeutic or preventive benefit with the potential to address a broad spectrum of diseases. Our platform builds on continuous advances in basic and applied mRNA science, delivery technology, and manufacturing, providing us the capability to pursue in parallel a robust pipeline of new development candidates. We are developing therapeutics and vaccines for infectious diseases, immuno-oncology, rare diseases, autoimmune diseases and cardiovascular diseases, independently and with our strategic collaborators.

Within our platform, we develop technologies that enable the development of mRNA medicines for diverse applications. When we identify technologies that we believe could enable a new group of potential mRNA medicines with shared product features, we call that group a "*modality.*" While the programs within a modality may target diverse diseases, they share similar mRNA technologies, delivery technologies, and manufacturing processes to achieve shared product features. The programs within a modality will also generally share similar pharmacology profiles, including the desired dose response, the expected dosing regimen, the target tissue for protein expression, safety and tolerability goals, and pharmaceutical properties. Programs within a modality often have correlated technology risk, but because they pursue diverse diseases they often have uncorrelated biology risk. We have created six modalities to date:

- prophylactic vaccines;
- cancer vaccines;
- intratumoral immuno-oncology;
- localized regenerative therapeutics;
- systemic secreted and cell surface therapeutics; and
- systemic intracellular therapeutics.

In 2019, we designated our prophylactic vaccines and systemic secreted and cell surface therapeutics modalities as our "core modalities" based on positive Phase 1 data from our infectious disease vaccine portfolio, including our cytomegalovirus, or CMV, vaccine and chikungunya antibody program. In these core modalities, our strategy is to invest in additional development candidates using our accumulated innovations in technology, our process insights and our preclinical and clinical experience. As such, we have brought five new development candidates forward in early 2020: a SARS-CoV-2 vaccine, interleukin-2, or IL-2, programmed death-ligand 1, or PD-L1, a pediatric Respiratory Syncytial Virus, or RSV vaccine, and an Epstein-Barr Virus, or EBV vaccine, as part of our mission to use our technology to advance global public health. Our exploratory modalities continue to be a critical part of advancing our strategy to maximize the application of our potential mRNA medicines.

In response to the global coronavirus pandemic, we are pursuing the rapid development and manufacture of our vaccine candidate, mRNA-1273, for the treatment of SARS-CoV-2, the novel strain of coronavirus that causes COVID-19, in collaboration with the Vaccine Research Center and Division of Microbiology and Infectious Diseases of the National Institute of Allergy and Infectious Diseases ("NIAID"), part of the National Institutes of Health ("NIH"). The progress of mRNA-1273 during 2020 has resulted in the need for us to devote significant resources toward the development and manufacture of this product. Significant capital investment is necessary to prepare for the clinical development, manufacturing and distribution of a vaccine at a scale necessary to meet demand in a global pandemic environment. BARDA has committed to fund up to $954.9 million to accelerate the clinical development and manufacturing process scale-up of mRNA-1273. Under the terms of the agreement, BARDA will fund the advancement of mRNA-1273 to FDA licensure and the scale-up of manufacturing processes. The agreement does not contemplate any product stockpiling.

In May 2020, we completed a public offering of 17,600,000 shares of common stock resulting in net proceeds of from the offering were $1.30 billion, net of underwriting discount, commission and offering expenses. This additional funding has enabled us to substantially expand our manufacturing network, purchase the required capital equipment, hire appropriate global staff and secure the raw materials and other consumables to manufacture substantial doses of mRNA-1273.

mRNA-1273 is currently being tested in several clinical trials in collaboration with NIAID. We are in discussions with the United States government and many other governmental agencies outside the United States related to the potential sale of doses of mRNA-1273 should the product be approved by the relevant regulatory requirements in each such country. As part of those discussions and in certain cases, we may receive upfront deposits for our future mRNA-1273 vaccine supply, initially recorded as deferred revenue. During the three months ended June 30, 2020, we recognized approximately $75.0 million in deferred revenue in connection with such deposits. We will recognize revenue when revenue recognition criteria have been met. As such, in the event that

mRNA-1273 is approved for distribution, we may expect to capitalize inventory costs and record revenue related to product sales during 2020. Pre-launch inventory costs are expensed in the period incurred and included in research and development expense. Our initial product gross margin may be higher as our pre-launch inventory costs will not be included in cost of goods sold.

COVID-19 has resulted in a significant burden of disease for the worldwide population, especially those with pre-existing diseases and other comorbid conditions such as cardiovascular disease, diabetes, chronic kidney disease, chronic lung disease and obesity. In determining the pricing for a potentially approved vaccine, we considered a health economic assessment framework that uses standard metrics like the incremental cost effectiveness ratio (ICER) and the standard willingness to pay thresholds as judged by quality adjusted life years (QALY) gained from a therapy. This analysis does not reflect the costs of factors like social disruption and economic loss. This assessment has resulted in a potential assigned value to an effective COVID-19 vaccine on an ICER basis with a QALY of $50,000 that ranges from $300 per 2-dose course to $725 per 2-dose course, with the value dependent on the age category and the epidemiology of the disease, depending on whether the spread continues on the current trajectory or there is increased transmission of COVID-19. With these values in mind, our approach during the pandemic period has resulted in our working to develop a safe and effective vaccine and to price that vaccine well below its value during the pandemic period. To date, we have entered into smaller volume agreements, primarily with governments, executed at $32-$37 per dose or $64-$74 per 2-dose course. It is expected that future larger volume agreements, if any, may result in a lower price per dose. As and if the pandemic recedes and the world enters an endemic period where a vaccine against COVID-19 is still required, we expect that our vaccine will be priced in-line with other innovative vaccines and will be dependent on market forces, including vaccine efficacy and number of competitors. During the endemic period, we expect to use traditional approaches to vaccine pricing, sale and distribution.

We have a diverse development pipeline, and the broad potential applications of mRNA medicines have led us to raise significant capital and adopt a long-term approach to capital allocation that balances near-term risks and long-term value creation. As of June 30, 2020, we had cash, cash equivalents, and investments of approximately $3.07 billion. We use this capital to fund operations and investing activities for technology creation, drug discovery and clinical development programs, infrastructure and capabilities to enable our research engine and early development engine (which includes our Moderna Technology Center), our digital infrastructure, creation of our portfolio of intellectual property and administrative support.

Since our inception, we have incurred significant operating losses. Our net loss was $514.0 million and $384.7 million for the years ended December 31, 2019 and 2018, respectively. Our net loss was $116.7 million and $240.9 million for the three and six months ended June 30, 2020, respectively. As of June 30, 2020, our accumulated deficit was $1.74 billion.

For the foreseeable future, we may continue to incur significant expenses and operating losses in connection with our ongoing activities, including as we:

- continue our platform research and drug discovery and development efforts;
- build up our commercial operations and organization;
- conduct clinical trials for our investigational medicines;
- manufacture clinical trial materials and develop large-scale manufacturing capabilities;
- seek regulatory approval for our investigational medicines;
- maintain, expand, and protect our intellectual property;
- hire additional personnel to support our program development effort to obtain regulatory approval and secure additional facilities for operations; and
- continue to operate as a public company.

We do not expect to recognize revenue from the sale of potential mRNA medicines unless and until we successfully complete clinical development and obtain regulatory approval for one or more of our investigational medicines. If we seek to obtain regulatory approval for and commercialize any of our investigational medicines, we expect to incur significant commercialization expenses, which include establishing a sales, marketing, manufacturing, and distribution infrastructure globally.

As a result, we expect we will need substantial additional funding to support our continued operations and pursue our growth strategy in addition to commercial revenue that we may receive upon any sale of any of our products. Until we can generate significant revenue from sales of our medicines, if ever, we expect to finance our operations through a combination of public or private equity offerings, structured financings and debt financings, government funding arrangements, strategic alliances and marketing, manufacturing, distribution, and licensing arrangements. We may be unable to raise additional funds or enter into such other agreements on favorable terms, or at all. If we fail to raise capital or enter into such agreements as, and when, needed, we may have to significantly delay, scale back, or discontinue the development and commercialization of one or more of our programs. Because of the numerous risks and

uncertainties associated with pharmaceutical development, we are unable to predict the timing or amount of expenses or when or if we will be able to achieve or maintain profitability. Even if we are able to generate revenues from the sale of our medicines, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce our operations.

In response to the global outbreak of coronavirus, we are pursuing the rapid clinical testing and manufacture of our vaccine candidate, mRNA-1273. In May and July 2020, we announced positive interim data from the NIH-led Phase 1 study. of mRNA-1273. The Phase 2 placebo-controlled, dose-confirmation study of mRNA-1273 completed enrollment in early July 2020, and enrollment in the Phase 3 study of mRNA-1273 began on July 27, 2020. We continue to commit financial resources and personnel to the development of mRNA-1273, which may cause delays in or otherwise negatively impact our other development programs.

The ultimate impacts of COVID-19 on our business are currently unknown. In March 2020, we announced that, based on the special concerns for the safety and health of pediatric patients and their caregivers, and the risks of disruption to the integrity of trials from COVID-19, we decided to pause new enrollment of our Phase 1 rare disease clinical trials (mRNA-3704 for MMA, mRNA-3927 for PA) and our age de-escalation trial for our pediatric respiratory vaccine (mRNA-1653 for hMPV/PIV3). These decisions will be re-evaluated on an ongoing basis as the COVID-19 situation evolves. We will continue to actively monitor the situation and may take further precautionary and preemptive actions as may be required by federal, state or local authorities or that we determine are in the best interests of public health and safety and that of our patient community, employees, partners, suppliers and stockholders. We cannot predict the effects that such actions, or the impact of COVID-19 on global business operations and economic conditions, may have on our business or strategy, including the effects on our ongoing and planned clinical development activities and prospects, or on our financial and operating results.

Our Pipeline

This section describes the pipeline that has emerged thus far from the combination of our strategy, our platform, our infrastructure, and the resources we have amassed.

Since we nominated our first program in late 2014, we and our strategic collaborators have advanced in parallel a diverse development pipeline which currently consists of 23 development candidates across our 22 programs. Since December 2015 we have dosed approximately 2,000 subjects in our clinical trials and in our Phase 3 trial of mRNA-1273 started in late July we expect to dose 30,000 people with our vaccine or placebo. Our diverse pipeline comprises programs across six modalities and a broad range of therapeutic areas. A modality is a group of potential mRNA medicines with shared product features, and the associated combination of mRNA technologies, delivery technologies, and manufacturing processes. Aspects of our pipeline have been supported through strategic alliances, including with AstraZeneca plc, or AstraZeneca, Merck & Co, Inc., or Merck, and Vertex Pharmaceuticals Inc., or Vertex, and government-sponsored organizations and private foundations focused on global health initiatives, the U.S. Biomedical Advanced Research and Development Authority, or BARDA, the Defense Advanced Research Projects Agency, or DARPA, the NIH, CEPI and the Bill & Melinda Gates Foundation, or the Gates Foundation.

The following chart shows our current pipeline of 23 development candidates across our 22 programs, grouped into modalities-first the two core modalities where we believe we have reduced the technology risk, followed by the four exploratory modalities in which we are continuing to investigate the clinical use of mRNA medicines.

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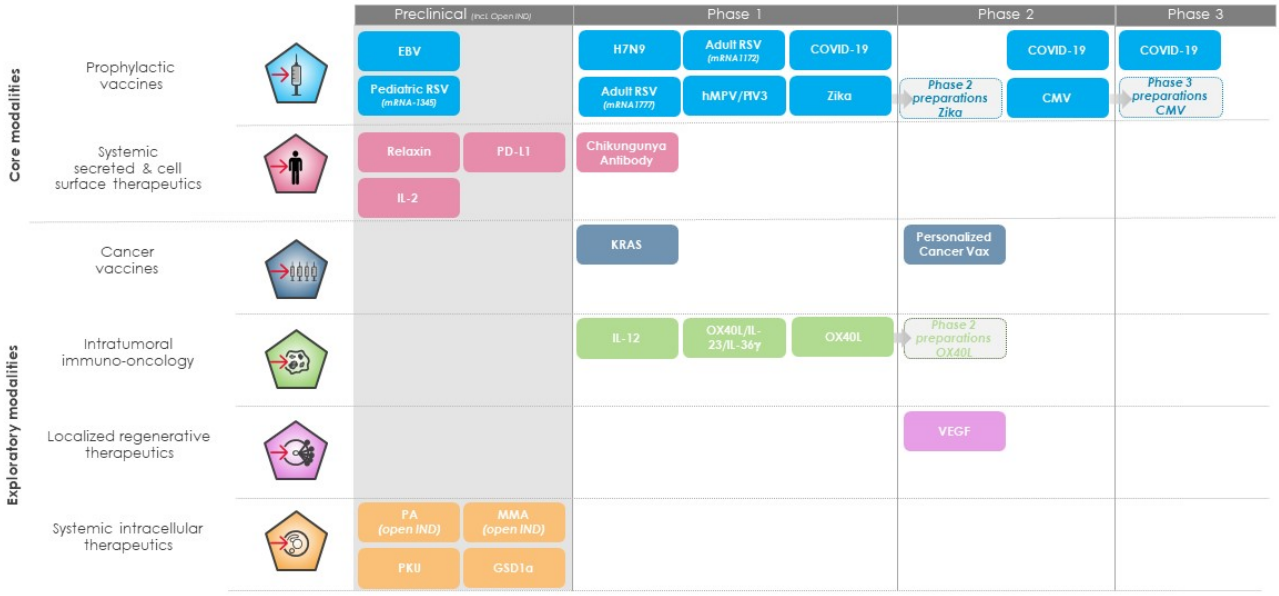

Abbreviations: IL-12, interleukin 12; IL-23, interleukin 23; IL-36γ, interleukin 36 gamma; VEGF-A, vascular endothelial growth factor A.

The breadth of biology addressable using mRNA technology is reflected in our current development pipeline of 22 programs. These span 26 different proteins or protein complexes: 11 different antigens (including virus-like particles) for infectious disease vaccines; two different cancer vaccines, one personalized cancer vaccine addressing neoantigens and one for a shared cancer antigen; four different immuno-modulator targets (including membrane and systemically secreted proteins) for immuno-oncology programs; one secreted, local regenerative factor for a heart failure program; four secreted or cell surface proteins of diverse biology (an antibody, an engineered protein hormone, a secreted cytokine and a cell surface receptor); and four intracellular enzymes for rare disease programs.

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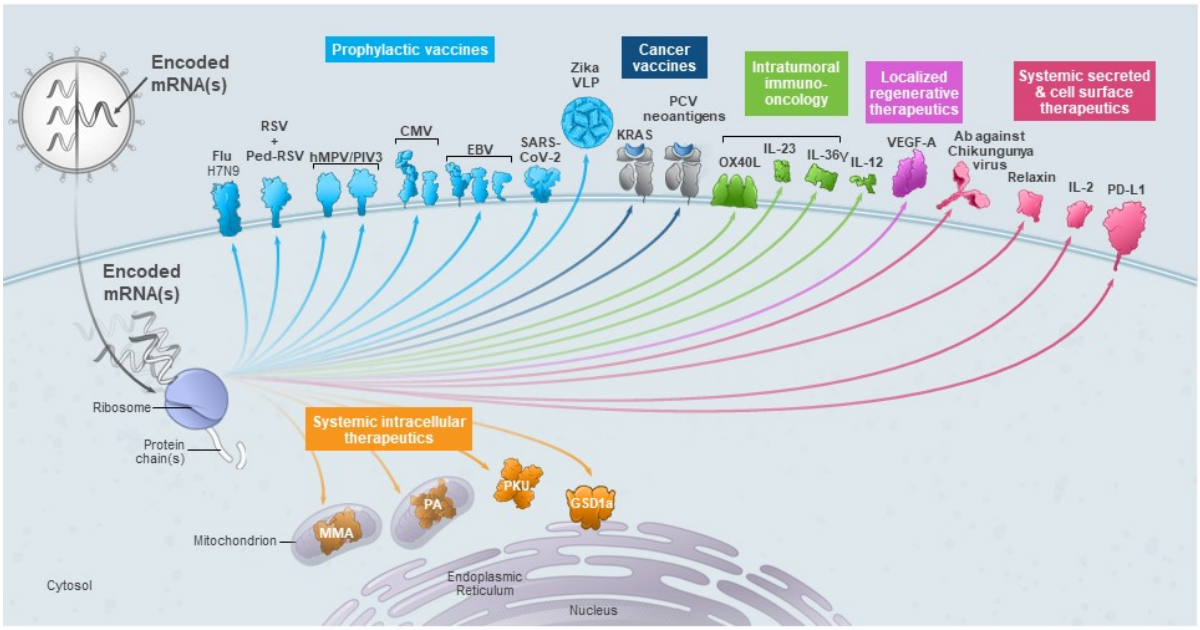
The diversity of proteins made from mRNA within our development pipeline is shown in the figure below.



We have developed six modalities, which are summarized as follows:

- **Prophylactic vaccines:** Our prophylactic vaccines modality currently includes eight programs, six of which have entered into clinical trials. Of these programs, we have demonstrated desired pharmacology, in the form of immunogenicity, in the positive Phase 1 clinical trials for the following eight programs: H10N8 vaccine (mRNA-1440), H7N9 vaccine (mRNA-1851), RSV vaccine (mRNA-1777), Chikungunya vaccine (mRNA-1388), human metapneumovirus (hMPV)/ parainfluenza virus type 3 (PIV3) vaccine (mRNA-1653), Zika vaccine (mRNA-1893), CMV vaccine (mRNA-1647) and SARC-CoV-2 (mRNA-1273). We have an ongoing Phase 1 trial for the next generation Zika vaccine (mRNA-1893) and Merck is conducting a Phase 1 trial for an additional RSV vaccine (mRNA-1172). Our SARS-CoV-2 vaccine (mRNA-1273) is described in detail below. In addition to the eight programs being developed, the H10N8 vaccine (mRNA-1440) and Chikungunya vaccine (mRNA-1388) are two public health programs that are not being further developed without government or other funding.

- **Systemic secreted therapeutics:** We have four systemic secreted and cell surface therapeutics development candidates in our pipeline. Our secreted programs include our antibody against Chikungunya virus (mRNA-1944), Relaxin (AZD7970) for the treatment of heart failure, and IL-2 (mRNA-6231) for autoimmune disorders. Our antibody against Chikungunya virus (mRNA-1944) has had positive Phase 1 readouts to date and is currently being evaluated in an ongoing Phase 1 dose escalation study in healthy adults that is randomized and placebo-controlled. The Phase 1 study evaluating escalating doses of mRNA-1944 administered via intravenous infusion in healthy adults has restarted after COVID-19 disruptions. Both cohorts, one cohort at the 0.6 mg/kg dose with steroid premedication and one cohort with two doses of 0.3 mg/kg (without steroid premedication) given one week apart, are fully enrolled and all participants have been dosed. The remaining programs for Relaxin (AZD7970) and IL-2 (mRNA-6231) are currently in preclinical development. We have a cell surface therapeutic program in this modality, PDL-1 (mRNA-6981) for autoimmune hepatitis, which is currently in preclinical development.

- **Cancer vaccines:** We are currently developing two programs within our cancer vaccines modality. Our personalized cancer vaccine program mRNA-4157 is being developed in collaboration with Merck and is in a multiple-arm Phase 1 trial and a randomized Phase 2 trial. A second personalized cancer vaccine, NCI-4650 was being developed in collaboration with the National Cancer Institute, or NCI, and was in an investigator-initiated single-arm Phase 1 trial which has been completed. The two vaccines mRNA-4157 and NCI-4650 differ in the neoantigen selection protocols used, but are otherwise

substantially the same. Our second program within this modality, mRNA-5671, is a KRAS vaccine. Our strategic collaborator Merck has a Phase 1 clinical trial ongoing for mRNA-5671.

- **Intratumoral immuno-oncology:** We have three programs in this modality. The first program in this modality, OX40L (mRNA-2416), was designed to overcome technological challenges in advancing this modality, including engineering the mRNA sequence to minimize off-target effects, utilizing our proprietary lipid nanoparticles (LNPs) to enhance safety and tolerability, and to demonstrate expression of a membrane protein in patients. OX40L (mRNA-2416) is currently being evaluated in an ongoing Phase 1/2 trial in the United States, and protein expression has been demonstrated in a number of patients. Data from the monotherapy arm of this ongoing study of mRNA-2416 showed that mRNA-2416 was well-tolerated at all dose levels studied with the majority of adverse events reported as grade 1 and 2 and no grade 3 adverse events reported. This data supports the evaluation of intratumoral mRNA-2416 with the anti-PD-L1 inhibitor durvalumab in solid tumors, which is ongoing in Part B of this study with a focus on advanced ovarian carcinoma. Our second program, OX40L/IL-23/IL-36γ (Triplet) (mRNA-2752), has dosed patients in a Phase 1 study for the treatment of advanced or metastatic solid tumor malignancies or lymphoma. Our third program, IL-12 (MEDI1191), is being developed in collaboration with AstraZeneca.

- **Localized regenerative therapeutics:** Our localized VEGF-A program, AZD8601, which is being developed by AstraZeneca, has completed a Phase 1a/b trial to describe its safety, tolerability, protein production, and activity in diabetic patients. The study has met its primary objectives of describing safety and tolerability and secondary objectives of demonstrating protein production and changes in blood flow post AZD8601 administration. In this trial, AZD8601 was administered by intradermal injection in the forearm skin of patients for single ascending doses. These data are consistent with studies previously conducted in preclinical models. We believe these data provide clinical proof of mechanism for our mRNA technology outside of the vaccine setting. AstraZeneca has initiated a Phase 2a study of AZD8601 for VEGF-A for ischemic heart disease in patients undergoing coronary artery bypass grafting (CABG) surgery with moderately impaired systolic function, and the trial is ongoing.

- **Systemic intracellular therapeutics:** We have four systemic intracellular therapeutics development candidates in our pipeline. Our intracellular programs address methylmalonic acidemia, or MMA (mRNA-3704), propionic acidemia, or PA (mRNA-3927), phenylketonuria, or PKU (mRNA-3283), and glycogen storage disorder type 1a, or GSD1a (mRNA-3745). We have an open IND for mRNA-3704 for a planned Phase 1/2 trial, and the FDA has also designated the investigation of mRNA-3704 for the treatment of isolated MMA due to MUT deficiency as a Fast Track development program. We have an open IND for mRNA-3927 for a planned Phase 1/2 trial and this program has also been designated as a Fast Track development program. PKU (mRNA-3283) is currently in preclinical development.

Our Vaccine Candidate Against SARS-CoV-2 (mRNA-1273)

In response to the global coronavirus pandemic, we are pursuing the rapid development and manufacture of our vaccine candidate, mRNA-1273, for the treatment of SARS-CoV-2, the novel strain of coronavirus that causes COVID-19, in collaboration with NIAID.

Preclinical Studies

On July 29, 2020, we announced the publication in *The New England Journal of Medicine* of data from a preclinical study of mRNA-1273 in non-human primates. In the study, immunogenicity and protective efficacy were assessed after a two-dose vaccination schedule of 10 or 100 µg doses of mRNA-1273 or control given four weeks apart (n=24; 8 per group). Four weeks after the second vaccination, animals were challenged with high doses of SARS-CoV-2 through intranasal and intratracheal routes.

After two vaccinations, the immune response observed in this non-human primate study was consistent with the Phase 1 human study of mRNA-1273, also published in *The New England Journal of Medicine*. At the 10 µg dose, the geometric mean titer (GMT, ID50) measured in a pseudovirus (PsV) neutralization assay was 103, similar to the GMT for a panel of convalescent sera reported previously (109), and below the GMT achieved by mRNA-1273 in the Phase 1 human study at the 100 µg dose (231) in the same PsV assay. At the higher dose in the non-human primates (100 µg), neutralizing antibody titers increased further, with PsV GMT reaching 1,862. Vaccination also led to a significant increase in T cell responses, primarily Th1 CD4 T cells.

Two doses of mRNA-1273 provided protection against lung inflammation following viral challenge with SARS-CoV-2 in non-human primates at both the 10 µg and 100 µg dose levels. In addition, both the 10 µg and 100 µg dose groups demonstrated protection against viral replication in the lungs, with the 100 µg dose also protecting against viral replication in the nose of the animals. Of note, none of the eight animals in the 100 µg group showed detectable viral replication in the nose compared to six out of eight in the placebo group on day 2.

Preclinical results from a viral challenge study in mice conducted in collaboration with NIAID and its academic partners are also available. In this study, vaccination with mRNA-1273 prevented viral replication in the lungs of mice challenged with SARS-CoV-2. Neutralizing titers in Phase 1 clinical trial participants at the 25 µg and 100 µg dose levels (described below) were consistent with neutralizing titers that were protective in the mouse and NHP challenge models.

Phase 1 Study

A Phase 1 open-label study of mRNA-1273 is being conducted by the National Institutes of Health (NIH). This study, which began on March 16, 2020, originally enrolled 45 healthy adult volunteers ages 18 to 55 years and is evaluating three dose cohorts (25 µg, 100 µg and 250 µg). An additional seven cohorts in the Phase 1 study have since completed enrollment: a 50 µg cohort in adults 18-55 (n=15), three cohorts of older adults (n=30, ages 56-70, 25 µg, 50 µg, and 100 µg) and three cohorts of elderly adults (n=30, ages 71 and above, 25 µg, 50 µg, and 100 µg).

On July 14, 2020, we announced the publication in *The New England Journal of Medicine* of an interim analysis of data from the original cohorts obtained through Day 57 in the Phase 1 study.

This interim analysis demonstrated that mRNA-1273 induced binding antibodies to the full-length SARS-CoV-2 Spike protein (S) in all participants after the first vaccination, with all participants seroconverting by Day 15. Dose dependent increases in binding titers were seen across the three dose levels, and between prime and boost vaccinations within the dose cohorts. After two vaccinations, at Day 57, geometric mean titers exceeded those seen in convalescent sera obtained from 38 individuals with confirmed COVID-19 diagnosis. Of the 38 individuals in the convalescent sera group, 15% were classified as having severe symptoms (hospitalization requiring intensive care and/or ventilation), 22% had moderate symptoms and 63% had mild symptoms. Convalescent sera samples were tested using the same assays as the study samples.

Neutralizing activity was assessed in two different assays, a live SARS-CoV-2 plaque-reduction neutralization test (PRNT) and a pseudovirus neutralization assay (pseudotyped lentivirus reporter single-round-of-infection neutralization assay, PsVNA). No participants had detectable live SARS-CoV-2 virus neutralization or PsVNA responses prior to vaccination. After two vaccinations, mRNA-1273 elicited robust neutralizing antibody titers. At Day 43, neutralizing activity against SARS-CoV-2 (PRNT80) was seen in all evaluated participants. At the Phase 3 selected dose of 100 µg, the geometric mean titer levels were 4.1-fold above those seen in reference convalescent sera (n=3). After the second vaccination, PsVNA neutralizing antibody titers were detected in all participants in all dose cohorts. The Day 57 geometric mean titers at the 100 µg dose were 2.1-fold higher than those seen in convalescent sera (n=38)3. Strong correlations were observed between the binding and neutralization assays, and between the live virus and pseudovirus neutralization assays. A clear dose response was seen in geometric mean titers between the 25 µg and 100 µg dose levels, with minimal additional increases at the 250 µg dose. T-cell responses were also evaluated at the 25 µg and 100 µg dose levels. Following second vaccination, mRNA-1273 elicited Th1-biased CD4 T-cell responses without significant elevation of Th2-biased CD4 T-cell responses.

mRNA-1273 was generally safe and well-tolerated, with no serious adverse events reported through Day 57. Adverse events were generally transient and mild to moderate in severity. The most notable adverse events were seen at the 250 µg dose level, with three of those 14 participants (21%) reporting one or more severe events. Solicited systemic adverse events were more common after the second vaccination and occurred in seven of 13 (54%) participants in the 25 µg group, all 15 participants in the 100 µg group and all 14 participants in the 250 µg group. The most commonly reported systemic adverse events following second vaccination at the 100 µg dose were fatigue (80%), chills (80%), headache (60%) and myalgia (53%), all of which were transient and mild or moderate in severity. The most common solicited local adverse event at the 100 µg dose was pain at the injection site (100%), which was also transient and mild or moderate in severity. Evaluation of clinical safety laboratory values grade 2 or higher and unsolicited adverse events revealed no patterns of concern.

Evaluation of the durability of immune responses is ongoing, and participants will be followed for one year after the second vaccination, with scheduled blood collections throughout that period.

Phase 2 Study

We are conducting a Phase 2 placebo-controlled, dose-confirmation study evaluating the safety, reactogenicity and immunogenicity of two vaccinations of mRNA-1273 given 28 days apart. Each cohort -- healthy adults ages 18-55 years (n=300) and older adults ages 55 years and above (n=300) -- is receiving placebo, a 50 µg or a 100 µg dose at both vaccinations. On July 8, 2020, we announced that the Phase 2 study was fully enrolled. Participants will be followed for one year after the second vaccination.

Phase 3 Study

We are conducting a Phase 3 randomized, 1:1 placebo-controlled study of mRNA-1273, named the COVE study, which began enrollment on July 27, 2020. The study protocol, which has been reviewed by the U.S. Food and Drug Administration (FDA) and is

aligned to recent FDA guidance on clinical trial design for COVID-19 vaccine studies, provides for approximately 30,000 participants in the United States at the 100 µg dose level. The primary endpoint will be the prevention of symptomatic COVID-19 disease. Key secondary endpoints include prevention of severe COVID-19 disease (as defined by the need for hospitalization) and prevention of infection by SARS-CoV-2. The primary efficacy analysis will be an event-driven analysis based on the number of participants with symptomatic COVID-19 disease. The target vaccine efficacy (VE) against COVID-19 for powering assumptions is 60% (95% confidence interval to exclude a lower bound >30%). Data will be reviewed by an independent Data Safety Monitoring Board organized by NIH. The trial is expected to have two interim analyses (at approximately 53 and 106 events), prior to a final event-driven analysis at approximately 151 events.

Regulatory

On May 11, 2020, the FDA granted Fast Track designation for mRNA-1273. Fast Track is designed to facilitate the development and expedite the review of therapies and vaccines for serious conditions and fill an unmet medical need. Programs with Fast Track designation may benefit from early and frequent communication with the FDA, in addition to a rolling submission of the marketing application.

Manufacturing

We are continuing to manufacture mRNA-1273 at the Moderna Technology Center, our dedicated manufacturing facility. We have also recently entered into arrangements with third parties to enable larger scale manufacturing and fill-finish capabilities.

In May 2020, we announced a 10-year strategic collaboration agreement with Lonza Ltd. to enable larger scale manufacture of mRNA-1273 and additional Moderna products in the future. The companies are establishing manufacturing suites at Lonza's facilities in the United States and Switzerland for the manufacture of mRNA-1273 at both sites, and the first batches of mRNA-1273 at Lonza's U.S. facility were manufactured in July.

In June 2020, we announced a collaboration with Catalent, Inc. for large-scale, commercial fill-finish manufacturing of mRNA-1273 at Catalent's biologics facility in Indiana. As part of the agreement, Catalent will provide vial filling and packaging capacity, as well as additional staffing required for 24x7 manufacturing operations at the site to support production of an initial 100 million doses of the vaccine candidate intended to supply the U.S. market starting in the third quarter of 2020. Catalent will also provide clinical supply services from its facilities in Philadelphia, Pennsylvania, including packaging and labeling, as well as storage and distribution to support our Phase 3 clinical study.

In addition, in July 2020, we announced a collaboration with ROVI for large-scale, commercial fill-finish manufacturing of mRNA-1273 intended in principle to supply markets outside of the United States starting in early 2021 from ROVI's facility in Madrid, Spain.

Key Updates for our Other Development Candidates

- **CMV vaccine (mRNA-1647):** We completed the third planned interim analysis of data from the Phase 1 clinical trial of mRNA-1647, which has completed enrollment and is evaluating the safety and immunogenicity of mRNA-1647 in 181 healthy adult volunteers. The clinical trial population includes those who are naïve to CMV infection (CMV-seronegative) and those who had previously been infected by CMV (CMV-seropositive). Participants were randomized to receive either placebo, or 30, 90, 180 or 300 µg of mRNA-1647 on a dosing schedule of 0, 2 and 6 months. This third planned interim analysis assessed immunogenicity of the first three dose levels (30, 90, and 180 µg) at twelve months (six months after the third vaccination). Neutralizing antibody titers (levels of circulating antibodies that block infection) were assessed in two assays utilizing epithelial cells and fibroblasts, which measure immune response to the pentamer and gB vaccine antigens, respectively. gB antigen-specific T cell responses after the second and third vaccinations were measured in a subset of CMV-seronegative participants in the 30, 90 and 180 µg dose levels utilizing an ELISpot assay. Pentamer-specific T cell assays remain in development. Vaccine-induced neutralizing antibody responses in the CMV-seronegative group were compared to the baseline neutralizing antibody titers in the CMV-seropositive group, noting that prior maternal CMV infection is associated with an approximately 30-fold lower risk of congenital CMV infection compared to the risk in the setting of maternal primary CMV infection.

In CMV-seronegative participants at twelve months (six months after the third vaccination) in the 30, 90 and 180 µg dose levels:

  - A dose-related increase in neutralizing antibody titers was observed in epithelial cell assays.
  - Neutralizing antibody titers against epithelial cell infection were 3.6-fold and 3.9-fold higher in the 90 and 180 µg dose levels than CMV-seropositive baseline titers at the 90 and 180 µg dose levels.
  - Neutralizing antibody titers against fibroblast infection were 0.7 and 0.9 times the CMV-seropositive baseline titers at the 90 and 180 µg dose levels.

In CMV-seropositive participants at twelve months (six months after the third vaccination) in the 30, 90 and 180 µg dose levels:

- A dose-related increase in neutralizing antibody titers was observed in both epithelial cell and fibroblast assays.
- Neutralizing antibody titers against epithelial cell infection ranged between 14-fold to 31-fold over baseline titers in all dose levels.
- Neutralizing antibody titers against fibroblast infection ranged from 6-fold to 8-fold over baseline titers in all dose levels.

The interim data analysis also included an assessment of safety for the highest dose level (300 µg). Safety and tolerability data at the 300 µg dose level were generally similar to that observed at the 180 µg dose level, indicating that the vaccine was generally well-tolerated. There were no vaccine-related serious adverse events. The most common solicited local adverse reaction at the 300 µg dose level was injection site pain. The most common solicited systemic adverse reactions at the 300 µg dose level were headache, fatigue, myalgia and chills and for seropositive participants, fever and arthralgia.

- **hMPV/PIV3 vaccine (mRNA-1653):** The first 10 subjects in the Phase 1b age de-escalation clinical trial of mRNA-1653 have been enrolled and dosed. Further screening and enrollment in this trial is paused due to the COVID-19 pandemic.

- **Zika virus vaccine (mRNA-1893):** All four cohorts (10 µg, 30 µg, 100 µg, 250 µg) of the Phase 1 study of mRNA-1893 have been dosed. In April, we announced positive data from an interim analysis of the 10 µg and 30 µg cohorts. The clinical trial population includes those who had not been infected by the Zika virus (flavivirus seronegative) and those who had previously been infected by the Zika virus (flavivirus seropositive). Participants were randomized to receive either placebo, 10, 30, 100 or 250 µg of mRNA-1893 on a dosing schedule of day 1 and day 29. This second planned interim analysis assessed safety and immunogenicity of the higher dose levels (100 and 250 µg) at day 57, 28 days after the second vaccination. Neutralizing antibody titers (levels of circulating antibodies that block infection) were assessed using Plaque Reduction Neutralizing Test ($PRNT_{50}$) and microneutralization assays (MN), which provide equivalent guidance for interpreting the neutralizing immune response.

  In the flavivirus-seronegative group:

  - Seroconversion rates after the second vaccination reached 100% in the 100 µg dose level and 98.7% in the 250 µg dose level, based on the $PRNT_{50}$. MN data were consistent with $PRNT_{50}$ data.
  - A single vaccination at both the 100 and 250 µg dose levels was sufficient to seroconvert baseline flavivirus seronegative participants. However, there was a clear benefit of a two-dose series given 28 days apart.
  - Each of the 100 and 250 µg dose levels induced a strong neutralizing Zika virus-specific antibody response.
  - When compared with the 100 µg dose level, the 250 µg dose level did not show a higher neutralizing antibody response at either Day 29 (after one dose) or Day 57 (after the second dose).

  In the flavivirus-seropositive group:

  - The percentage of participants achieving a 4-fold boost in pre-existing $PRNT_{50}$ titers after the second vaccination reached 100% in the 100 µg dose level and 75% in the 250 µg dose level, based on the $PRNT_{50}$. MN data were generally consistent with $PRNT_{50}$ data.

  A safety analysis indicated that the 100 and 250 µg dose levels were both generally well tolerated. There were no vaccine-related serious adverse events. The most common solicited local adverse reaction was local pain at the injection site. The most common solicited systemic adverse reactions were headache, fatigue, myalgia, fever and chills.There was a trend towards more observations of local erythema and swelling/induration at the injection site with higher dose levels, in particular after the second vaccine administration, as well as a trend of more solicited systemic adverse events with the 250 µg dose after the second administration.

  For each of the dose cohorts in the Phase 1 study of mRNA-1893, further analysis of safety and immunogenicity at month 7 and month 13 is pending.

- **OX40L (mRNA-2416):** Based on available data, earlier this year we decided to focus the development of mRNA-2416 for the treatment of patients with ovarian cancer in combination with durvalumab (IMFINZI), a PD-L1 inhibitor. The safety cohort of the combination arm (mRNA-2416 and durvalumab) of this Phase 1/2 clinical trial continues to enroll, and the Phase 2 dose expansion cohort in patients with ovarian cancer is actively recruiting participants.

- **Antibody against Chikungunya virus (mRNA-1944):** We are conducting a Phase 1 dose-escalation study in healthy adults that is randomized and placebo-controlled. The objective is to evaluate the safety and tolerability of escalating doses (0.1, 0.3, 0.6, mg/kg dose levels, without dexamethasone included in the premedication regimen, a dose level cohort at 0.6 mg/kg dose level, with dexamethasone included in the premedication regimen, with 8 subjects per cohort) of mRNA-1944 administered

via intravenous infusion. In addition, there is a dose level cohort in which subjects were administered two IV infusions of 0.3 mg/kg, one infusion on Day 1 and another subsequent infusion on Day 8, without dexamethasone in the premedication regimen. No further dose escalation beyond 0.6 mg/kg is planned. Following a pause due to COVID-19 disruption, enrollment and dosing in this study resumed, and dosing of all dose level cohorts has been completed.

- **Methylmalonic Acidemia (MMA) (mRNA-3704):** Enrollment continues to be paused for this study due to difficulties caused by the pandemic. As a result of the study pause, the single patient previously enrolled was unable to be dosed in accordance with study criteria, resulting in de-enrollment of the patient.

Financial Operations Overview

Revenue

To date, we have not recognized any revenue from the sale of potential mRNA medicines. Our revenue has been primarily derived from strategic alliances with Merck, Vertex and AstraZeneca, and from government-sponsored and private organizations including BARDA, DARPA and the Gates Foundation to discover, develop, and commercialize potential mRNA medicines.

Total revenue for the three and six months ended June 30, 2020 was $66.4 million and $74.7 million, respectively. Total revenue for the three and six months ended June 30, 2019 was $13.1 million and $29.1 million, respectively. In each period total revenue was comprised of collaboration revenue and grant revenue.

Collaborative revenue from our strategic alliances as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Collaboration revenue:				
AstraZeneca	$ 15,884	$ 188	$ 17,154	$ 1,002
Merck	10,365	8,659	11,341	19,346
Vertex	2,193	1,183	4,249	3,797
Other	—	—	155	—
Total collaboration revenue	$ 28,442	$ 10,030	$ 32,899	$ 24,145

Cash received from strategic alliances was $8.1 million and $10.5 million for the six months ended June 30, 2020 and 2019, respectively. The timing of revenue recognition is not directly correlated to the timing of cash receipts. Total deferred revenue related to our strategic alliances as of June 30, 2020 and December 31, 2019 was $173.0 million and $199.5 million, respectively.

Grant revenue was comprised as follows for the periods presented (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Grant revenue:				
BARDA	$ 37,048	$ 1,876	$ 39,816	$ 3,365
Other	861	1,177	2,025	1,598
Total grant revenue	$ 37,909	$ 3,053	$ 41,841	$ 4,963

Our ability to recognize revenue from sales of mRNA medicines and become profitable depends upon our ability to successfully develop and commercialize mRNA medicines. The rapid acceleration of our work on mRNA-1273 may result in revenue to us, either based on sales of the product directly or through collaborators. In addition, we expect to continue to receive funding from our contract with BARDA, which may result in significant additional amounts of revenue to Moderna during 2020. To the extent that existing or potential future strategic alliances generate revenue, our revenue may vary due to many uncertainties in the development of our mRNA medicines under these strategic alliances and other factors. We may continue to incur losses for the foreseeable future, and we expect these losses to increase as we continue our research and development efforts. We expect our programs to mature and advance

to later stage clinical development, and we expect expenses to increase as we seek regulatory approvals for our investigational medicines and begin to commercialize any approved mRNA medicines.

Research and development expenses

The nature of our business and primary focus of our activities generate a significant amount of research and development costs. Research and development expenses represent costs incurred by us for the following:

- cost to develop our platform;
- discovery efforts leading to development candidates;
- preclinical, nonclinical, and clinical development costs for our programs;
- costs related to pre-launch inventory;
- cost to develop our manufacturing technology and infrastructure; and
- digital infrastructure costs.

The costs above comprise the following categories:

- personnel-related expenses, including salaries, benefits, and stock-based compensation expense;
- expenses incurred under agreements with third parties, such as consultants, investigative sites, contract research organizations, or CROs, that conduct our preclinical studies and clinical trials, and in-licensing arrangements;
- expenses associated with developing manufacturing capabilities and acquiring materials for preclinical studies, clinical trials and pre-launch inventory, including both internal manufacturing and third-party contract manufacturing organizations, or CMOs;
- 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 use our employee and infrastructure resources for the advancement of our platform, and for discovering and developing programs. Due to the number of ongoing programs and our ability to use resources across several projects, indirect or shared operating costs incurred for our research and development programs are generally not recorded or maintained on a program- or modality-specific basis. The following table reflects our research and development expenses, including direct program-specific expenses summarized by modality and indirect or shared operating costs summarized under other research and development expenses during the three and six months ended June 30, 2020 and 2019 (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Program expenses by modality:				
Prophylactic vaccines	$ 35,657	$ 12,398	$ 44,397	$ 32,660
Cancer vaccines	11,652	13,375	16,119	23,461
Intratumoral immuno-oncology	1,443	2,775	3,476	7,193
Localized regenerative therapeutics	—	8	—	16
Systemic secreted and cell surface therapeutics	578	4,484	1,270	9,117
Systemic intracellular therapeutics	5,235	9,829	12,430	16,572
Total program-specific expenses by modality [(1)]	54,565	42,869	77,692	89,019
Other research and development expenses:				
Discovery programs	10,229	15,635	20,727	28,550
Platform research	18,659	24,256	40,245	48,753
Technical development and unallocated manufacturing expenses	29,284	18,258	58,422	39,443
Shared discovery and development expenses	24,416	14,355	43,168	29,238
Stock-based compensation	14,703	12,932	26,739	23,715
Total research and development expenses	$ 151,856	$ 128,305	$ 266,993	$ 258,718

(1) Include a total of 23 and 21 development candidates at June 30, 2020 and 2019, respectively. Program-specific expenses include external costs and allocated manufacturing costs of pre-launch inventory, mRNA supply and consumables, and are reflected as of the beginning of the period in which the program was internally advanced to development or removed if development was ceased.

A *"modality"* refers to a group of programs with common product features and the associated combination of enabling mRNA technologies, delivery technologies, and manufacturing processes. The program-specific expenses by modality summarized in the table above include expenses we directly attribute to our programs, which consist primarily of external costs, such as fees paid to outside consultants, central laboratories, investigative sites, and CROs in connection with our preclinical studies and clinical trials, CMOs, and allocated manufacturing costs of pre-launch inventory, mRNA supply and consumables. Costs to acquire and manufacture pre-launch inventory, mRNA supply for preclinical studies and clinical trials are recognized and included in unallocated manufacturing expenses when incurred, and subsequently allocated to program-specific manufacturing costs after completion of the program-specific production. The timing of allocating manufacturing costs to the specific program varies depending on the program development and production schedule. We generally do not allocate personnel-related costs, including stock-based compensation, costs associated with our general platform research, technical development, and other shared costs on a program-specific basis. These costs were therefore excluded from the summary of program-specific expenses by modality.

Discovery program expenses are costs associated with research activities for our programs in the preclinical discovery stage, and primarily consist of external costs for CROs and lab services, and allocated manufacturing cost of preclinical mRNA supply and consumables.

Platform research expenses are mainly costs to develop technical advances in mRNA science, delivery science, and manufacturing process design. These costs include personnel-related costs, computer equipment, facilities, preclinical mRNA supply and consumables, and other administrative costs to support our platform research. Technology development and unallocated manufacturing expenses are primarily related to non-program-specific manufacturing process development and manufacturing costs.

Shared discovery and development expenses are research and development costs such as personnel-related costs and other costs, which are not otherwise included in development programs, discovery programs, platform research, technical development and unallocated manufacturing expenses, stock-based compensation, and other expenses.

The largest component of our total operating expenses has historically been our investment in research and development activities, including development of our platform, mRNA technologies, and manufacturing technologies. We expense research and development costs as incurred and cannot reasonably estimate the nature, timing, and estimated costs required to complete the development of the development candidates and investigational medicines we are currently developing or may develop in the future. There are numerous risks and uncertainties associated with the research and development of such development candidates and investigational medicines, including, but not limited to:

- scope, progress, and expense of developing ongoing and future development candidates and investigational medicines;
- entry in and completion of related preclinical studies;
- enrollment in and completion of subsequent clinical trials;
- safety and efficacy of investigational medicines resulting from these clinical trials;
- changes in laws or regulations relevant to the investigational medicines in development;
- receipt of the required regulatory approvals; and
- commercialization, including establishing manufacturing and marketing capabilities.

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. Investigational medicines in later stages of clinical development, including mRNA-1273 and mRNA-1647, generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect our research and development costs to continue to increase in the foreseeable future as our investigational medicines progress through the development phases, as we continue to advance the development of mRNA-1273 and mRNA-1647 and identify and develop additional programs. There are numerous factors associated with the successful commercialization of any of our investigational medicines, including future trial design and various regulatory requirements, many of which cannot be determined with accuracy at this time due to the early stage of development of our investigational medicines. Moreover, future commercial and regulatory factors beyond our control will impact our clinical development programs and plans.

As we continue to progress mRNA-1273 through the development process in order to be useful during the current pandemic, we expect to incur significant additional expenses, including those related to clinical trials, expanding our manufacturing capabilities, costs of pre-launch inventory, regulatory filings and the related costs, expansion of our operations into foreign jurisdictions and commercialization and distribution efforts. At this time, the magnitude of these potential expenditures and whether or not they will be funded by third party contributions in whole or in part is not known. In connection with the new BARDA agreement to accelerate development of mRNA-1273, our revenue and expenses are expected to increase significantly. BARDA's funding is expected to offset those increased expenses that are covered under the BARDA agreement, subject to our obtaining reimbursement from BARDA.

General and administrative expenses

General and administrative expenses consist primarily of personnel-related costs, including stock-based compensation, for executives, finance, legal, human resources, business development and other administrative and operational functions, professional fees, accounting and legal services, information technology and facility-related costs, and expenses associated with obtaining and maintaining intellectual property, or IP. 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 we continue to expand the number of programs in development and prepare for the potential earlier establishment of commercial activities both within and outside the United States. In addition, if we obtain regulatory approval for any of our investigational medicines, including the potential accelerated approval for mRNA-1273, and do not enter into one or more third-party commercialization collaboration and manufacturing arrangements, we will incur significant expenses related to building a regulatory, manufacturing, sales and marketing team to support medicine sales, marketing, and distribution activities.

We have a broad IP portfolio covering our development and commercialization of mRNA vaccine and therapeutic programs, including those related to mRNA design, formulation, and manufacturing platform technologies. We regularly file patent applications to protect innovations arising from our research and development. We also hold trademarks and trademark applications in the United States and foreign jurisdictions. Costs to secure and defend our IP are expensed as incurred and are classified as general and administrative expenses.

General and administrative expenses, including IP-related expenses, were $36.6 million and $60.7 million for the three and six months ended June 30, 2020, respectively. General and administrative expenses, including IP-related expenses, were $28.5 million and $55.7 million for the three and six months ended June 30, 2019, respectively. IP-related expenses, including our internal personnel-related costs, were $3.2 million and $5.6 million for the three and six months ended June 30, 2020, respectively. IP-related expenses, including our internal personnel-related costs, were $4.4 million and $7.2 million for the three and six months ended June 30, 2019, respectively. We did not incur litigation expenses related to our IP during the three months or six months ended June 30, 2020 and 2019.

Interest income

Interest income consists of interest generated from our investments in cash and cash equivalents, money market funds, and high-quality fixed income securities.

Other expense, net

Other expense, net consists of interest expense, gains (losses) from the sale of investments in marketable securities, and other income and expense unrelated to our core operations. Interest expense is primarily derived from our finance lease related to our Moderna Technology Center manufacturing facility, or MTC South.

Critical accounting policies and significant judgments and estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our condensed consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these condensed consolidated financial statements requires us to make judgments and estimates that affect the reported amounts of assets, liabilities, revenues, and expenses and the disclosure of contingent assets and liabilities in our condensed consolidated financial statements. We base our estimates on historical experience, known trends and events, and various other factors that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. On an ongoing basis, we evaluate our judgments and estimates in light of changes in circumstances, facts, and experience. The effects of material revisions in estimates, if any, are reflected in the condensed consolidated financial statements prospectively from the date of change in estimates.

There have been no material changes in our critical accounting policies and estimates in the preparation of our condensed consolidated financial statements during the three months ended June 30, 2020 compared to those disclosed in our Annual Report on Form 10-K for the year ended December 31, 2019, or 2019 Form 10-K.

Recently issued accounting pronouncements

We have reviewed all recently issued standards and have determined that, other than as disclosed in Note 2 to our condensed consolidated financial statements, such standards will not have a material impact on our financial statements or do not otherwise apply to our operations.

Results of operations

The following tables summarize our condensed consolidated statements of operations for each period presented (in thousands):

	Three Months Ended June 30,		Change 2020 vs. 2019	
	2020	2019	$	%
Revenue:				
Collaboration revenue	$ 28,442	$ 10,030	$ 18,412	184%
Grant revenue	37,909	3,053	34,856	1142%
Total revenue	66,351	13,083	53,268	407%
Operating Expenses:				
Research and development	151,856	128,305	23,551	18%
General and administrative	36,622	28,487	8,135	29%
Total operating expenses	188,478	156,792	31,686	20%
Loss from operations	(122,127)	(143,709)	21,582	(15)%
Interest income	7,092	10,322	(3,230)	(31)%
Other expense, net	(1,530)	(1,877)	347	(18)%
Loss before income taxes	(116,565)	(135,264)	18,699	(14)%
Provision for (benefit from) income taxes	148	(324)	472	(146)%
Net loss	$ (116,713)	$ (134,940)	$ 18,227	(14)%

	Six Months Ended June 30,		Change 2020 vs. 2019	
	2020	2019	$	%
Revenue:				
Collaboration revenue	$ 32,899	$ 24,145	$ 8,754	36%
Grant revenue	41,841	4,963	36,878	743%
Total revenue	74,740	29,108	45,632	157%
Operating Expenses:				
Research and development	266,993	258,718	8,275	3%
General and administrative	60,736	55,740	4,996	9%
Total operating expenses	327,729	314,458	13,271	4%
Loss from operations	(252,989)	(285,350)	32,361	(11)%
Interest income	14,944	21,294	(6,350)	(30)%
Other expense, net	(2,684)	(3,808)	1,124	(30)%
Loss before income taxes	(240,729)	(267,864)	27,135	(10)%
Provision for (benefit from) income taxes	214	(348)	562	(161)%
Net loss	$ (240,943)	$ (267,516)	$ 26,573	(10)%

Revenue

Total revenue increased by $53.3 million, or 407%, for the three months ended June 30, 2020 compared to the same period in 2019, due to increases in both collaboration revenue and grant revenue. Collaboration revenue increased by $18.4 million for the three months ended June 30, 2020 compared to the same period in 2019, primarily driven by an increase in revenue due to delivery of drug materials under the collaboration agreements with AstraZeneca. Grant revenue increased by $34.9 million for the three months ended June 30, 2020 compared to the same period in 2019, mainly due to an increase in revenue from BARDA related to our mRNA-1273 vaccine candidate development.

Total revenue increased by $45.6 million, or 157%, for the six months ended June 30, 2020 compared to the same period in 2019, due to increases in both collaboration revenue and grant revenue. Collaboration revenue increased by $8.8 million for the six months ended June 30, 2020 compared to the same period in 2019, mainly attributable to an increase in revenue in the second quarter of 2020, particularly from AstraZeneca, partially offset by cumulative catch-up adjustments in revenue in the first quarter of 2020 due to changes in estimated costs for our future performance obligations under the collaboration agreements with AstraZeneca and Merck.

Grant revenue increased by $36.9 million for the six months ended June 30, 2020 compared to the same period in 2019, mainly driven by an increase in revenue in the second quarter of 2020 from BARDA related to our mRNA-1273 vaccine candidate development.

Operating expenses

Research and development expenses

Research and development expenses increased by $23.6 million, or 18%, for the three months ended June 30, 2020 compared to the same period in 2019. The increase was primarily attributable to an increase in personnel-related costs of $12.4 million and an increase in consulting and outside services of $12.2 million, mainly driven by increased headcount and mRNA-1273 clinical development. The increases were partially offset by a decrease in raw materials and manufacturing costs of $4.2 million, mainly due to change in timing of raw material inventory management and manufacturing lead time.

Research and development expenses increased by $8.3 million, or 3%, for the six months ended June 30, 2020 compared to the same period in 2019. The increase was primarily attributable to an increase in personnel related costs of $15.5 million, an increase in consulting and outside services of $11.2 million, and an increase in stock-based compensation of $3.1 million, largely attributable to increased headcount and mRNA-1273 clinical development. The increases were partially offset by a decrease in raw materials and manufacturing costs of $19.4 million and a decrease in lab supplies of $2.8 million, mainly due to change in timing of raw material inventory management and manufacturing lead time.

General and administrative expenses

General and administrative expenses increased by $8.1 million, or 29%, for the three months ended June 30, 2020 compared to the same period in 2019. The increase was mainly due to an increase in personnel-related costs of $3.6 million and an increase in legal-related costs of $3.6 million.

General and administrative expenses increased by $5.0 million, or 9%, for the six months ended June 30, 2020 compared to the same period in 2019. The increase was mainly due to an increase in personnel-related costs of $3.8 million, an increase in legal-related costs of $2.0 million, and an increase in stock-based compensation of $1.3 million. The increases were partially offset by a decrease in consulting and outside services of $2.3 million.

These increases for both the three and six month periods in 2020 were primarily attributable to increased headcount and mRNA-1273 vaccine candidate development-related activities.

Interest income

Interest income decreased by $3.2 million, or 31%, for the three months ended June 30, 2020 compared to the same period in 2019. Interest income decreased by $6.4 million, or 30%, for the six months ended June 30, 2020 compared to the same period in 2019. The decreases in interest income from our investments in marketable securities for the three and six month periods in 2020 were mainly attributable to an overall lower interest rate.

Other expense, net

The following table summarizes other expense, net for each period presented (in thousands):

	Three Months Ended June 30,		Change 2020 vs. 2019	
	2020	2019	$	%
Gain on investments	$ 570	$ 17	$ 553	3253%
Interest expense	(1,878)	(1,765)	(113)	6%
Other expense, net	(222)	(129)	(93)	72%
Total other expense, net	$ (1,530)	$ (1,877)	$ 347	(18)%

	Six Months Ended June 30,		Change 2020 vs. 2019	
	2020	2019	$	%
Gain on investments	$ 891	$ 14	877	6264%
Interest expense	(3,544)	(3,298)	(246)	7%
Other expense, net	(31)	(524)	493	(94)%
Total other expense, net	$ (2,684)	$ (3,808)	$ 1,124	(30)%

Total other expense, net remained relatively flat for the three and six months ended June 30, 2020, compared to the same periods in 2019.

Liquidity and capital resources

We have historically funded our operations primarily from the sale of equity instruments and from proceeds from certain strategic alliance arrangements and grant agreements. As of June 30, 2020, we had cash, cash equivalents and investments of $3.07 billion. Cash, cash equivalents and investments are invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation. Investments, consisting primarily of government and corporate debt securities, are stated at fair value. As of June 30, 2020, we had current and non-current investments of approximately $955.4 million and $354.9 million, respectively.

We began construction of our manufacturing facility in Massachusetts, MTC South, in the second half of 2016 and completed construction during 2019. In the second quarter of 2019, we entered into an additional lease for office and laboratory space nearby, or MTC North. We started construction of MTC North in the fourth quarter of 2019. Our capital expenditures related to our MTC facilities were $20.0 million and $3.7 million for the six months ended June 30, 2020 and 2019, respectively. Cash disbursements related to our MTC facilities were $15.3 million and $10.9 million for the six months ended June 30, 2020 and 2019.

In the second quarter of 2020, we received deposits of $75.0 million for our future mRNA-1273 vaccine supply based on preliminary agreements with certain of our potential customers.

Cash flow

The following table summarizes the primary sources and uses of cash for each period presented (in thousands):

	Six Months Ended June 30,	
	2020	2019
Net cash provided by (used in):		
Operating activities	$ (130,066)	$ (252,853)
Investing activities	(303,539)	(258,660)
Financing activities	1,959,358	4,470
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 1,525,753	$ (507,043)

Operating activities

We derive cash flows from operations primarily from cash collected from certain strategic alliances. 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 and will continue to expect negative cash flows from operating activities due to our investments in mRNA technologies, digital infrastructure, manufacturing technology and infrastructure, and advancing our program development efforts and pipeline.

Net cash used in operating activities for the six months ended June 30, 2020 was $130.1 million and consisted of net loss of $240.9 million and non-cash adjustments of $61.6 million, plus a net change in assets and liabilities of $49.3 million. Non-cash items primarily included stock-based compensation of $44.3 million, and depreciation and amortization of $15.0 million. The net change in assets and liabilities was due to an increase in deferred revenue of $51.4 million, an increase in accrued liabilities of $20.2 million, an increase in operating lease liabilities of $14.0 million, an increase in accounts payable of $11.5 million and an increase in other liabilities of $4.4 million, partially offset by an increase in accounts receivable of $28.0 million, an increase in right-of-use assets related to operating leases of $12.4 million, an increase in prepaid expenses and an increase in other assets of $11.8 million.

Net cash used in operating activities for the six months ended June 30, 2019 was $252.9 million and consisted of net loss of $267.5 million and non-cash adjustments of $52.4 million, minus a net change in assets and liabilities of $37.8 million. Non-cash items primarily included stock-based compensation of $40.0 million, depreciation and amortization of $14.8 million and amortization of investment premium and discount of $2.4 million. The net change in assets and liabilities was primarily due to a decrease in accrued liabilities of $27.8 million, a decrease in deferred revenue of $23.1 million and an increase in right-of-use assets relating to operating leases of $3.4 million, partially offset by a decrease in accounts receivable of $8.1 million, a decrease in prepaid expense and other assets of $6.0 million, and an increase of right-of-use assets relating to operating leases of $3.6 million.

Investing activities

Our primary investing activities consist of purchases, sales, and maturities of our investments and capital expenditures for manufacturing, laboratory, computer equipment and software.

Net cash used in investing activities for the six months ended June 30, 2020 was $303.5 million, which included purchases of marketable securities of $903.6 million and purchases of property and equipment of $24.9 million, partially offset by proceeds from maturities of marketable securities of $516.9 million and proceeds from sales of marketable securities of $108.0 million.

Net cash used in investing activities for the six months ended June 30, 2019 was $258.7 million, which included purchases of marketable securities of $843.3 million and purchases of property and equipment of $18.2 million, partially offset by proceeds from maturities of marketable securities of $563.6 million and proceeds from sales of marketable securities of $39.2 million.

Financing activities

We generated cash from financing activities of $1.96 billion for the six months ended June 30, 2020, primarily from net proceeds from equity offerings of $1.85 billion and net proceeds from the issuance of common stock through our equity plans of $106.6 million.

We had insignificant financing activities for the six months ended June 30, 2019.

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. We have an accumulated deficit of $1.74 billion as of June 30, 2020. We may continue to incur significant losses in the foreseeable future and expect our expenses to increase, as we continue research and development of our development candidates and clinical activities for our investigational medicines. We also expect our expenses to increase associated with manufacturing costs, pre-launch inventory expenses, the establishment of late stage clinical and commercial capabilities, including our arrangements with our international supply and manufacturing partners. Our ongoing work on mRNA-1273 will require significant additional investment during 2020, some of which may not be reimbursed or otherwise paid for by our partners or collaborators. In addition, we expect to continue to incur additional costs associated with operating as a public company driven, in part, by the increased compliance requirements of being a publicly traded company that no longer qualifies as an emerging growth company as of December 31, 2019.

We are subject to all the risks related to the development and commercialization of novel medicines, and we may encounter unforeseen expenses, difficulties, complications, delays, and other unknown factors including the expenses related to the ongoing coronavirus pandemic, which may adversely affect our business. Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. We believe that our cash, cash equivalents, and investments as of June 30, 2020, will be sufficient to enable us to fund our projected operations through at least the next 12 months from the issuance of our financial statements.

Until we can generate a sufficient amount of revenue from our programs, we expect to finance future cash needs through a combination of public or private equity offerings, structured financings and debt financings, government funding arrangements, potential future strategic alliances from which we receive upfront fees, milestone payments, and other forms of consideration, and marketing, manufacturing, distribution and licensing arrangements. Additional capital may not be available on reasonable terms, if at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back, or discontinue the development or commercialization of one or more of our investigational medicines, or slow down or cease work on one or more of our programs. If we raise additional funds through the issuance of additional equity or debt securities, it could result in dilution to our existing stockholders or increased fixed payment obligations, and any such securities may have rights senior to those of our common stock. If we incur indebtedness, we could become subject to covenants that would restrict our operations and potentially impair our competitiveness, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. If we raise funds through strategic alliances or marketing, distribution, or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs, or investigational medicines or grant licenses on terms that may not be favorable to us. Any of these events could significantly harm our business, financial condition, and prospects.

Contractual Obligations

As of June 30, 2020, other than disclosed at Note 7 and Note 8 to our condensed consolidated financial statements, there have been no material changes to our contractual obligations and commitments from those described under "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in our 2019 Form 10-K.

Off balance sheet arrangements

As of June 30, 2020, we did not have any off-balance sheet arrangements, as defined in Item 303(a)(4)(ii) of Regulation S-K.

Item 3. Quantitative and Qualitative Disclosures about Market Risk
Interest Rate Risk

Our primary exposure to market risk relates to changes in interest rates. As of June 30, 2020 and December 31, 2019, we had cash, cash equivalents, and investments in marketable securities of $3.07 billion and $1.26 billion, respectively. Our investment portfolio is comprised of money market funds and marketable debt securities (including U.S. Treasury securities, debt securities of U.S. government agencies and corporate entities, and commercial paper). Our primary investment objectives are the preservation of capital and the maintenance of liquidity and our investment policy defines allowable investments based on quality of the institutions and financial instruments designed to minimize risk exposure. Our exposure to interest rate sensitivity is affected by changes in the general level of U.S. interest rates. Our available for sale securities are subject to interest rate risk and will fall in value if market interest rates increase.

We generally hold investments in marketable debt securities to maturity to limit our exposure to interest rate risk. Due to the short-term maturities and low risk profiles of our investments, we do not anticipate a significant exposure to interest rate risk. If market interest rates were to increase immediately and uniformly by 100 basis points, or one percentage point, from levels at June 30, 2020, the net fair value of our interest sensitive marketable securities would not experience a material change in fair market value.

Foreign Currency Risk

Historically, our operations and revenue generating activities have been denominated in U.S. dollars. Our expenses are generally denominated in the currencies of the jurisdictions in which our operations are located, which is primarily in the United States. As we expand internationally our results of operations and cash flows will become increasingly subject to fluctuations due to changes in foreign currency exchange rates. The volatility of exchange rates depends on many factors that we cannot forecast with reliable accuracy. We will experience fluctuations in our net loss as a result of transaction gains or losses and remeasurement of certain current asset and current liability balances that are denominated in currencies other than U.S. dollars.

To date, our exposure to exchange rate volatility, resulting from foreign currency transaction gains and losses and remeasurement of local currency assets and liabilities into U.S. dollars, has not been material. We currently hold no foreign exchange contracts, option contracts, or foreign currency hedging contracts. If foreign currency exchange rates had changed by 10% during the periods presented, it would not have had a material impact on our financial position or results of operations.

Item 4. Controls and Procedures

Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2020. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, or the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of June 30, 2020, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the three months ended June 30, 2020, which have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls

Our management, including our Chief Executive Officer and Chief Financial Officer, believes that our disclosure controls and procedures and internal control over financial reporting are designed to provide reasonable assurance of achieving their objectives and are effective at the reasonable assurance level. However, our management does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent all errors and all fraud. A control system, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. These inherent limitations include the realities that judgments in decision making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by the collusion of two or more people or by a management override of the controls. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

PART II

Item 1. Legal Proceedings

From time to time, we may be subject to legal proceedings and claims in the ordinary course of business. We are not currently a party to any material legal proceedings.

Item 1A. Risk Factors

Our business involves significant risks, some of which are described below. You should carefully consider the risks and uncertainties described below, together with all of the other information contained in this Quarterly Report on Form 10-Q, including "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the condensed consolidated financial statements and the related notes. If any of the following risks actually occur, it could harm our business, prospects, operating results and financial condition and future prospects. In such event, the market price of our common stock could decline and you could lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations. This Quarterly Report on Form 10-Q also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of factors that are described below and elsewhere in this Quarterly Report.

Those risk factors below denoted with an "" are newly added or have been materially updated from our Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission, or the SEC, on May 7, 2020.*

Risks related to our business and creating a new class of medicines

Our business may continue to be adversely affected by the ongoing coronavirus pandemic.

The outbreak of SARS-CoV-2, the novel strain of coronavirus that causes COVID-19, has evolved into a global pandemic. The extent to which COVID-19 impacts our business and operating results will depend on future developments that are highly uncertain and cannot be accurately predicted, including new information that may emerge concerning COVID-19 and the actions taken to contain COVID-19 or treat its impact, among others.

The spread of COVID-19 has resulted in the delay and interruption of certain of our business operations. Many of our clinical trials have been affected by the pandemic. Site initiation, participant recruitment and enrollment, participant dosing, distribution of clinical trial materials, study monitoring and data analysis may be paused or delayed (or continue to be paused or delayed) due to changes in hospital or university policies, federal, state or local regulations or restrictions, prioritization of hospital resources toward pandemic efforts, travel restrictions, concerns for patient safety in a pandemic environment, or other reasons related to the pandemic. More specifically, as previously disclosed, certain of our clinical trials have already been adversely affected, including the suspension of

enrollment for our hMPV/PIV3 trial (mRNA-1653) and the pausing of enrollment and new site initiation for our rare disease clinical trials with open Investigational New Drug (IND) applications, methylmalonic acidemia (mRNA-3704) and propionic acidemia (mRNA-3927). As COVID-19 continues to spread, some participants and clinical investigators may not be able to comply with clinical trial protocols. For example, quarantines or other travel limitations (whether voluntary or required) have been implemented in many countries, and may impede participant movement, affect sponsor access to study sites, or interrupt healthcare services, and we may be unable to conduct our clinical trials. Further, if the spread of the COVID-19 pandemic continues and our operations are adversely impacted, including due to facility access restrictions or from an outbreak in a facility, we risk a delay, default and/or nonperformance under existing agreements.

Infections and deaths related to the pandemic have disrupted and may continue to disrupt the United States' healthcare and healthcare regulatory systems. Such disruptions could divert healthcare resources away from, or materially delay U.S. Food and Drug Administration, or FDA, review and/or approval with respect to, our clinical trials. Any elongation or de-prioritization of our clinical trials or delay in regulatory review resulting from such disruptions could materially affect the development and study of our development candidates.

We currently utilize third parties to, among other things, manufacture raw materials, components, parts, and consumables, and to perform quality testing. For example, we rely on third-party manufacturers such as Lonza Ltd., Catalent Inc. and ROVI to enable larger scale manufacture and/or fill/finish capabilities for our mRNA vaccine candidate (mRNA-1273) against the SARS-CoV-2 virus. We also manufacture our development candidates and investigational medicines and perform various services at our manufacturing facility. Certain of our third party manufacturers and suppliers may pause their operations in response to the COVID-19 outbreak or otherwise encounter delays in providing their services. If either we or any third-party manufacturers or third parties in the supply chain for materials used in the production of our development candidates and investigational medicines are adversely impacted by restrictions resulting from the COVID-19 outbreak, our supply chain may be disrupted, limiting our ability to manufacture our investigational medicines for our clinical trials, research and development operations and potential commercialization. In addition, delays and disruptions experienced by our strategic collaborators due to the COVID-19 outbreak could adversely impact the ability of such parties to fulfill their obligations, which could affect the clinical development or regulatory approvals of development candidates and investigational medicines under joint control.

In response to the pandemic, we have closed our offices with our administrative employees continuing their work outside of our offices, and restricted on-site staff to only those essential employees required to execute their job responsibilities. Due to mandated facility closure and travel restrictions, certain of our employees conducting non-essential research and development or manufacturing activities are not able to access our laboratory or manufacturing space, and our core activities may be significantly limited or curtailed, possibly for an extended period of time.

The spread of COVID-19, which has caused a broad impact globally, including restrictions on travel and quarantine policies put into place by businesses and governments, may have a material economic effect on our business, including our ability to successfully commercialize mRNA-1273, if approved. Due to the pandemic, we may not be able to meet expectations with respect to commercial sales. While the potential economic impact brought by and the duration of the pandemic may be difficult to assess or predict, it has already caused, and is likely to result in further, significant disruption of global financial markets, which may reduce our ability to access capital either at all or on favorable terms. In addition, a recession, depression or other sustained adverse market event resulting from the spread of COVID-19 could materially and adversely affect our business, prospectus, operating results and financial condition, and the value of our common stock.

The ultimate impact of the current pandemic, or any other health epidemic, is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, our clinical trials, our research programs, healthcare systems or the global economy as a whole. However, these effects could have a material impact on our operations, and we will continue to monitor the situation closely.

Our pursuit of mRNA-1273, a potential vaccine for SARS-CoV-2, continues to be subject to completion of the required clinical trials and regulatory approval in the United States and elsewhere. We may be unable to produce a vaccine that successfully treats the virus in a timely manner, if at all.

In response to the global outbreak of coronavirus, we are pursuing the rapid manufacture and clinical testing of mRNA-1273 in collaboration with the Vaccine Research Center and Division of Microbiology and Infectious Diseases of the National Institute of Allergy and Infectious Diseases, or NIAID, part of the National Institutes of Health, or NIH. Our development of the vaccine remains subject to several ongoing clinical trials, and we may be unable to produce a vaccine that successfully vaccinates against the virus in a timely manner, if at all. Additionally, our ability to develop an effective vaccine depends on the success of our scaled up manufacturing capability both at our own location and those of our manufacturing partners, which we have not previously tested and which will need to be funded appropriately in order to enable us to have sufficient capacity to respond to a global health challenge. We are also committing substantial financial resources and personnel to the development of mRNA-1273, including to support a scale-up of manufacturing to enable a potential pandemic response, which may cause delays in or otherwise negatively impact our other

development programs, despite uncertainties surrounding the longevity and extent of coronavirus as a global health concern. Our business could be negatively impacted by our allocation of significant resources, including managerial and financial, to a global health threat that is unpredictable and could rapidly dissipate or against which our vaccine, if developed, may not be partially or fully effective, and may ultimately prove unsuccessful or unprofitable. Furthermore, there are no assurances that our vaccine will be approved for inclusion in government stockpile programs, which may be material to the commercial success of the product candidate, either in the United States or abroad.

Although we have a dedicated manufacturing facility, we do not have sufficient manufacturing infrastructure to support a global roll-out of mRNA-1273 on our own. For example, we rely on Lonza Ltd. to enable larger scale manufacture of mRNA-1273. As a result, we have formed a strategic collaboration with Lonza Ltd. and will need to form additional collaborations with third parties, including contract manufacturing organizations, government and non-government organizations, and other funding and manufacturing sources to do so. We have formed a collaboration with Catalent, Inc. for large-scale, commercial fill-finish manufacturing of mRNA-1273, and a collaboration with Laboratorios Farmacéuticos Rovi, S.A., or ROVI, for large-scale, commercial fill-finish manufacturing of mRNA-1273 intended in principle to supply markets outside of the U.S. starting in early 2021 at ROVI's facility in Madrid, Spain. We have not previously ramped our organization for a commercial launch of any product, and doing so in a pandemic environment with an urgent, critical global need creates additional challenges such as distribution channels, intellectual property disputes or challenges, and the need to establish teams of people with the relevant skills worldwide. We may also face challenges with sourcing a sufficient amount of raw materials to support the demand for a vaccine. We may be unable to effectively create a supply chain for mRNA-1273 that will adequately support demand. Furthermore, we will encounter significant additional capital requirements as we move through clinical studies of mRNA-1273 and toward a potential commercial launch. While our collaboration with BARDA will help us meet these capital requirements, additional investment, whether from our own capital resources or through collaborations with others, will be necessary. We cannot guarantee that any of these new challenges and requirements will be met in a timely manner or at all.

In addition, another party may be successful in producing a more efficacious vaccine or other treatment for COVID-19 which may also lead to the diversion of governmental and quasi-governmental funding away from us and toward other companies. In particular, given the widespread media attention on the current COVID-19 pandemic, there are efforts by public and private entities to develop a COVID-19 vaccine as fast as possible, including by Johnson & Johnson, GlaxoSmithKline, AstraZeneca, Sanofi and Pfizer. Those other entities may develop COVID-19 vaccines that, as compared to any that we may develop, are more effective, become the standard of care, have broader market acceptance, are safer or have fewer or less severe side effects, are more convenient, are developed at a lower cost or earlier, or may be more successfully commercialized. Many of these other organizations are much larger than we are and have access to larger pools of capital and broader manufacturing infrastructure. Larger pharmaceutical and biotechnology companies have extensive experience in clinical testing and obtaining regulatory approval for their products, and may have the resources to heavily invest to accelerate discovery and development of their vaccine candidates. Our business could be materially and adversely affected if competitors develop and commercialize one or more COVID-19 vaccines before we can complete development and seek approval for our vaccine candidate.

The success or failure of other entities, or perceived success or failure, may adversely impact our ability to obtain any future funding for our COVID-19 vaccine development efforts or to ultimately commercialize our vaccine, if approved. In addition, we may not be able to compete effectively if our product candidates do not satisfy government procurement requirements with respect to biodefense products.

We are devoting significant resources to the scale-up and development of mRNA-1273, including for use by the U.S. government and other global governmental and commercial partners.

We are working toward the large scale technical development, manufacturing scale-up in several countries and larger scale deployment of this potential vaccine. The number of doses of this potential vaccine that we are able to produce is dependent on our ability, and the ability of our contract manufacturers, to successfully and rapidly scale up manufacturing capacity. The number of doses that we will be able to produce is dependent in large part on the dosage of the vaccine required to be administered to patients we have selected 100 μg as the dose level for our Phase 3 study of mRNA-1273. To support the scale-up, we have expended and will need to contine to expend significant resources and capital. We may need to, or we may be required by the federal government to, divert resources and capital from our other programs. We may also seek and secure significant additional funding through contractual arrangements and collaborations with third parties. We may be unable to enter into such arrangements on favorable terms, or at all, which would adversely affect our ability to develop, manufacture and distribute a potential vaccine.

As part of this effort, we have a commitment from BARDA to fund up to $954.9 million to enable the initiation of and support the planning and execution of Phase 2 and Phase 3 clinical trials of mRNA-1273 under our own IND, as well as the scale-up of mRNA-1273 manufacture in 2020 to enable a potential pandemic response. To the extent our funding collaborators have discretion over the distribution of funding commitments, we may not ultimately receive the full amount of committed funds and could be exposed to urgent needs for additional funding to support our manufacturing activities. Our funding collaborators may also impose

restrictions on or mandate input as to our conduct of clinical trials, manufacturing activities or distribution activities, which may cause delays in the event of disagreement.

We have entered into, and plan to continue entering into, supply agreements for mRNA-1273 that include cash deposits from the purchasers. In the event we are unable to successfully develop and commercialize mRNA-1273 or fail to meet certain product volume or delivery timing obligations under our supply agreements, we may be required to refund significant portions of the deposits, which could have a material and adverse effect on our financial condition.

In addition, since the path to licensure of any vaccine against COVID-19 is unclear, we may have a widely used vaccine in circulation in the United States or another country prior to our receipt of marketing approval. Unexpected safety issues, including any that we have not yet observed in our Phase 1 or 2 clinical trials for mRNA-1273, could lead to significant reputational damage for Moderna and our technology platform 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.

The positive interim data from the ongoing Phase 1 study of mRNA-1273, our vaccine candidate for the treatment of SARS-CoV-2, may not be predictive of the results of later-stage clinical trials, which is one of a number of factors that may delay or prevent us from receiving regulatory approval of our vaccine candidate.

The positive interim data we have announced from the ongoing Phase 1 study of mRNA-1273 are based on only the limited number of subjects enrolled in the first phase of the Phase 1 clinical study. Further results from the ongoing Phase 1 study or any interim results of our Phase 2 or Phase 3 studies for mRNA-1273 could show diminished efficacy as compared to the interim Phase 1 study results or that the neutralizing antibodies are not sufficiently durable without repeated boosting. We also may observe new, more frequent or more severe adverse events in subjects participating in these clinical studies. In addition, the interpretation of the data from our clinical trials of mRNA-1273 by FDA and other regulatory agencies may differ from our interpretation of such data and the FDA or other regulatory agencies may require that we conduct additional studies or analyses. Further, the assays being used to measure and analyze the effectiveness of vaccines being developed to treat SARS-CoV-2 have only recently been developed and are continuing to evolve. The validity and standardization of these assays has not yet been established, and the results obtained in clinical studies of mRNA-1273 with subsequent versions of these assays may be less positive than the results we have obtained to date. Moreover, the samples of convalescent sera, or blood samples from people who have recovered from COVID-19, used to benchmark the level of antibodies produced by subjects receiving mRNA-1273 in clinical studies, have been taken from a small number of people and may not be representative of the antibody levels in a broader population of people who have recovered from COVID-19. The future results in clinical studies of mRNA-1273 may not be as positive when compared to the antibody levels in other samples of convalescent sera. Various preclinical animal studies of mRNA-1273 are ongoing, including preclinical studies in non-human primates. If safety data observed in these preclinical studies are inconsistent with safety data from clinical studies, we may be required to conduct additional studies of mRNA-1273. Any of these factors could delay or prevent us from receiving regulatory approval of mRNA-1273 and there can be no assurance that mRNA-1273 will be approved in a timely manner, if at all.

If we are unable to manufacture our vaccines in sufficient quantities, at sufficient yields or are unable to obtain regulatory approvals for a manufacturing facility for our vaccines, we may experience delays in product development, clinical trials, regulatory approval and commercial distribution.

Completion of our clinical trials and commercialization of our vaccine candidates require access to, or development of, facilities to manufacture our vaccine candidates at sufficient yields and at commercial-scale. We have limited experience manufacturing any of our vaccine candidates in the volumes that will be necessary to support large-scale clinical trials or commercial sales. Efforts to establish these capabilities may not meet initial expectations as to scheduling, scale-up, reproducibility, yield, purity, cost, potency or quality. In addition, other companies, many with substantial resources, may compete with us for access to materials needed to manufacture our vaccines.

Manufacturing our vaccine candidates involves a complicated process with which we have limited experience. We are dependent on third-party organizations to conduct a portion of our vaccine manufacturing activities. If third-party manufacturing organizations are unable to manufacture our vaccine candidates in clinical quantities or, when necessary, in commercial quantities and at sufficient yields, then we will need to identify and reach supply arrangements with additional third parties. Third-party manufacturers must also be inspected by the FDA as part of the FDA's review of our marketing application. Our vaccines may be in competition with other products for access to these facilities and may be subject to delays in manufacture if third parties give other products higher priority. We may not be able to enter into any necessary additional third-party manufacturing arrangements on acceptable terms, or on a timely basis. In addition, we have to enter into technical transfer agreements and share our know-how with the third-party manufacturers, which can be time-consuming and may result in delays. Any delay in the manufacture or delivery of a vaccine could adversely affect our ability to sell the vaccines, if approved.

Our reliance on third-party manufacturers may adversely affect our operations or result in unforeseen delays or other problems beyond our control. Because of contractual restraints and the limited number of third-party manufacturers with the expertise, required regulatory approvals and facilities to manufacture our bulk vaccines on a commercial scale, replacement of a manufacturer may be

expensive and time-consuming and may cause interruptions in the production of our vaccine. A third-party manufacturer may also encounter difficulties in production. These problems may include:

- difficulties with production costs, scale up and yields;
- availability of raw materials and supplies;
- quality control and assurance;
- shortages of qualified personnel;
- compliance with strictly enforced federal, state and foreign regulations that vary in each country where products might be sold; and
- lack of capital funding.

As a result, any delay or interruption could have a material adverse effect on our business, financial condition, or results of operations.

The regulatory pathway for mRNA-1273 is continually evolving, and may result in unexpected or unforeseen challenges.

To date, mRNA-1273 has moved rapidly through the FDA regulatory review and approval process. The speed at which all parties are acting to create and test many therapeutics and vaccines for COVID-19 is unusual, and evolving or changing plans or priorities within the FDA, including changes based on new knowledge of COVID-19 and how the disease affects the human body, may significantly affect the regulatory timeline for mRNA-1273. Results from clinical testing of our vaccine candidate or others may raise new questions and require us to redesign proposed clinical trials, including revising proposed endpoints or adding new clinical trial sites or cohorts of subjects. Our Phase 3 study protocol has been reviewed by the FDA and is aligned to recent FDA guidance on clinical trial design for COVID-19 vaccine studies. The incidence of COVID-19 in the communities where the Phase 3 study participants reside will vary across different locations. If the overall incidence of COVID-19 in the Phase 3 study participants is low, it may be difficult for this study to demonstrate differences in infection rates between participants in the study who receive placebo and participants in the study who receive mRNA-1273.

The FDA has the authority to grant an Emergency Use Authorization to allow unapproved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions when there are no adequate, approved, and available alternatives. If we are granted an Emergency Use Authorization for mRNA-1273, we would be able to distribute mRNA-1273 prior to FDA approval. Furthermore, the FDA may revoke an Emergency Use Authorization where it is determined that the underlying health emergency no longer exists or warrants such authorization, and we cannot predict how long, if ever, an Emergency Use Authorization would remain in place. Such revocation could adversely impact our business in a variety of ways, including if mRNA-1273 is not yet approved by the FDA and if we and our manufacturing partners have invested in the supply chain to provide mRNA-1273 under an Emergency Use Authorization.

Our ability to produce a successful vaccine may be curtailed by one or more government actions or interventions, which may be more likely during a global health crisis such as COVID-19.

Given the significant global impact of the COVID-19 pandemic, it is possible that one or more government entities may take actions that directly or indirectly have the effect of diminishing some of our rights or opportunities with respect to mRNA-1273 and the economic value of a COVID-19 vaccine to us could be limited. In the U.S., the Defense Production Act of 1950, as amended, or the Defense Production Act, gives the U.S. government rights and authorities that may directly or indirectly diminish our own rights or opportunities with respect to mRNA-1273 and the economic value of a COVID-19 vaccine to us could be limited. Our potential third-party service providers may be impacted by government entities regarding potentially invoking the Defense Production Act or other potential restrictions to all or a portion of services they might otherwise offer. Government entities imposing restrictions or limitations on our third-party service providers may require us to obtain alternative service sources for our vaccine candidates, including mRNA-1273. If we are unable to timely enter into alternative arrangements, or if such alternative arrangements are not available on satisfactory terms, we will experience delays in the development or production of our vaccine candidates, increased expenses, and delays in potential distribution or commercialization of our vaccine candidates, when and if approved.

In addition, during a global health crisis, such as the COVID-19 pandemic, where the spread of a disease needs to be controlled, closed or heavily regulated national borders will create challenges and potential delays in our development and production activities and may necessitate that we pursue strategies to develop and produce our vaccine candidates within self-contained national or international borders, at potentially much greater expense and with longer timeframes for public distribution.

We will need to seek and secure significant funding through financings or from other sources. Clinical data or trial execution that creates delays, setbacks, or failures in one or more of our programs or modalities or the entire pipeline could result in an impaired ability or inability to finance or fund the Company in the future.

We are currently advancing our pipeline of 23 development candidates across our 22 programs. Discovering development candidates and developing investigational medicines is expensive, and we expect to continue to spend substantial amounts to (i) perform basic research, perform preclinical studies, and conduct clinical trials of our current and future programs, (ii) continue to develop and

expand our platform and infrastructure and supply preclinical studies and clinical trials with appropriate grade materials (including cGMP materials), (iii) seek regulatory approvals for our investigational medicines, and (iv) launch and commercialize any products for which we receive regulatory approval, including building our own commercial sales, marketing, and distribution organization. Furthermore, our ongoing work on mRNA-1273 will require significant additional investment during 2020 and beyond, some of which may not be reimbursed or otherwise paid for by our collaborators.

As of June 30, 2020, we had approximately $3.07 billion in cash, cash equivalents, and investments. We expect that our existing cash, cash equivalents, and investments will be sufficient to fund our current operations through at least the next twelve months. However, our operating plan may change as a result of many factors currently unknown to us, including with respect to our development, manufacturing and commercialization of mRNA-1273, and we may need to seek additional funds sooner than planned, through public or private equity or debt financings, structured 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. In any event, we will require additional capital to obtain regulatory approval for, and to commercialize, our investigational medicines. 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. Because the length of time and activities associated with discovery of development candidates and development of our investigational medicines are highly uncertain, 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 development candidates and investigational medicines;
- the results of research and our other platform activities;
- the clinical development plans we establish for our investigational medicines;
- the terms of any agreements with our current or future strategic collaborators;
- the number and characteristics of development candidates and investigational medicines that we develop or may in-license;
- the outcome, timing, and cost of meeting regulatory requirements established by the U.S. Food and Drug Administration, or FDA, the European Medicines Agency, or the EMA, and other comparable foreign regulatory authorities;
- the cost of filing, prosecuting, defending, and enforcing our patent claims and other intellectual property, or IP, rights, including patent infringement actions brought by third parties against us regarding our investigational medicines or actions by us challenging the patent or IP rights of others;
- the effect of competing technological and market developments, including other products that may compete with one or more of our development candidates or investigational medicines;
- 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, whether in-house or outsourced; and
- the cost of establishing sales, marketing, and distribution capabilities for any investigational medicines for which we may receive marketing approval and reimbursement in regions where we choose to commercialize our medicines on our own.

To date, we have financed our operations primarily through the sale of equity securities and revenue from strategic alliances and we cannot be certain that additional funding will be available to us on favorable terms, or at all. Until we can generate sufficient product 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 or debt offerings, structured financings, debt financings, collaborations, strategic alliances, sales of assets, 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 investigational medicines. In addition, we cannot guarantee that future financing will be available in sufficient amounts, at the right time, on favorable terms, or at all. 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. If our development of mRNA-1273 is unsuccessful, there can be no assurance that we will have the funds necessary to meet our existing payment obligations to third parties, or be able to raise such funds when needed, on terms acceptable to us, or at all. Moreover, the terms of any financing may adversely affect the holdings or the rights of our stockholders 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 stockholders' rights.

Further, to the extent that we raise additional capital through the sale of common stock or securities convertible or exchangeable into common stock, your ownership interest will be diluted. If we raise additional capital through debt financings, we would be subject to fixed payment obligations and may be subject to 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 or other collaborations, strategic alliances, or licensing arrangements with third parties, we may have to relinquish certain valuable rights to our development candidates and investigational medicines, technologies, future revenue streams, or research programs. We also could be required to seek strategic collaborators for one or more of our current or future investigational

medicines at an earlier stage than otherwise would be desirable or relinquish our rights to development candidates, investigational medicines, or IP 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 investigational medicines, 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 our common stock to decline, and negatively impact our ability to fund operations.

We attempt to distribute our technology, biology, execution, and financing risks across a wide variety of therapeutic areas, disease states, programs, and technologies. However, our assessment of, and approach to, risk may not be comprehensive or effectively avoid delays or failures in one or more of our programs or modalities. Failures in one or more of our programs or modalities could adversely impact other programs or modalities in our pipeline and have a material adverse impact on our business, results of operations, and ability to fund our business.

We are creating a new class of medicines based on mRNA, to improve the lives of patients. From the beginning, we designed our strategy and operations to realize the full potential value and impact of mRNA over a long time horizon across a broad array of human diseases. We have made investments in our platform, infrastructure, and clinical capabilities that have enabled us to establish a large pipeline of development candidates, of which many are in clinical trials or have an open IND. As our development candidates and investigational medicines progress, we or others may determine that: certain of our risk allocation decisions were incorrect or insufficient; we made platform level technology mistakes; individual programs or our mRNA science in general has technology or biology risks that were unknown or under-appreciated; our choices on how to develop our infrastructure to support our scale will result in an inability to manufacture our investigational medicines for clinical trials or otherwise impair our manufacturing; or we have allocated resources in such a way that large investments are not recovered and capital allocation is not subject to rapid re-direction. All of these risks may relate to our current and future programs sharing similar science (including mRNA science) and infrastructure, and in the event material decisions in any of these areas turn out to have been incorrect or under-optimized, we may experience a material adverse impact on our business and ability to fund our operations and we may never realize what we believe is the potential of mRNA.

****No mRNA drug has been approved in this new potential class of medicines, and may never be approved as a result of efforts by others or us. mRNA drug development has substantial clinical development and regulatory risks due to the novel and unprecedented nature of this new class of medicines.***

As a potential new class of medicines, no mRNA medicines have been approved to date by the FDA or other regulatory agency. Successful discovery and development of mRNA medicines by either us or our strategic collaborators is highly uncertain and depends on numerous factors, many of which are beyond our or their control. We have made and will continue to make a series of business decisions and take calculated risks to advance our development efforts and pipeline, including those related to mRNA technology, delivery technology, and manufacturing processes, which may be shown to be incorrect based on further work by us, our strategic collaborators, or others. Prior to the Phase 3 trial for mRNA-1273 and that of one other company, there had never been a Phase 3 trial in which mRNA is the primary active ingredient, and there has never been and there may never be a commercialized product in which mRNA is the primary active ingredient. Our mRNA investigational medicines that appear promising in the early phases of development may fail to advance, experience delays in the clinic, experience clinical holds, or fail to reach the market for many reasons, including:

- discovery efforts at identifying potential mRNA medicines may not be successful;
- nonclinical or preclinical study results may show potential mRNA medicines to be less effective than desired or to have harmful or problematic side effects;
- clinical trial results may show potential mRNA medicines to be less effective than expected (e.g., a clinical trial could fail to meet one or more endpoint(s)) or to have unacceptable side effects or toxicities;
- adverse effects in any one of our clinical programs or adverse effects relating to our mRNA, or our lipid nanoparticles, or LNPs, may lead to delays in or termination of one or more of our programs;
- the insufficient ability of our translational models to reduce risk or predict outcomes in humans, particularly given that each component of our investigational medicines and development candidates may have a dependent or independent effect on safety, tolerability, and efficacy, which may, among other things, be species-dependent;
- manufacturing failures or insufficient supply of cGMP materials for clinical trials, or higher than expected cost could delay or set back clinical trials, or make mRNA-based medicines commercially unattractive;
- our improvements in the manufacturing processes for this new class of potential medicines may not be sufficient to satisfy the clinical or commercial demand of our investigational medicines or regulatory requirements for clinical trials;
- changes that we make to optimize our manufacturing, testing or formulating of cGMP materials could impact the safety, tolerability, and efficacy of our investigational medicines and development candidates;
- pricing or reimbursement issues or other factors that delay clinical trials or make any mRNA medicine uneconomical or noncompetitive with other therapies;

- 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, Biologics License Application, or BLA, or the equivalent application, discussions with the FDA or 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 of others and their competing products and technologies that may prevent our mRNA medicines from being commercialized.

Currently, mRNA is considered a gene therapy product by the FDA. Unlike certain gene therapies that irreversibly alter cell DNA and could act as a source of side effects, mRNA-based medicines are designed to not irreversibly change cell DNA; however, side effects observed in gene therapy could negatively impact the perception of mRNA medicines despite the differences in mechanism. In addition, because no product in which mRNA is the primary active ingredient has been approved, the regulatory pathway for approval is uncertain. The number and design of the clinical trials 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 may require safety testing like gene therapy products. Moreover, the length of time necessary to complete clinical trials and to submit an application for marketing approval for a final decision by a regulatory authority varies significantly from one pharmaceutical product to the next, and may be difficult to predict.

We have incurred significant losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future.

We have incurred net losses in each year since our inception in 2009, including net losses of $514.0 million, $384.7 million and $255.9 million for the years ended December 31, 2019, 2018 and 2017, respectively. As of June 30, 2020, we had an accumulated deficit of $1.74 billion.

We have devoted most of our financial resources to research and development, including our clinical and preclinical development activities and the development of our platform. To date, we have financed our operations primarily through the sale of equity securities and proceeds from strategic alliances and through grants from governmental and private organizations. The amount of our future net losses will depend, in part, on the rate of our future expenditures and our ability to obtain funding through equity or debt financings, sales of assets, strategic alliances, or additional grants. Other than with respect to mRNA-1273, we have not commenced or completed pivotal clinical trials for any of our programs in clinical trials, which means that for most of our investigational medicines it may be several years, if ever, before we or our strategic collaborators have a product ready for commercialization. Even if we obtain regulatory approval to market an investigational medicine, our future revenues will depend upon the size of any markets in which our investigational medicines have received approval, and our ability to achieve sufficient market acceptance, reimbursement from third-party payors, and adequate market share in those markets. We may never achieve profitability.

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

- continue or expand our research or development of our programs in preclinical development;
- continue or expand the scope of our mRNA clinical trials for our investigational medicines;
- initiate additional preclinical, clinical, or other studies for our development candidates and investigational medicines, including under our strategic alliance agreements;
- continue to invest in our platform to conduct research to identify novel mRNA technology improvements, including identifying novel methods of mRNA delivery, such as lipid nanoparticles, or LNPs, that improve distribution and uptake of mRNA to specific tissues;
- change or add to internal manufacturing capacity or capability;
- change or add additional manufacturers or suppliers;
- add additional infrastructure to our quality control and quality assurance groups to support our operations as we progress our investigational medicines, including mRNA-1273, toward commercialization;
- attract and retain skilled personnel, particularly in Cambridge and Norwood, Massachusetts and in other global regions where we may establish operations;
- create additional infrastructure to support our operations as a public company and our product development and planned future commercialization efforts, including new sites in the United States and abroad;
- seek marketing approvals and reimbursement for our investigational medicines;
- establish a sales, marketing, and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- seek to identify and validate additional development candidates and investigational medicines;
- acquire or in-license other development candidates, investigational medicines, and technologies;
- make milestone or other payments under any in-license agreements;

- maintain, protect, and expand our IP portfolio; and
- experience any delays or encounter issues with any of the above.

Our quarterly and annual operating results may fluctuate. As a result, we may fail to meet or exceed the expectations of research analysts or investors, which could cause our stock price to decline and negatively impact our financing or funding ability as well as negatively impact our ability to exist as a standalone company.

Our financial condition and operating results have varied in the past and will continue to fluctuate from quarter-to-quarter and year-to-year in the future 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 Quarterly Report on Form 10-Q:

- delays or failures in advancement of existing or future development candidates into the clinic or investigational medicines in clinical trials;
- the feasibility of developing, manufacturing, and commercializing our programs;
- 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 strategic collaborators;
- our ability to develop or successfully commercialize mRNA medicines;
- the ability of our strategic collaborators to develop and successfully commercialize mRNA medicines or other products developed from our IP;
- our relationships, and any associated exclusivity terms, with strategic collaborators;
- our contractual or other obligations to provide resources to fund our development candidates and investigational medicines, and to provide resources to our strategic collaborators or to the strategic alliances themselves;
- our operation in a net loss position for the foreseeable future;
- risks associated with the international aspects of our business including the conduct of clinical trials in multiple locations and potential commercialization in such locations;
- our ability to consistently manufacture our development candidates and investigational medicines;
- risks associated with committing financial resources and personnel to the development of mRNA-1273, including to support a scale-up of manufacturing to enable a potential pandemic response;
- our ability to accurately report our financial results in a timely manner;
- our dependence on, and the need to attract and retain, key management and other personnel;
- our ability to obtain, protect, and enforce our IP rights;
- our ability to prevent the theft or misappropriation of our IP, know-how, or technologies;
- advantages that our competitors and potential competitors may have in securing funding, obtaining the rights to critical IP or developing competing technologies or products;
- our ability to obtain additional capital that may be necessary to expand our business;
- our strategic collaborators' ability to obtain additional capital that may be necessary to develop and commercialize products under our strategic alliance agreements;
- business interruptions such as power outages, strikes, acts of terrorism, or natural disasters;
- the ultimate impact of the COVID-19 pandemic, or any other health epidemic, on our business, our clinical trials, our research programs, healthcare systems or the global economy as a whole; and
- our ability to use our net operating loss carryforwards to offset future taxable income.

Due to the various factors mentioned herein, and others, the results of any of our prior quarterly or annual periods should not be relied upon as indications of our future operating performance.

The net losses we incur may fluctuate significantly from quarter-to-quarter and year-to-year, 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 quarter or quarters, our operating results could be below the expectations of securities analysts or investors, which could cause our stock price to decline. We do not control the timing of disclosure of any such milestones related to any of our programs that are managed by our strategic collaborators. Any disclosure by our strategic collaborators or competitors of data or other events 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 our stock price or overall valuation. Our stock price 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.

Our business is highly dependent on the clinical advancement of our programs and modalities. Delay or failure to advance programs or modalities could adversely impact our business.

Using our platform, we are developing product features for medicines based on mRNA. Over time, our platform work led to commonalities, where a specific combination of mRNA technologies, delivery technologies, and manufacturing processes generated a

set of product features shared by multiple programs. This is what we call a "*modality*." We have historically utilized, and expect to continue to utilize, earlier programs in a modality to understand the technology risks within the modality, including manufacturing and pharmaceutical properties. Even if our earlier programs in a modality are successful in any phase of development any of such earlier programs may fail at a later phase of development, and other programs within the same modality may still fail at any phase of development including at phases where earlier programs in that modality were successful. This may be a result of technical challenges unique to that program or due to biology risk, which is unique to every program. As we progress our programs through clinical development, there may be new technical challenges that arise that cause an entire modality to fail.

While we aim to segregate risk using modalities, there may be foreseen and unforeseen risks across modalities in whole or in part. These include, but are not limited to, mRNA, chemical modifications, and LNPs and their components. In addition, if any one or more of our clinical programs encounter safety, tolerability, or efficacy problems, developmental delays, regulatory issues, or other problems, our platform approach and business could be significantly harmed. We may believe that a particular modality has been de-risked but later determine that new and different risks exist with respect to such modality.

In addition, the biology risk across the majority of our pipeline represents targets and pathways not clinically validated by one or more approved drugs. While we believe we have made progress in seeking to reduce biology risk in certain settings, such as for vaccine targets for which we and others have shown the utility of neutralizing antibodies, the risk that the targets or pathways that we have selected may not be effective will continue to apply across the majority of our current and future programs.

While we attempt to diversify our risks by developing one or more programs in each modality, there are risks that are unique to each modality and risks that are applicable across modalities. These risks may impair our ability to advance one or more of our programs in clinical development, obtain regulatory approval, or ultimately commercialize our programs, or cause us to experience significant delays in doing so, any of which may materially harm our business.

Certain features in our development candidates and investigational medicines, including those related to mRNA, chemical modifications, surface chemistries, LNPs, and their components, may result in foreseen and unforeseen risks that are active across some or all of our modalities. Any such portfolio spanning risks, whether known or unknown, if realized in any one of our programs would have a material and adverse effect on our other programs and on our business as a whole.

There are specific additional risks to certain of our modalities and our programs as a whole. For example, prophylactic vaccines typically require clinical testing in thousands to tens of thousands of healthy volunteers to define an approvable benefit-risk profile. The need to show a high degree of safety and tolerability when dosing healthy individuals could result in rare and even spurious safety findings, negatively impacting a program prior to or after commercial launch. While we believe that certain safety, tolerability, and levels of immunogenicity we have observed in the early-stage clinical trials in our prophylactic vaccine programs are sufficient to initiate additional trials, there can be no assurance that we will observe acceptable safety or efficacy profiles in later-stage trials required for approval of these programs. For neoantigen cancer vaccines, to date, no molecular (non-cell-based) therapeutic protein vaccine has been shown to be effective against cancer and there are many clinical and manufacturing challenges to personalized medicines, including cell-based therapies and vaccines. These risks include: a rapid production turn-around time that is measured in weeks in order to supply patients in our clinical trials before further progression and mutation of their tumors, the significant costs incurred in making individualized vaccines, and potential lack of immune responses potentially due to the biology of the tumor or immune status of the patient. These and other risks apply to our PCV and other neoepitope investigational medicine programs. Additionally, there may be challenges in delivering an adequate quantity of active pharmaceutical ingredient, or API, required to drive efficacy due to the limitation in volume of API that can be delivered to a specific location, like a tumor or injured tissue. Our therapies for local injections often require specialized skills for conducting a clinical trial that could delay trials or slow or impair commercialization of an approved investigational medicine due to the poor adoption of injected local therapeutics or intratumoral therapies. In addition, the uncertain translatability of target selection from preclinical animal models, including mouse and non-human primate models, to successful clinical trial results may be impossible, particularly for immuno-oncology and systemic therapies, and cancer vaccines. In general, several biological steps are required for delivery of mRNA to translate into therapeutically active medicines. These processing steps may differ between individuals or tissues, and this could lead to variable levels of therapeutic protein, variable activity, immunogenicity, or variable distribution to tissues for a therapeutic effect. Gene therapies and mRNA-based medicines may activate one or more immune responses against any and all components of the drug product (e.g., the mRNA or the delivery vehicle, such as an LNP) as well as against the encoded protein, giving rise to potential immune reaction related adverse events. Eliciting an immune response against the encoded protein may impede our ability to achieve a pharmacologic effect upon repeat administration or a side effect. These risks apply to all of our programs, including our systemic secreted therapeutics and systemic intracellular therapeutics modalities.

Risks related to the research, development, regulatory review, and approval of our existing and future pipeline

Preclinical development is lengthy and uncertain, especially for a new class of medicines such as mRNA, and therefore our preclinical programs or development candidates may be delayed, terminated, or may never advance to the clinic, any of which may affect our ability to obtain funding and may have a material adverse impact on our platform or 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 a development candidate, we must complete extensive preclinical studies, including IND-enabling good laboratory practice, or GLP, toxicology testing, that support our planned INDs in the United States, or similar applications in other jurisdictions. We must also complete extensive work on Chemistry, Manufacturing, and Controls, or CMC, activities (including yield, purity and stability data) to be included in the IND submission. CMC activities for a new class of medicines such as mRNA require extensive manufacturing processes and analytical development, which is uncertain and lengthy. For instance, batch failures as we scale up our manufacturing have occurred and may continue to occur. In addition, we have 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 development candidates. If we are required to produce new batches of our development candidates due to insufficient shelf life, it may delay the commencement or completion of preclinical studies or clinical trials of such development 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 is lengthy and uncertain, especially with a new class of medicines such as mRNA medicines. Clinical trials of our investigational medicines 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 could affect our ability to obtain and maintain sufficient funding and would have a material adverse impact on our platform or our business.

Clinical testing is expensive and complex and can take many years to complete, and 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 investigational medicines. We and our strategic collaborators also may experience numerous unforeseen events during, or as a result of, any clinical trials that we or our strategic collaborators conduct that could delay or prevent us or our strategic collaborators from successfully developing our investigational medicines, including:

- the FDA, other regulators, Institutional Review Boards, or 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 in the past and intend to continue to optimize our manufacturing processes, including through changes to the scale and site of manufacturing, which may lead to 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 investigational medicines;
- 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 in the past and may continue to make changes to our investigational medicines after we commence clinical trials of an investigational medicine, which may require us to repeat earlier stages of clinical testing or delay later stage testing of the investigational medicine;
- clinical trials of any investigational medicines may fail to show safety or efficacy, or 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 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 investigational medicines believed to have performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval;
- our investigational medicines may have undesirable side effects, such as the immunogenicity of the LNPs or their components, the immunogenicity of the protein made by the mRNA, or degradation products, any of which could lead to serious adverse events, or other effects. 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 IRBs or ethics committees to suspend or terminate the trial of that investigational medicine or any other of our investigational medicines for which a clinical trial may be ongoing;
- the number of trial participants required for clinical trials of any investigational medicines 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, competitive trials, size of the patient population, 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 or 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 unacceptable benefit risk ratio;
- the cost of preclinical or nonclinical testing and studies and clinical trials of any investigational medicines may be greater than we anticipate;
- the supply or quality of our investigational medicines or other materials necessary to conduct clinical trials may be insufficient or inadequate;
- safety and efficacy concerns regarding one or more of our investigational medicines will be considered by us and by the FDA and other global regulators as we pursue clinical trials of new investigational medicines, develop effective informed consent documentation and work with IRBs and scientific review committees, or SRCs;
- safety or efficacy concerns regarding our investigational medicines may result from any safety or efficacy 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 data safety monitoring board for such trial. We have in the past been, and may in the future be, delayed in gaining clearance from the FDA or other regulators to initiate clinical trials through 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. The clinical trials of other companies working on mRNA medicines have been put on clinical hold by the FDA. 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, including those experienced by other investigational medicines in the same class as our investigational medicines, failure to demonstrate a benefit, or adequate benefit risk ratio, from using an investigational medicine, 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 investigational medicines. We must also complete extensive CMC activities that require extensive manufacturing processes and analytical development, which is uncertain and lengthy. For instance, batch failures as we scale up our manufacturing have occurred and may continue to occur. In addition, we have 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 clinical development candidates or investigational medicines. If we are required to produce new batches of our development candidates or investigational medicines due to insufficient shelf life, it may delay the commencement or completion of clinical trials of such development candidates or investigational medicines.

Moreover, the FDA has indicated that prior to commencing later-stage clinical trials for our programs we will need to develop assays to measure and predict the potency of a given dose of our investigational medicines. Any delay in developing assays that are acceptable to the FDA or other regulators 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 investigational medicines also could allow our competitors to bring products to market before we do, potentially impairing our ability to successfully commercialize our investigational medicines and harming our business and results of operations. Any delays in the development of our investigational medicines may harm our business, financial condition, and prospects significantly.

We may experience delays in identifying and enrolling participants in our clinical trials which would delay the progress of our investigational medicines and result in increased expenses.

We depend on enrollment of participants in our clinical trials for our investigational medicines. We may find it difficult to enroll trial participants in our clinical trials, which could delay or prevent clinical trials of our investigational medicines. Identifying and qualifying trial participants to participate in clinical trials of our investigational medicines is critical to our success. The timing of our clinical trials depends on the speed at which we can recruit trial participants to participate in testing our investigational medicines. 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 investigational medicines. If trial participants are unwilling to participate in our trials because of negative publicity from adverse events in our trials or other trials of similar products, or those related to specific therapeutic area, or for other reasons, including competitive clinical trials 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 trials 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 trial 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, including age-based eligibility criteria limiting subject enrollment to adolescent or pediatric populations;
- 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 as to the potential advantages and side effects of the investigational medicine being studied in relation to other available therapies, including any new drugs or treatments that may be approved for the indications we are investigating;
- the need, in the case of our personalized cancer vaccine, to wait for the manufacture of the personalized drug product; and
- our ability to obtain and maintain participant informed consent.

In addition, our clinical trials will compete with other clinical trials for investigational medicines that are in the same therapeutic areas as our investigational medicines, 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 investigational medicines 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 mRNA investigational medicines. Additionally, if new investigational medicines, 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 investigational medicines. If such new investigational medicines 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. We also have entered into strategic alliances under which our strategic collaborators control the development of certain of our investigational medicines, which may provide us limited or no ability to influence the enrollment rate of our clinical trials.

Even if we are able to enroll trial participants, there is no guarantee that they will ultimately be dosed as part of, or complete, a clinical trial. For example, although we announced that the first patient was enrolled in the Phase 1/2 study of mRNA-3704 in patients with isolated methylmalonic acidemia, or MMA, due to MUT deficiency, this patient later de-enrolled as a result of the COVID-19 pandemic.

mRNA medicines are a novel approach, and negative perception of the efficacy, safety, or tolerability of any investigational medicines that we develop could adversely affect our ability to conduct our business, advance our investigational medicines, or obtain regulatory approvals.

As a potential new class of medicines, no mRNA medicines have been approved to date by the FDA or other regulators. Adverse events in clinical trials of our investigational medicines or in clinical trials of others developing similar products and the resulting publicity, as well as any other adverse events in the field of mRNA medicine, or other products that are perceived to be similar to mRNA medicines, such as those related to gene therapy or gene editing, could result in a decrease in the perceived benefit of one or more of our programs, increased regulatory scrutiny, decreased confidence by patients and clinical trial collaborators in our investigational medicines, and less demand for any product that we may develop. Our large pipeline of development candidates and investigational medicines could result in a greater quantity of reportable adverse events, including suspected unexpected serious adverse reactions, or SUSARs, other reportable negative clinical outcomes, manufacturing reportable events or material clinical events

that could lead to clinical delay or hold by the FDA or applicable regulatory authority or other clinical delays, any of which could negatively impact the perception of one or more of our programs, as well as our business as a whole. In addition, responses by U.S., state, or foreign governments to negative public perception may result in new legislation or regulations that could limit our ability to develop any investigational medicines or commercialize any approved products, obtain or maintain regulatory approval, or otherwise achieve profitability. More restrictive statutory regimes, government regulations, or negative public opinion would have an adverse effect on our business, financial condition, results of operations, and prospects and may delay or impair the development of our investigational medicines and commercialization of any approved products or demand for any products we may develop.

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

There are no pharmacologic therapies approved to treat the underlying causes of many diseases that we currently attempt to address or may address in the future. For instance, for MMA or PA, few clinical trials have been attempted. In addition, there has been limited clinical trial experience for the development of pharmaceuticals to treat these rare diseases in general, and we are not aware of a registrational trial that led to approval of a drug to treat these diseases. There have been some historical trials with other agents to address organic acidemias which may have utilized clinical endpoints that are less applicable to our efforts with our MMA and PA programs that address the underlying defect. As a result, the design and conduct of clinical trials of investigational medicines for the treatment of these disorders and other disorders may take longer, be more costly, or be less effective as part of the novelty of development in these diseases.

Even if 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 strategic 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.

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

There have been few approvals of gene therapy products in the United States or foreign 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 the DNA, or otherwise make any permanent changes to cell DNA. Consequently, we expect that our investigational medicines will have a different potential side effect profile from gene therapies.

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 are 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 investigational medicines and gene therapies, the classification of some of our mRNA investigational medicines as gene therapies in the United States, the European Union, and potentially other countries could adversely impact our ability to develop our investigational medicines, 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 investigational medicines 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 development candidates and investigational medicines are designed not to make any permanent changes to cell DNA, regulatory agencies or others could believe that adverse effects of gene therapies 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 investigational medicines, or lead to significant post-approval studies, limitations, or restrictions. As we advance our investigational medicines, 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 investigational medicines.

A breakthrough therapy designation or fast track designation by the FDA for a drug may not lead to a faster development or regulatory review or approval process, and it would not increase the likelihood that the drug will receive marketing approval.

We may seek a breakthrough therapy designation for one or more of our investigational medicines. 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 investigational medicines 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. Even if we are successful in obtaining accelerated approval in the United States or under comparable pathways in other jurisdictions, we may face requirements and limitations that will adversely affect our prospects. For example, we may be approved only for a very limited indication, we may not successfully complete required post-approval trials, such trials may not confirm the clinical benefit of our drug, or approval of the drug may be withdrawn. In addition, even if one or more of our investigational medicines qualify as breakthrough therapies, the FDA may later decide that the investigational medicine 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 have received Fast Track Designation for some of our investigational medicines and may seek Fast Track Designation for others. 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 investigational medicine is eligible for this designation, we cannot assure you 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 may fail to obtain and maintain orphan drug designations from the FDA for our future investigational medicines, as applicable.

Our strategy includes filing for orphan drug designation where available for our investigational medicines, and we have received orphan drug designation from both the FDA and the European Commission for MMA (mRNA-3704) and PA (mRNA-3927). 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 greater than 200,000 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. However, 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. 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 NDA, or 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.

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 effectively protect the product 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. In addition, while we may seek additional orphan drug designation for our investigational medicines, we may never receive such further designations.

Our investigational medicines may face competition from biosimilars approved through an abbreviated regulatory pathway.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, the ACA, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or 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 investigational medicines approved as a biological product under a BLA should qualify for the 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 investigational medicines 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.

Any clinical trials of our oncology-related products that we conduct with a seamless trial design may not be acceptable to regulatory authorities in the form submitted, or at all, which may delay our clinical development and limit or change the type of information we may gather from our clinical trials.

We may pursue a development program for our oncology-related products that relies upon a seamless trial design, which presents additional risks compared to traditional three-phase development programs. A seamless trial design can be achieved through a first-in-human, or FIH, multiple expansion cohort trial, which has a single protocol with an initial dose-escalation phase and also contains three or more additional patient cohorts with cohort-specific objectives. FIH multiple expansion cohort trials are intended to expedite development by seamlessly proceeding from initial determination of a potential effective dose to individual cohorts that have trial objectives typical of Phase 2 trials. Challenges and risks associated with such seamless trial designs include challenges in the timely dissemination of new safety information to investigators, IRBs, and regulators, exposing a large number of patients across cohorts to potentially suboptimal or toxic doses of an investigational drug, exposing more patients than is needed to achieve the cohort's objectives, and missed interpretations of preliminary trial results and unplanned analyses which can lead to delays in clinical development. Regulatory authorities may find our seamless trial designs unacceptable based on these and other risks of utilizing such designs.

If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we will not be able to commercialize, or will be delayed in commercializing, investigational medicines we may develop, and our ability to generate revenue will be materially impaired.

Even if we complete the necessary preclinical studies and clinical trials, the marketing approval process is expensive, time-consuming, and uncertain, and may prevent us from obtaining approvals for the commercialization of any development candidates and investigational medicines we may develop. Any mRNA medicine we may develop and the activities associated with its development and commercialization, including design, testing, manufacture, record-keeping, 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 investigational medicines, we and our strategic collaborators must demonstrate through extensive preclinical studies and clinical trials that our products are safe, pure, and potent or effective in humans, including the target population. Successful completion of clinical trials is a prerequisite to submitting a BLA to the FDA, a Marketing Authorization Application, or MAA, to the EMA, and similar marketing applications to comparable global regulatory authorities, for each investigational medicine and, consequently, the ultimate approval and commercial marketing of any investigational medicines.

Failure to obtain marketing approval for an investigational medicine will prevent us from commercializing the investigational medicine in a given jurisdiction. We have not received approval to market any investigational medicines from regulatory authorities in any jurisdiction, and it is possible that none of our investigational medicines or any investigational medicines 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 or regulatory consultants to assist us in this process. To our knowledge, there is no current precedent for an mRNA-based medicine such as the types we are developing being approved for sale by the FDA or any other global regulatory agency. Although we expect to submit BLAs for our mRNA-based investigational medicines in the United States, other jurisdictions may consider our mRNA-based investigational medicines to be new drugs, not biologics, 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 investigational medicine'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 investigational medicines 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, both in the United States and abroad, 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 investigational medicines 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 and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical, or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit, or prevent marketing approval of an investigational medicine. 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 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 mRNA medicine 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 investigational medicines.

The FDA and other regulatory agencies review the 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 conduct pre-approval inspections at the time of a BLA. Any findings by regulatory agencies and failure to comply with requirements may lead to delay in approval and failure to commercialize the potential mRNA investigational medicine.

If we experience delays in obtaining approval or if we fail to obtain approval of any investigational medicines we may develop, the commercial prospects for those investigational medicines will be harmed, and our ability to generate revenues will be materially impaired.

We may never obtain EMA or other foreign regulatory body approval for any of our investigational medicines, and even if we do, we may never be able to commercialize any of our investigational medicines in any other jurisdiction, which would limit our ability to realize their full market potential.

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 eventually market any of our investigational medicines in any particular foreign 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 foreign regulatory approval 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 foreign regulatory approval process involves all of the risks associated with FDA approval. We do not have any investigational medicines approved for sale in any jurisdiction, including international markets, and we do not have experience in obtaining regulatory approval in international markets. 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.

Our planned clinical trials or those of our strategic 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 investigational medicines.

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 investigational medicines 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 investigational medicines.

Some of our investigational medicines are developed or intended to be co-administered with other developmental therapies or approved medicines. For example, our PCV investigational medicine (mRNA-4157) and our KRAS investigational medicine (mRNA-5671) in collaboration with Merck may be co-administered with Merck's anti-PD-1 therapy, pembrolizumab. Our IL-12 investigational medicine (MEDI1191) in collaboration with AstraZeneca is being developed to be co-administered with checkpoint inhibitors (e.g., anti-PD-L1, anti-CTLA4). These combinations may have additional side effects. The uncertainty resulting from the use of our investigational medicines in combination with other therapies may make it difficult to accurately predict side effects in future clinical trials.

Some of our development candidates and investigational medicines are developed or intended for adolescent and/or pediatric patients under the age of eighteen, including our MMA development candidate (mRNA-3704) for which we are conducting a first-in-human Phase 1/2 trial in patients between one and eighteen years of age. Enrollment for this trial is paused due to the COVID-19 pandemic. If participants are enrolled in the trial and successfully dosed, they will be the first of our investigational medicines given to subjects eighteen years of age or younger and mRNA-3704 will be the first of our rare disease investigational medicines from our systemic intracellular therapeutics modality dosed in humans. The uncertainty resulting from the first dosing of young, human subjects with an investigational medicine from our systemic intracellular therapeutics modality makes it difficult to accurately predict if significant adverse events or other side effects will be observed.

Most of our investigational medicines are formulated and administered in an LNP which, when administered, may lead to systemic side effects related to the components of the LNP, some of which may not have been previously tested in humans. While we have continued to optimize our LNPs, there can be no assurance that our LNPs will not have undesired effects. Our LNPs could contribute, in whole or in part, to one or more of the following: immune reactions, infusion reactions, complement reactions, opsonization reactions, antibody reactions, or reactions to PEG. Certain aspects of our investigational medicines may induce immune reactions from either the mRNA or the lipid as well as adverse reactions within liver pathways or degradation of the mRNA or the LNP, any of which could lead to significant adverse events in one or more of our clinical trials. Many of these types of side effects have been seen for previously developed LNPs. There may be resulting uncertainty as to the underlying cause of any such adverse event, which would make it difficult to accurately predict side effects in future clinical trials and would result in significant delays in our programs.

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 development candidates or investigational medicines altogether. We, the FDA or other applicable regulatory authorities, or an IRB, may impose a clinical hold or suspend or terminate clinical trials of an investigational medicine 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, 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.

Even if we obtain regulatory approval for an investigational medicine, including mRNA-1273, our products will remain subject to regulatory scrutiny.

Even if we obtain regulatory approval in a jurisdiction, 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 investigational medicines, 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 trials;
- 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 investigational medicines 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. Investigational medicines 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 investigational medicines, the administration process or related procedures also can cause undesirable side effects. If any such events occur, the clinical trials of any of our investigational medicines 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 investigational medicine, the FDA, the EMA, or other regulatory authorities could order us to cease further development of, or deny approval of, any of our investigational medicines 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 investigational medicines, the commercial prospects of such investigational medicines may be harmed and our ability to generate product revenues from any of these investigational medicines may be delayed or eliminated. Any of these occurrences may harm our ability to identify and develop investigational medicines, and may harm our business, financial condition, result of operations, and prospects significantly.

Additionally, if we successfully obtain regulatory approval for an investigational medicine, the FDA or other regulatory authority could require us to adopt a Risk Evaluation and Mitigation Strategy to ensure that the benefits of treatment with such investigational medicine 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 impact on our business, financial condition, results of operations, and prospects.

If we are successful in gaining approval for any of our investigational medicines, 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 cGMP 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.

If mRNA-1273 is approved and used commercially, we or others could identify previously unknown side effects, or known side effects could be observed as being more frequent or severe than in clinical studies or earlier post-marketing periods, in which case:

- sales of mRNA-1273 may be more modest than originally anticipated;

- licenses may be revoked or regulatory approvals may be restricted or withdrawn for mRNA-1273;
- we may decide, or be required, to conduct recalls or send field alerts to physicians, pharmacists and hospitals;
- additional nonclinical or clinical studies, changes in labeling, adoption of a REMS, or changes to manufacturing processes, specifications and/or facilities may be required; and
- government investigations or lawsuits, including class action suits, may be brought against us.

Any of the above occurrences could reduce or prevent sales of mRNA-1273, increase our expenses and impair our ability to successfully commercialize mRNA-1273.

Our ability to generate product revenue is dependent on the success of one or more of our development candidates or investigational medicines, each of which is at an early stage of development and will require significant additional development and clinical testing before we can seek marketing approval and begin commercial sales.

Our ability to generate product revenue is highly dependent on our or our strategic collaborators' ability to develop, obtain regulatory approval of, and successfully commercialize one or more of our development candidates or investigational medicines. Our development candidates and investigational medicines are in the early stages of development and will require additional clinical and nonclinical development, regulatory review, and approval in each jurisdiction in which we intend to market the products. In addition, substantial investment, access to sufficient commercial manufacturing capacity, and significant marketing efforts will be required before we can generate any revenue from product sales. Before obtaining marketing approval from regulatory authorities for the sale of our investigational medicines, we must conduct extensive clinical trials to demonstrate the safety and efficacy of the investigational medicines in humans. We cannot be certain that any of our investigational medicines will be successful in clinical trials and they may not receive regulatory approval even if they are successful in clinical trials. Even if approved, our investigational medicines also need to demonstrate health economic benefit in order to establish pricing and reimbursement. We may also need to conduct additional evaluation of safety and health outcomes in a post-approval setting.

Risks related to the manufacturing of our development candidates, investigational medicines and our future pipeline

Our mRNA development candidates and investigational medicines are based on novel technologies and any development candidates and investigational medicines 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 our third-party manufacturers encounter such difficulties, our ability to supply material for clinical trials or any approved product could be delayed or stopped.

The manufacturing processes for our development candidates and investigational medicines are novel and complex. There are no mRNA medicines commercialized to date or manufactured at such scale. 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, 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 development candidates or investigational medicines in their manufacturing and stability formulation and conditions. This has in the past and may in the future result in our having to resupply batches for preclinical or clinical activities when there is insufficient product stability during storage and insufficient supply. Insufficient stability or shelf life of our development candidates and investigational medicines could materially delay our or our strategic collaborators' ability to continue the clinical trial for that development candidate or investigational medicine or require us to begin a new clinical trial with a newly formulated drug product, due to the need to manufacture additional preclinical or clinical supply.

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 investigational medicines encapsulated in LNPs is complex and, if not developed and manufactured under well-controlled conditions, can adversely impact pharmacological activity. Furthermore, we have not manufactured mRNA medicines at commercial scale. We may encounter difficulties in scaling up our manufacturing process, thereby potentially impacting clinical and commercial supply.

We are scaling up our batch size to accommodate the clinical supply requirements of some of our programs. However, in many cases, we may have to utilize multiple batches of drug substance and drug product to meet the clinical supply requirement of a single clinical trial. Failure in our ability to scale up batch size or failure in any batch may lead to a substantial delay in our clinical trials.

As we continue developing new manufacturing processes for our drug substance and drug product, the changes we implement to manufacturing process may in turn impact specification and stability of the drug product. Changes in our manufacturing processes

may lead to failure of batches and this could lead to a substantial delay in our clinical trials. Our mRNA investigational medicines may prove to have a stability profile that leads to a lower than desired shelf life of the final approved mRNA medicine. 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 investigational medicines. 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 investigational medicines inside of our factories, CROs, suppliers, or in the clinic that affect the integrity of our investigational medicines.

As we scale the manufacturing output for particular programs, we plan to continuously improve yield, purity, and the pharmaceutical properties of our development candidates and investigational medicines from IND-enabling studies through commercial launch, including shelf life stability, and solubility properties of drug product and drug substance. Because of 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 6 or 12 month stability testing. That may require resupplying clinical material or making additional cGMP 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 have a single source of supply, are new to the pharmaceutical industry, and 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 investigational medicines.

We have established a number of analytical assays, and may have to establish several more, to assess the quality of our mRNA investigational medicines. 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 investigational medicines 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 investigational medicines 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 investigational medicines 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.

As our drug development pipeline increases and matures, the increased demand for clinical and commercial supplies from our facilities and third parties may impact our ability to operate. We will require increased capacity across our entire supply chain. Furthermore, we rely on many service providers, including those that provide manufacturing or testing services, all of whom have inherent risks in their operations that may adversely impact our operations.

We currently utilize, and expect to continue to utilize, third parties to, among other things, manufacture raw materials, components, parts, and consumables, and to perform quality testing. If the field of mRNA and other nucleic acid medicines continues to expand, we may encounter increasing competition for these materials and services. Demand for third-party manufacturing or testing facilities may grow at a faster rate than their existing capacity, which could disrupt our ability to find and retain third-party manufacturers capable of producing sufficient quantities of such raw materials, components, parts, and consumables required to manufacture our mRNA investigational medicines. The use of service providers and suppliers could expose us to risks, including, but not limited to:

- termination or non-renewal of supply and service agreements with third parties in a manner or at a time that is costly or damaging to us;
- disruptions to the operations of these suppliers and service providers caused by conditions unrelated to our business or operations, including the bankruptcy of the supplier or service provider; and
- inspections of third-party facilities by regulatory authorities that could have a negative outcome and result in delays to or termination of their ability to supply our requirements.

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.

In 2018, we completed construction of a new manufacturing facility, Moderna Technology Center, or MTC, in Norwood, Massachusetts that, among other things, is intended for cGMP manufacture of drug substance and drug product. While the design of the facility is based on current standards for biotechnology facilities, it has not been reviewed or pre-approved by any regulatory agency, nor has the facility been inspected by any regulatory agency such as the FDA. We have only recently begun producing drug substance and drug product at the MTC for our preclinical and clinical use. We could incur delays in implementing the full operational

state of the facility, causing delays to clinical supply or extended use of third-party service providers, resulting in unplanned expenses. In constructing the MTC facility, we have incurred substantial expenditures, and expect to incur significant additional expenditures in validating and operating the facility in the future.

We have designed the MTC 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 a clinical manufacturing facility 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 facility. Any disruption in our manufacturing capabilities at the MTC 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 inside the MTC footprint or 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 investigational medicines could be delayed or curtailed. Additional investments may be needed if changes in our manufacturing process lead to required changes in the MTC's infrastructure.

There are risks inherent in pharmaceutical manufacturing operations that could affect our ability and the ability of our third-party manufacturers or contract manufacturing organizations to meet our delivery requirements or provide adequate amounts of material.

The convergence of process and analytical technology, raw materials, consumables, equipment, physical infrastructure, including a clean room environment, and air handling and other utilities, results in complex procedures and systems that have to work effectively to manufacture our investigational medicines. Failure or process defects in any of the interrelated systems at either our manufacturing facilities or those of our third-party providers, could adversely impact our ability to manufacture and supply our investigational medicines.

Our investigational medicines are inherently sensitive to shipping and storage conditions, which, in some cases, requires cold-chain logistics and could subject our investigational medicines to risk of loss or damage.

Our investigational medicines are sensitive to temperature, storage, and handling conditions. Loss in investigational medicines could occur if the product or product intermediates are not stored or handled properly. Shelf life for our investigational medicines may vary by product and is not fully quantified and is expected to be variable, and it is possible that our investigational medicines could be lost due to expiration prior to use. Cold-chain logistics are required for certain of our investigational medicines. If we do not effectively maintain our cold-chain supply logistics, then we may experience an unusual number of returned or out of date products.

Failure to effectively maintain our cold-chain supply logistics, by us or third parties, has in the past and could in the future lead to additional manufacturing costs and delays in our ability to supply required quantities for clinical trials or otherwise.

****We are subject to significant regulatory oversight with respect to manufacturing our mRNA investigational medicines. Our manufacturing facilities or the manufacturing facilities of our third-party manufacturers or suppliers may not meet regulatory requirements. Failure to meet cGMP requirements set forth in regulations promulgated by the FDA, EMA, and other global health authorities could result in significant delays in any approval of and costs of our products.***

The manufacturing of vaccines and therapeutics for clinical trials or commercial sale is subject to extensive regulation. Components of a finished product approved for commercial use or used in clinical trials must be manufactured in accordance with cGMP requirements. These regulations 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 clinical trials. Poor control of the cGMP production processes can lead to product quality failures that can impact our ability to supply product, resulting in cost overruns and delays to clinical timelines, 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, EMA's, and other countries' cGMP 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 cGMP 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, the product approval to commercialize 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 cGMP 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 and foreign regulatory authority approval process, and we may need to contract with manufacturers who we believe can meet applicable FDA and foreign regulatory authority requirements on an ongoing basis. If we or our third-party manufacturers are unable to reliably produce investigational medicines to specifications acceptable to the FDA or other regulatory authorities, we or our strategic collaborators may not obtain or maintain the approvals we or they need to commercialize such products. Even if we or our strategic collaborators obtain regulatory approval for any of our mRNA medicines, there is no assurance that either we or our contract manufacturing organizations will be able to manufacture the approved medicine to specifications acceptable to the FDA 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 investigational medicines, 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 prospects.

In addition, we may not have direct control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance, and qualified personnel. Furthermore, all of our contract manufacturers are engaged with other companies to supply or manufacture materials or products for such companies, which exposes our contract manufacturers 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 contract manufacturers' facility. In addition, to the extent that we rely on foreign contract manufacturers, including for mRNA-1273, we are or will be subject to additional risks, including the need to comply with import and export regulations. 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 investigational medicines or products, operating restrictions, and criminal prosecutions, any of which could significantly and adversely affect supplies of our products and investigational medicines (including those of our strategic collaborators) and our overall business operations. Our potential future dependence upon others for the manufacture of our investigational medicines 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 foreign 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, the EMA, or other foreign 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 third-party contract manufacturers have, in the past, experienced lot failures and some may have experienced product recalls. Lot failures have in the past caused, and lot failures or product recalls in the future with respect to product produced by either our own facilities or those of our third-party manufacturers could cause, us and our strategic 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 will 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 specific to certain investigational medicines

Our PCV investigational medicine is uniquely manufactured for each patient using a novel, complex manufacturing process and we may encounter difficulties in production.

We custom design and manufacture PCVs that are unique and tailored specifically for each patient. Manufacturing unique lots of PCVs 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;
- 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 investigational medicine, 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 patient site of care; and
- the ability to define a consistent safety profile at a given dose when each participant receives a unique vaccine.

We have built and installed custom manufacturing equipment for PCV that has been incorporated into a personalized vaccine unit in the MTC. This unit is currently operational and we are producing batches of PCV from the MTC. 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 our PCV product is approved. This expansion or addition of new facilities could also lead to product comparability issues which can further delay introduction of new capacity.

Because our PCVs 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, results of analysis 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 has in the past and may in the future 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 PCV investigational medicine is developed through early-stage clinical trials to later-stage clinical trials towards approval and commercialization, we expect that multiple aspects of the complicated collection, analysis, manufacture, and delivery process 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 PCVs to perform differently than we expect, potentially affecting the results of clinical trials.

Risks related to our reliance on third parties

****We have in the past entered into, and in the future may enter into, strategic alliances with third parties for the development and commercialization of our development candidates and investigational medicines. If these strategic alliances are not successful, our business could be adversely affected.***

We have limited resources to conduct clinical operations and have not yet established infrastructure for sales, marketing, or distribution. Accordingly, we have entered into strategic alliances under which our strategic collaborators have provided, and may in the future provide, funding and other resources for developing, manufacturing and potentially commercializing our investigational medicines. We expect to enter into additional strategic alliances to access additional funding, capabilities, and expertise in the future. Our existing strategic alliances, and any future strategic alliances we enter into, may pose a number of risks, including the following:

- strategic collaborators may not perform their obligations as expected;
- the clinical trials conducted as part of such strategic alliance may not be successful;
- strategic collaborators may not pursue development and commercialization of any investigational medicines 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 strategic collaborators' focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;
- strategic collaborators may delay clinical trials, provide insufficient funding for clinical trials, stop a clinical trial, abandon an investigational medicine, repeat or conduct new clinical trials, or require a new formulation of an investigational medicine for clinical testing;
- strategic collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our investigational medicines if the strategic 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;
- investigational medicines developed in strategic alliances with us may be viewed by our strategic collaborators as competitive with their own investigational medicines or products, which may cause strategic collaborators to cease to devote resources to the development or commercialization of our investigational medicines;
- a strategic collaborator with marketing and distribution rights to one or more of our investigational medicines that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of any such product;
- disagreements with strategic collaborators, including disagreements over proprietary rights, contract interpretation, or the preferred course of development of any investigational medicines, may cause delays or termination of the research, development, or commercialization of such investigational medicines, may lead to additional responsibilities for us with respect to such investigational medicines, or may result in litigation or arbitration, any of which would be time-consuming and expensive;
- strategic collaborators may not properly maintain or defend our IP rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our IP or proprietary information or expose us to potential litigation;
- disputes may arise with respect to the ownership of IP developed pursuant to our strategic alliances;
- strategic collaborators may infringe the IP rights of third parties, which may expose us to litigation and potential liability;
- strategic alliances may be materially amended, or terminated for the convenience of the strategic collaborator and, if materially amended, or terminated, the development of our investigational medicines may be delayed, and we could be required to raise additional capital to pursue further development or commercialization of the applicable investigational medicines;
- 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 stockholders, or disrupt our management and business;
- we could face significant competition in seeking appropriate strategic 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 strategic alliances do not result in the successful development and commercialization of programs, or if one of our strategic collaborators materially amends, or terminates its agreement with us, we may not receive any future research funding or milestone, earn-out, royalty, or other contingent payments under the strategic alliances. If we do not receive the funding we expect under these agreements, our development of investigational medicines could be delayed and we may need additional resources to develop our investigational medicines. In addition, in general our strategic collaborators have the right to terminate their agreements with us for convenience. A strategic collaborator has in the past terminated its agreement with us. If one of our strategic collaborators terminates its agreement with us, we may find it more difficult to attract new strategic 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 Quarterly Report on Form 10-Q apply to the activities of our strategic collaborators.

Our strategic collaborators control aspects of our clinical trials, regulatory activities, and other aspects of our strategic alliances, which could result in delays and other obstacles in the development and commercialization of our proposed products and materially harm our results of operations.

For some programs, we depend on strategic collaborators to design and conduct clinical trials for our investigational medicines. As a result, we may not control the manner or time schedule in which these clinical trials are conducted, which may negatively impact our business operations. In addition, if any of our strategic collaborators withdraws support for one or more of our programs or proposed products or otherwise impairs their development, our business could be negatively affected.

We may seek to establish additional strategic alliances and, if we are not able to establish them on commercially reasonable terms, we may have to alter our development and commercialization plans. Certain of our strategic alliance agreements may restrict our ability to develop certain products.

Our development programs and the potential commercialization of our development candidates and investigational medicines will require substantial additional cash to fund expenses. For some of our investigational medicines, we may decide to collaborate with pharmaceutical and biotechnology companies for the development and potential commercialization of those investigational medicines.

We face significant competition in seeking appropriate strategic collaborators. Whether we reach a definitive agreement for any additional strategic alliances will depend, among other things, upon our assessment of the strategic collaborator's resources and expertise, the terms and conditions of the proposed strategic alliance, and the proposed strategic collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for the subject investigational medicine, the costs and complexities of manufacturing and delivering such investigational medicine to trial participants, the potential of competing drugs, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge, and industry and market conditions generally. The strategic collaborator may also consider alternative investigational medicines 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 for our investigational medicine. The terms of any additional strategic alliances or other arrangements that we may establish may not be favorable to us.

We are also restricted under our existing strategic alliance agreements from entering into certain future agreements on certain terms with potential strategic collaborators to pursue other targets on our own. These restrictions on working with targets, polypeptides, routes of administration, and fields could limit our ability to enter into strategic collaborations with future strategic collaborators or to pursue certain potentially valuable development candidates or investigational medicines.

We may not be able to negotiate additional strategic alliances on a timely basis, on favorable terms, or at all. Strategic alliances are complex and time-consuming to negotiate and document. If we are unable to negotiate and enter into new strategic alliances, we may have to curtail the development of the investigational medicine for which we are seeking to collaborate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on favorable terms or at all. If we do not have sufficient funds, we may not be able to further develop our investigational medicines or bring them to market and generate product revenue.

We are dependent on single-source suppliers for some of the components and materials used in, and the processes required to develop, our development candidates and investigational medicines.

We currently depend on single-source suppliers for some of the components and materials used in, and manufacturing processes required to develop and commercialize, our development candidates and investigational medicines. We cannot ensure that these suppliers or service providers will remain in business, 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 development candidates or investigational medicines 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 investigational medicines, 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 products, 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 investigational medicines.

In addition, as part of the FDA's approval of our investigational medicines, 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 development candidates or investigational medicines;
- 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.

We rely on and expect to continue to rely on third parties to conduct aspects of our research, preclinical studies, protocol development, and clinical trials for our development candidates or investigational medicines. If these third parties do not perform satisfactorily, comply with regulatory requirements, or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our investigational medicines and our business could be substantially harmed.

We currently rely and expect to continue to rely on third parties, such as CROs, clinical data management organizations, medical institutions, and clinical investigators, to conduct 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 will be 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 will remain 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 regulations, commonly referred to as GCPs 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 will be required to comply with regulations, including GCPs, 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 Competent Authorities of the Member States of the European Economic Area, and comparable foreign regulatory authorities for any investigational medicines 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 GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, the FDA will determine that any of our future clinical trials will comply with GCPs. In addition, our clinical trials must be conducted with investigational medicines produced in accordance with the requirements in cGMP 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 intend to design the clinical trials for certain of our investigational medicines, our strategic 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, will be outside of our direct control. Our reliance on third parties to conduct future preclinical studies and clinical trials will also result 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 cyber-attacks.

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 investigational medicines may be delayed, we may not be able to obtain regulatory approval and commercialize our investigational medicines, 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 expect to 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 investigational medicines we may develop or commercialization of our medicines, if approved, producing additional losses and depriving us of potential product 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.

Risks related to our intellectual property

Other companies or organizations may challenge our patent rights or may assert patent rights that prevent us from developing and commercializing our products.

mRNA medicines are a relatively new scientific field, the continued development and potential use of which has resulted in many different patents and patent applications from organizations and individuals seeking to obtain IP protection in the field. We have obtained grants and issuances of patents on mRNA medicines and our delivery technology. The issued patents and pending patent applications in the United States and in key markets around the world that we own, claim many different methods, compositions, and processes relating to the discovery, development, manufacture, and commercialization of mRNA medicines and our delivery technology, including LNPs.

As the field of mRNA therapeutics and vaccines is maturing, patent applications are being processed by national patent offices around the world. There is uncertainty about which patents will issue, and, if they do, as to when, to whom, and with what claims. It is likely that there will be significant litigation and other proceedings, such as interference, reexamination, and opposition proceedings, as well as *inter partes* and post-grant review proceedings introduced by provisions of the America Invents Act, which became available to third-party challengers on September 16, 2012, in various patent offices relating to patent rights in the mRNA field. We expect that oppositions will be filed in the European Patent Office, or EPO, and elsewhere relating to patents and patent applications in our portfolio. 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. For example, a third party request for reexamination has been granted against one of our U.S. patents, which relates to our infectious disease vaccine program. We cannot be certain that such patent will survive or that the claims will remain in the current form. In addition, third parties may attempt to invalidate our IP rights. Even if our rights are not directly challenged, disputes could lead to the weakening of our IP rights. Our defense against any attempt by third parties to circumvent or invalidate our IP 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 in the field of mRNA therapeutics.

There are many issued and pending third-party patents that claim aspects of oligonucleotide delivery technologies that we may need for our mRNA therapeutic and vaccine candidates or marketed products, including mRNA-1273, if approved. There are also many issued third-party patents that claim targeting genes or portions of genes that may be relevant for mRNA medicines we wish to develop. For example, we are aware of a third-party patent directed to methods of using mRNA to treat Fabry disease. 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 our mRNA therapeutic candidates. Thus, it is possible that one or more organizations will hold patent rights to which we may need a license, or hold patent rights which could be asserted against us. If those organizations refuse to grant us a license to such patent rights on reasonable terms or a court rules that we need such patent rights that have been asserted against us and we are not able to obtain a license on reasonable terms, we may be unable to perform research and development or other activities or market products, including mRNA-1273, covered by such patents.

If we become involved in patent litigation or other proceedings related to a determination of rights, we could incur substantial costs and expenses, substantial liability for damages, or be required to stop our product development and commercialization efforts.

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other IP 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 U.S. Patent and Trademark Office, or the USPTO, and corresponding foreign patent offices. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are pursuing development candidates. 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 mRNA medicines. We have a number of these proceedings ongoing against third-party patents related to RNA vaccinations and mRNA delivery. If we are unsuccessful in invalidating certain of the third-party patents that we are currently challenging, those third parties may attempt to assert those patents against us should certain of our investigational medicines obtain regulatory approval. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our development candidates may be subject to claims of infringement of the patent rights of third parties.

Third parties may assert that we are employing their 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 or manufacture of our investigational medicines. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our investigational medicines 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 investigational medicines, 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 commercialize such investigational medicine 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 investigational medicine 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.

Defense of infringement and other claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement 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.

In addition, such licenses are likely to be non-exclusive and, therefore, our competitors may have access to the same 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 products, which could limit our ability to generate revenues or achieve profitability and possibly prevent us from generating revenue sufficient to sustain our operations. Moreover, we expect that a number of our collaborations will provide that royalties payable to us for licenses to our IP may be offset by amounts paid by our collaborators to third parties who have competing or superior IP positions 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 strategic alliance agreements, we have agreed to indemnify certain third parties for certain costs incurred in connection with litigation relating to IP rights or the subject matter of the agreements. The cost to us of any litigation or other proceeding relating to IP rights, even if resolved in our favor, could be substantial, and litigation would divert our management's efforts. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Uncertainties resulting from the initiation and continuation of any litigation could delay our research, development and commercialization efforts and limit our ability to continue our operations.

We may not be successful in obtaining or maintaining necessary IP rights to product components and manufacturing processes for our development pipeline.

Presently we have rights to certain IP, through licenses from third parties and under patents that we own, to develop our development candidates and investigational medicines. Because our pipeline may involve additional development candidates that could require the use of proprietary rights held by third parties, the growth of our business could depend in part on our ability to acquire, in-license, or use these proprietary rights. In addition, our development candidates and investigational medicines may require specific formulations to work effectively and efficiently and these rights may be held by others. We may be unable to acquire or in-license any compositions, methods of use, processes, or other third-party IP rights from third parties that we identify. The licensing and acquisition of third-party IP rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party IP rights that we may consider attractive. 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 U.S. and foreign academic institutions to accelerate 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. Regardless of such right of first negotiation for IP, we may 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 IP rights to other parties, potentially blocking our ability to pursue our program.

In addition, companies 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 IP 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 IP rights, our business, financial condition, and prospects for growth could suffer.

If we are not able to obtain and enforce patent protection for our discoveries, our ability to effectively compete using our development candidates will be harmed.

Our success depends, in part, on our ability to protect proprietary methods and technologies that we develop under the patent and other IP laws of the United States and other countries, so that we can prevent others from unlawfully using our inventions and proprietary information. However, we may not hold proprietary rights to some patents required for us to develop, manufacture, and commercialize our proposed products.

Because certain U.S. patent applications are confidential until the patents issue, such as applications filed prior to November 29, 2000, or applications filed after such date which will not be filed in foreign countries, third parties may have filed patent applications for technology covered by our pending patent applications without our being aware of those applications, and our patent applications may not have priority over those applications. In addition, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after
filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions, including mRNA-1273.

For this and other reasons, we may be unable to secure desired patent rights, thereby losing exclusivity. Further, we may be required to obtain licenses under third-party patents to market our proposed products or conduct our research and development or other activities. If licenses are not available to us on favorable terms, we may not be able to market the affected products or conduct the desired activities.

Our strategy depends on our ability to rapidly identify and seek patent protection for our discoveries. In addition, we may rely on third-party strategic collaborators to file patent applications relating to proprietary technology that we develop jointly as a part of certain strategic alliances. The process of obtaining patent protection is expensive and time-consuming. If our present or future strategic collaborators fail to file and prosecute all necessary and desirable patent applications at a reasonable cost and in a timely manner, our business may be adversely affected. Despite our efforts and the efforts of our strategic collaborators to protect our proprietary rights, unauthorized parties may be able to obtain and use information that we regard as proprietary. While issued patents are presumed valid, this does not guarantee that the patent will survive a validity challenge or be held enforceable. Any patents we have obtained, or obtain in the future, may be challenged, invalidated, adjudged unenforceable, or circumvented by parties attempting to design around our IP. Moreover, third parties or the USPTO may commence interference proceedings involving our patents or patent applications. Any challenge to, finding of unenforceability or invalidation, or circumvention of, our patents or patent applications, would be costly, would require significant time and attention of our management, could reduce or eliminate royalty payments to us from third-party licensors, and could have a material adverse impact on our business.

Our pending patent applications may not result in issued patents. The patent position of pharmaceutical or biotechnology companies, including ours, is generally uncertain and involves complex legal and factual considerations. The standards that the USPTO and its foreign 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 foreign countries, remains uncertain and is dependent upon the scope of the protection decided upon by patent offices, courts, and lawmakers. Moreover, there are periodic discussions in the U.S. Congress and in international jurisdictions about modifying various aspects of patent law. For example, the America Invents Act, which took effect in March 2013, included a number of changes to the patent laws of the United States. If any of the enacted changes prevent us from adequately protecting our discoveries, including our ability to pursue infringers of our patents to obtain injunctive relieve or for substantial damages, our business could be adversely affected. One major provision of the America Invents Act changed U.S. patent practice from a first-to-invent to a first-to-file system. If we fail to file an invention before a competitor files on the same invention, we no longer have the ability to provide proof that we were in possession of the invention prior to the competitor's filing date, and thus would not be able to obtain patent protection for our invention. There is also 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.

Accordingly, we do not know the degree of future protection for our proprietary rights or the breadth of claims that will be allowed in any patents issued to us or to others. 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.

Failure to obtain and maintain all available regulatory exclusivities and broad patent scope and to maximize patent term restoration or extension on patents covering our products may lead to loss of exclusivity and early biosimilar entry resulting in a loss of market share and/or revenue.

We license patent rights from third-party owners. If such owners do not properly or successfully obtain, maintain, or enforce the patents underlying such licenses, our competitive position and business prospects may be harmed.

We are a party to licenses that give us rights to third-party IP that is necessary or useful for our business. In particular, we have obtained licenses from Cellscript, LLC and its affiliates to patent rights covering modified mRNA chemistries and from certain other parties for IP useful in our formulation efforts. We may enter into additional licenses to third-party IP in the future.

Our success will depend in part on the ability of our licensors to obtain, maintain, and enforce patent protection for our licensed IP. Our licensors may not successfully prosecute the patent applications we license. Even if patents issue 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 IP 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 strategic collaborators. Any impairment of these sublicensed rights could result in reduced revenues under our strategic alliance agreements or result in termination of an agreement by one or more of our strategic collaborators.

If we fail to comply with our obligations in the agreements under which we license IP 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.

Licensing of IP 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. We are a party to certain IP license agreements that are important to our business and expect to enter into additional license agreements in the future. Our existing license agreements impose, and we expect that future license agreements will impose, various diligence, milestone payment, royalty, 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, in which event we would not be able to market products covered by the license.

In some cases, patent prosecution of our licensed technology is controlled solely by the licensor. If our licensors fail to obtain and maintain patent or other protection for the proprietary IP we license from them, we could lose our rights to the IP and our competitors could market competing products using the IP. In certain cases, we control the prosecution of patents resulting from licensed technology. In the event we breach any of our obligations related to such prosecution, we may incur significant liability to our strategic collaborators. Disputes may arise regarding IP subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes that are not subject to the licensing agreement infringe on IP of the licensor;
- the sublicensing of patent and other rights under our collaborative development relationships;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the ownership of inventions and know-how resulting from the joint creation or use of IP by our licensors and us and our strategic collaborators; and
- the priority of invention of patented technology.

If disputes over IP that we have licensed 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 development candidates or investigational medicines. We are generally also subject to all of the same risks with respect to protection of IP that we license, as we are for IP that we own, which are described below. If we or our licensors fail to adequately protect this IP, our ability to commercialize products could suffer.

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

In addition to patent protection, we rely heavily upon know-how and trade secret protection, as well as non-disclosure agreements and invention assignment agreements with our employees, consultants, and third parties, to protect our confidential and proprietary information, especially where we do not believe patent protection is appropriate or obtainable. In addition to contractual measures, we try to protect the confidential nature of our proprietary information using physical and technological security measures. Such measures may not, for example, in the case of misappropriation of a trade secret by an employee or third party with authorized access, provide adequate protection for our proprietary information. Our security measures may not prevent an employee or consultant from misappropriating our trade secrets and providing them to a competitor, and recourse we take against such misconduct may not provide an adequate remedy to protect our interests fully. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive, and time-consuming, and the outcome is unpredictable. In addition, trade secrets may be independently developed by others in a manner that could prevent legal recourse by us. If any of our confidential or proprietary information, such as our trade secrets, were to be disclosed or misappropriated, or if any such information was independently developed by a competitor, our competitive position could be harmed.

Certain former employees have obtained employment with companies or academic institutions that could be considered competitive with us and are operating their business in areas that are similar to ours, including in their business model, product discovery efforts, mRNA-based product development, or formulation technology such as our LNPs. This competition may be limited by contractual provisions which may or may not be enforceable by us in the Commonwealth of Massachusetts or other jurisdictions. In addition, we may not be aware of such competitive employment arrangements until after our trade secrets have been disclosed to potentially competitive companies.

We may be subject to claims 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 employ individuals who 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, and independent contractors do not use the proprietary information or know-how of others in their work for us, from time to time we are subject to claims that we, or our employees, consultants, or independent contractors, have inadvertently or otherwise used or disclosed IP, including trade secrets or other proprietary information, of any of our employees' former employers or other third parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable IP rights or personnel, which could adversely impact our business. 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.

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

We may be subject to claims that former employees, collaborators, or other third parties have an ownership interest in our patents or other IP. Ownership disputes may arise, for example, from conflicting obligations of consultants or others who are involved in developing our development 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 IP rights, such as exclusive ownership of, or right to use, valuable IP. Such an outcome could have a material adverse impact on our business. 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.

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 or 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. 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. In such an event, our competitors might be able to enter the market and this circumstance could have a material adverse impact on our business.

Issued patents covering our development candidates and investigational medicines could be found invalid or unenforceable if challenged in court.

If we or one of our strategic collaborators initiated legal proceedings against a third party to enforce a patent covering one of our development candidates or investigational medicines, the defendant could counterclaim that the patent covering our development candidate or investigational medicine is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including patent eligible subject matter, lack of novelty, obviousness, or non-enablement. Grounds for an unenforceability assertion could be 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 administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include reexamination, post-grant review, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in revocation of or amendment to our patents in such a way that they no longer cover our development candidates or investigational medicines. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, there may be invalidating prior art that we and the patent examiner were unaware of during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part of the patent protection for our development candidates and investigational medicines. Such a loss of patent protection could have a material adverse impact on our business.

Changes in U.S. patent law 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 IP, particularly patents. 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. In addition, the United States has recently enacted and is currently implementing wide-ranging patent reform legislation. 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, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

We may not be able to protect our IP rights throughout the world.

Filing, prosecuting, and defending patents on development candidates and investigational medicines in all countries throughout the world would be prohibitively expensive, and our IP rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect IP rights to the same extent as federal and state laws in 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 into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products 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 products and our patents or other IP rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending IP rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other IP protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign 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 IP rights around the world may be inadequate to obtain a significant commercial advantage from the IP that we develop or license.

****Our reliance on government funding and collaboration from government and quasi-governmental entities for certain of our programs adds uncertainty to our research and development efforts with respect to those programs and may impose requirements that increase the costs of development, commercialization and production of any programs developed under those government-funded programs.***

The development of each of our Zika vaccine (mRNA-1893), our antibody against Chikungunya virus (mRNA-1944), and our Chikungunya vaccine (mRNA-1388), are currently being funded through subcontracts with funding from either the Biomedical Advanced Research and Development Authority, or BARDA, or Defense Advanced Research Projects Agency, or DARPA. Our

SARS-CoV-2 vaccine (mRNA-1273) is being developed in collaboration with NIAID. BARDA has agreed to fund the advancement of mRNA-1273 to FDA licensure. Contracts and grants funded by the U.S. government and its agencies, including our agreements funded by BARDA and DARPA and our collaboration with NIAID, include provisions that reflect the government's substantial rights and remedies, many of which are not typically found in commercial contracts, including powers of the government to:

- terminate agreements, in whole or in part, for any reason or no reason;
- reduce or modify the government's obligations under such agreements without the consent of the other party;
- claim rights, including IP rights, in products and data developed under such agreements;
- audit contract-related costs and fees, including allocated indirect costs;
- suspend the contractor or grantee from receiving new contracts pending resolution of alleged violations of procurement laws or regulations;
- impose U.S. manufacturing requirements for products that embody inventions conceived or first reduced to practice under such agreements;
- suspend or debar the contractor or grantee from doing future business with the government;
- control and potentially prohibit the export of products;
- pursue criminal or civil remedies under the False Claims Act, False Statements Act, and similar remedy provisions specific to government agreements; and
- limit the government's financial liability to amounts appropriated by the U.S. Congress on a fiscal-year basis, thereby leaving some uncertainty about the future availability of funding for a program even after it has been funded for an initial period.

We may not have the right to prohibit the U.S. government from using certain technologies developed by us, and we may not be able to prohibit third-party companies, including our competitors, from using those technologies in providing products and services to the U.S. government. The U.S. government generally takes the position that it has the right to royalty-free use of technologies that are developed under U.S. government contracts.

In addition, government contracts and grants, and subcontracts and subawards awarded in the performance of those contracts and grants, normally contain additional requirements that may increase our costs of doing business, reduce our profits, and expose us to liability for failure to comply with these terms and conditions. These requirements include, for example:

- specialized accounting systems unique to government contracts and grants;
- mandatory financial audits and potential liability for price adjustments or recoupment of government funds after such funds have been spent;
- public disclosures of certain contract and grant information, which may enable competitors to gain insights into our research program; and
- mandatory socioeconomic compliance requirements, including labor standards, non-discrimination, and affirmative action programs, and environmental compliance requirements.

Further, under these agreements we are subject to the obligations to and the rights of the U.S. government set forth in the Bayh-Dole Act of 1980, or the Bayh-Dole Act. As a result, the U.S. government may have rights in certain inventions developed under these government-funded programs, including a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government has the right to require us to grant exclusive, partially exclusive, or nonexclusive 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 referred to as "march-in rights." While the U.S. government has sparingly used, and to our knowledge never successfully exercised, such march-in rights, any exercise of the march-in rights by the U.S. government could harm our competitive position, business, financial condition, results of operations, and prospects. If the U.S. government exercises such march-in rights, we may receive compensation that is deemed reasonable by the U.S. government in its sole discretion, which may be less than what we might be able to obtain in the open market. 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 invention generated through the use of U.S. government funding be manufactured substantially in the United States. The manufacturing preference requirement can be waived if the owner 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 substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for U.S. manufacturers may limit our ability to contract with non-U.S. manufacturers for products covered by such intellectual property.

As an organization, we are relatively new to government contracting and new to the regulatory compliance obligations that such contracting entails. If we fail to maintain compliance with those obligations, we may be subject to potential liability and to termination of our contracts.

As a U.S. government contractor, we are subject to financial audits and other reviews by the U.S. government of our costs and performance on their contracts, as well as our accounting and general business practices related to these contracts. Based on the results of its audits, the government may adjust our contract-related costs and fees, including allocated indirect costs. Although adjustments arising from government audits and reviews have not had a material adverse impact on our financial condition or results of operations in the past, we cannot assure you that future audits and reviews will not have those effects.

CEPI is a global organization that has publicly stated its intent to work with multiple global organizations on potential vaccines and therapies targeting the novel coronavirus, including other companies working on mRNA based approaches. There is a possibility that our confidential information may become exposed to others during this process, including the details and timing of our vaccine efforts.

Risks related to commercialization of our pipeline

We have no sales, distribution, or marketing experience, and may invest significant financial and management resources to establish these capabilities. If we are unable to establish such capabilities or enter into agreements with third parties to market and sell our future products, if approved, we may be unable to generate any revenues.

Given our stage of development, we have no sales, distribution, or marketing experience. To successfully commercialize any products that may result from our development programs, we will need to develop sales, marketing, distribution, managerial and other non-technical capabilities in the United States, Europe, or other regions, either on our own or with others. We may enter into strategic alliances 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. To the extent that we rely on third parties to commercialize our approved products, if any, we will receive lower revenues than if we commercialized these products ourselves. In addition, we may have little or no control over the sales efforts of third parties involved in our commercialization efforts. If our future strategic collaborators do not commit sufficient resources to commercialize 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 revenue to sustain our business. We will be competing with many companies that currently have extensive and well-funded marketing and sales operations. In the event that we develop our own marketing or sales force, we will also have to compete with such companies to recruit, hire, train and retain marketing and sales personnel. 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.

The pharmaceutical market is intensely competitive. If we are unable to compete effectively with existing products, new treatment methods, and new technologies, we may be unable to commercialize successfully any products that we develop.

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 products 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 products;
- investigational medicines 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 products that have already been approved and accepted by the medical community for the treatment of the conditions for which we may develop products. We also expect to face competition from new products that enter the market. There are a number of products 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 products. These products may be more effective, safer, less expensive, or marketed and sold more effectively, than any products we develop. While we believe that mRNA-1273 has and will continue to have a competitive profile, it is possible it will not compete favorably with these products and product candidates, or others, and as a result, we may not achieve commercial success. Moreover, positive data and/or the commercial success of competitive products could negatively impact our stock price.

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 vaccines. 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 mRNA medicines 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 investigational medicines, 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 mRNA medicine;
- reimbursement coverage; and
- patent 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 strategic alliances with or receive funding from larger pharmaceutical or biotechnology companies, providing them with an advantage over us. Our competitors may therefore 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 commercial success of any current or future investigational medicine, if approved, will depend upon the degree of market acceptance by physicians, patients, third-party payors, and others in the medical community.

Ethical, social, and legal concerns about genetic research could result in additional regulations restricting or prohibiting the products and processes we may use. 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 mRNA medicines 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. If these products do not achieve an adequate level of acceptance, we may not generate significant product revenue and may not become profitable. The degree of market acceptance of our investigational medicines, 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 products or therapies with which our products are co-administered;
- relative convenience and ease of 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 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.

Even if we are successful in obtaining marketing approval for any product, commercial success of any approved products will also depend in large part on the availability of coverage and adequate reimbursement from third-party payors, including government payors such as the Medicare and Medicaid programs, and entry into managed care organizations, which may be affected by existing and future healthcare reform measures designed to reduce the cost of healthcare. 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. If government and other healthcare payors do not provide adequate coverage and reimbursement levels for any of our products once approved, whether due to healthcare reform legislation or otherwise, market acceptance and commercial success would be reduced.

In addition, if any of our products are approved for marketing, we or a strategic 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 cGMP and current GCPs for any clinical trials that we or a strategic collaborator conduct post-approval. In addition, there is always the risk that we or a strategic 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 investigational medicines identified post-approval could have a material adverse impact on our business, financial condition, and results of operations.

We will need to obtain FDA approval of any proposed product names, and any failure or delay associated with such approval may adversely impact our business.

Any name we intend to use for our proposed products will require approval from the FDA regardless of whether we have secured a trademark registration from the U.S. Patent and Trademark Office, or USPTO. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. The FDA may object to any product name we submit if it believes the name inappropriately implies medical claims. If the FDA objects to any of our proposed product names, we may be required to adopt an alternative name for our proposed products. If we adopt an alternative name, we would lose the benefit of any existing trademark applications for such developmental candidate and may be required to expend significant additional resources in an effort to identify a suitable product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. We may be unable to build a successful brand identity for a new trademark in a timely manner or at all, which would limit our ability to commercialize our products, if approved.

We plan to market our products outside of the United States, and we will be subject to the risks of doing business outside of the United States.

Because we plan to market our products, including mRNA-1273 if approved, outside of the United States, our business is subject to risks associated with doing business outside of the United States, including an increase in our expenses, diversion of our management's attention from the acquisition or development of investigational medicines, or forgoing profitable licensing opportunities in these geographies. We are not permitted to market or promote any of our developmental candidates or investigational medicines before we receive regulatory approval from the applicable regulatory authority in that foreign market, and we may never receive such regulatory approval for any of our developmental candidates or investigational medicines. To obtain separate regulatory approval in many other countries we must comply with numerous and varying regulatory requirements of such countries regarding safety and efficacy and governing, among other things, clinical trials, manufacturing, commercial sales, pricing and distribution of our developmental candidates and investigational medicines, and we cannot predict success in these jurisdictions. We are rapidly expanding our global operations and third-party arrangements to support the worldwide manufacture and distribution of mRNA-1273, which is a complex task that we are undertaking on an accelerated timeline. Accordingly, our business and financial results may be adversely affected due to a variety of factors associated with our expanding global business, including:

- efforts to develop an international commercial sales, marketing, and supply chain and distribution organization; including efforts to mitigate longer accounts receivable collection times, longer lead times for shipping, and potential language barriers;
- our customers' ability to obtain reimbursement for our products in foreign markets;
- our inability to directly control commercial activities because we are relying on third parties;
- different medical practices and customs in foreign countries affecting acceptance in the marketplace;
- changes in a specific country's or region's political and cultural climate or economic condition, including as a result of the COVID-19 pandemic;
- increased legal and compliance burden associated with establishing, maintaining and operating legal entities in foreign countries;
- the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements, including the European General Data Protection Regulation 2016/679, or GDPR;
- the interpretation of contractual provisions governed by foreign laws in the event of a contract dispute, and the difficulty of effective enforcement of contractual provisions in local jurisdictions, and the existence of potentially relevant third-party IP rights;
- inadequate IP protection in foreign countries, and the existence of potentially relevant third-party IP rights;
- trade-protection measures including trade restrictions, import or export licensing requirements such as Export Administration Regulations promulgated by the U.S. Department of Commerce and fines, penalties, or suspension or revocation of export privileges, the imposition of government controls, and changes in tariffs;
- the effects of applicable foreign tax structures and potentially adverse tax consequences; and

- significant adverse changes in foreign currency exchange rates.

In addition to FDA and related regulatory requirements in the United States and abroad, we are subject to extensive additional federal, state and foreign anti-bribery regulations, which include the U.S. Foreign Corrupt Practices Act, or the FCPA, the U.K. Bribery Act, and similar laws in other countries outside of the United States.

The FCPA prohibits any U.S. individual or business from paying, offering, authorizing payment or offering anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions. Various laws, regulations and executive orders also restrict the use and dissemination outside the United States, or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. As we expand our presence outside the United States, it will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain products and product candidates outside the United States, which could limit our growth potential and increase our development costs.

We are developing and implementing a corporate compliance program based on what we believe are current best practices in the pharmaceutical industry for companies similar to ours, but we cannot guarantee that we, our employees, our consultants, or our third-party contractors are or will be in compliance with all federal, state, and foreign regulations regarding bribery and corruption. Moreover, our strategic collaborators and third-party contractors located outside the United States may have inadequate compliance programs or may fail to respect the laws and guidance of the territories in which they operate. The failure to comply with laws governing international business practices may result in substantial civil and criminal penalties and suspension or debarment from government contracting. The SEC also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could also have an adverse effect on our business, financial condition, and results of operations.

The insurance coverage and reimbursement status of newly-approved products, particularly in a new class of medicines, is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for new or current products 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 expensive treatments such as the medicines that we hope to develop and sell. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. In addition, because our personalized cancer vaccine and intratumoral immuno-oncology investigational medicines represent new approaches to the treatment of cancer, we cannot accurately estimate how these products would be priced, whether reimbursement could be obtained, or any potential revenue. Sales of our investigational medicines will depend substantially, both domestically and abroad, on the extent to which the costs of our investigational medicines 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 investigational medicines. 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 a sufficient return on our investment in any of our products. Further, due to the COVID-19 pandemic, millions of individuals have lost/will be losing employer-based insurance coverage, which may adversely affect our ability to commercialize our products, As noted above, in the U.S., we may establish various programs to help patients afford our products which may include patient assistance programs and co-pay coupon programs for eligible patients.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products, including genetic medicines and coverage may be more limited than the purposes for which the medicine is approved by the FDA or comparable foreign regulatory authorities. Third-party payors decide which medications they will pay for and establish reimbursement levels. 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. Factors payors consider in determining reimbursement are based on whether the 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.

In the United States, no uniform policy for coverage and reimbursement for products exists among third-party payors. Therefore, coverage and reimbursement for our products can differ significantly from payor to payor. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the reimbursement rate that the payor will pay for the product. One payor's determination to provide coverage for a product does not assure that other payors will also provide coverage and reimbursement for the product. Third-party payors may also limit coverage to specific products on an approved list, or formulary, which might not include all of the FDA-approved products for a particular indication. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors. Many third-party payors are also increasingly requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Furthermore, many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average sales price, or ASP, and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely. We cannot be sure that coverage and reimbursement will be available for, or accurately estimate the potential revenue from, our product candidates or assure that coverage and reimbursement will be available for any product that we may develop.

A decision by a third-party payor not to cover or not to separately reimburse for our medical products or therapies using our products could reduce physician utilization of our products once approved. Assuming there is coverage for our product candidates, or therapies using our product candidates by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. We cannot be sure that coverage and reimbursement in the United States will be available for our current or future product candidates, or for any procedures using such product candidates, and any reimbursement that may become available may not be adequate or may be decreased or eliminated in the future.

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 and 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, or medicinal products, as they are commonly referred to in the European Union, with limited participation from the marketing authorization holders. We cannot be sure that such prices and reimbursement will be acceptable to us or our strategic collaborators. If the regulatory authorities in these foreign jurisdictions set prices or reimbursement levels that are not commercially attractive for us or our strategic collaborators, our revenues from sales by us or our strategic 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 healthcare 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, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, CMS may develop new payment and delivery models, such as bundled payment models. Recently, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their products. Such scrutiny has resulted in several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. For example, at the federal level, the U.S. government's budget proposal for fiscal year 2021 includes a $135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. On March 10, 2020, the U.S. government sent "principles" for drug pricing to Congress, calling for legislation that would, among other things, cap Medicare Part D beneficiary out-of-pocket pharmacy expenses, provide an option to cap Medicare Part D beneficiary monthly out-of-pocket expenses, and place limits on pharmaceutical price increases.

Additionally, the U.S. government previously released a "Blueprint", or plan, to reduce the cost of drugs. This Blueprint contains certain measures that the HHS is already working to implement. For example, in May 2019, CMS issued a final rule that amends the Medicare Advantage and Medicare Part D prescription drug benefit regulations to reduce out of pocket costs for plan enrollees and allow Medicare plans to negotiate lower rates for certain drugs. Among other things, the final rule now allows Medicare Advantage plans the option to use step therapy, a type of pre-authorization, for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019. 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, or restrictions on certain product access, and marketing cost disclosure and transparency measures, which, in some cases, are designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions on coverage or access could harm our business, results of operations,

financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our product candidates that we successfully commercialize or put pressure on our product pricing.

We expect to experience pricing pressures in connection with the sale of any of our investigational medicines, 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.

Recent federal legislation and actions by state and local governments may permit reimportation of drugs from foreign countries into the United States, including foreign countries where the drugs are sold at lower prices than in the United States, which could materially adversely affect our operating results.

We may face competition in the United States for our development candidates and investigational medicines, if approved, from therapies sourced from foreign countries that have placed price controls on pharmaceutical products. In the United States, the Medicare Modernization Act contains provisions that may change U.S. importation laws and expand pharmacists' and wholesalers' ability to import cheaper versions of an approved drug and competing products from Canada, where there are government price controls. These changes to U.S. importation laws will not take effect unless and until the Secretary of the HHS certifies that the changes will pose no additional risk to the public's health and safety and will result in a significant reduction in the cost of products to consumers. On December 18, 2019, FDA issued a notice of proposed rulemaking that, if finalized, would allow for the importation of certain prescription drugs from Canada. The Secretary of HHS would make the above certification to Congress upon issuance of a final rule based on this proposal. The FDA intends to publish the Final Rule by December 2020. The FDA also issued a draft guidance document outlining a potential pathway for manufacturers to obtain an additional National Drug Code, or NDC, for an FDA-approved drug that was originally intended to be marketed in a foreign country and that was authorized for sale in that foreign country. The regulatory and market implications of the notice of proposed rulemaking and draft guidance are unknown at this time. Proponents of drug reimportation may attempt to pass legislation that would directly allow reimportation under certain circumstances. Legislation or regulations allowing the reimportation of drugs, if enacted, could decrease the price we receive for any products that we may develop and adversely affect our future revenues and prospects for profitability.

Healthcare legislative reform discourse and potential or enacted measures may have a material adverse impact on our business and results of operations and legislative or political discussions surrounding the desire for and implementation of pricing reforms may adversely impact our business.

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 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.

Since its enactment, some of the provisions of the ACA have yet to be fully implemented, while certain provisions have been subject to judicial, congressional, and executive challenges. As a result, there have been delays in the implementation of, and action taken to repeal or replace, certain aspects of the ACA. Since January 2017, President Trump has signed two Executive Orders designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. On January 20, 2017, President Trump signed the first Executive Order, 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. On October 13, 2017, President Trump signed the second Executive Order terminating the cost-sharing subsidies that reimburse insurers under the Affordable Care Act. The current administration has concluded that cost-sharing reduction, or CSR, payments to insurance companies required under the ACA have not received necessary appropriations from Congress and announced that it will discontinue these payments immediately until those appropriations are made. 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. The loss of the cost share reduction payments is expected to increase premiums on certain policies issued by qualified health plans under the ACA. Further, on June 14, 2018, the U.S. Court of Appeals for the Federal Circuit ruled that the federal government was not required to pay to third-party payors more than $12 billion in ACA risk corridor payments that they argued were owed to them. This decision was appealed to the U.S. Supreme Court, which on April 27, 2020, reversed the U.S. Court of Appeals for the Federal Circuit's decision and remanded the case to the U.S. Court of Federal Claims, concluding the government has an obligation to pay these risk corridor payments under the relevant formula. It is not clear what effect this result will have on our business, but we will continue to monitor any developments.

While Congress has not passed comprehensive repeal legislation to date, it has enacted laws that modify certain provisions of the Affordable Care Act such as the Tax Cuts and Jobs Act of 2017, or TCJA, which decreased, effective January 1, 2019, 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, commonly referred to as the "individual mandate," to $0. On December 14, 2018, a federal district court in Texas ruled the individual mandate is a critical and inseverable feature of the ACA, and therefore, because it was repealed as part of the TCJA, the remaining provisions of the ACA are invalid as well. The current administration and CMS have both stated that the ruling will have no immediate effect, and on December 18, 2019, the Fifth Circuit U.S. Court of Appeals held that the individual mandate is unconstitutional, and remanded the case to the lower court to reconsider its earlier invalidation of the full ACA. On March 2, 2020, the United States Supreme Court granted the petitions for writs of certiorari to review this case, and has allotted one hour for oral arguments, which are expected to occur in the fall. We cannot predict what affect further changes to the ACA would have on our business. Pending review, the ACA remains in effect, but it is unclear at this time what effect the latest ruling will have on the status of the ACA. Litigation and legislation over the ACA are likely to continue, with unpredictable and uncertain results.

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 the U.S. 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 2030 unless additional Congressional action is taken. However, pursuant to the Coronavirus Aid, Relief and Economic Security Act, or CARES Act, these Medicare sequester reductions will be suspended from May 1, 2020 through December 31, 2020 due to the COVID-19 pandemic. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Additionally, the BBA, among other things, amended the ACA, effective January 1, 2019, by increasing the point-of-sale discount (from 50% under the ACA to 70%) that is owed by pharmaceutical manufacturers who participate in Medicare Part D and closing the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole".

In December 2018, the CMS published a final rule permitting further collections and payments to and from certain ACA qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of federal district court litigation regarding the method the CMS uses to determine this risk adjustment. Since then, the ACA risk adjustment program payment parameters have been updated annually. In addition, the CMS has recently published a final rule that would give states greater flexibility, starting in 2020, 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. On January 22, 2018, the U.S. President signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. However, on December 20, 2019, the U.S. President signed into law the Further Consolidated Appropriations Act (H.R. 1865), which repeals the Cadillac tax, the health insurance provider tax, and the medical device excise tax.

Further, legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether FDA regulations, guidance, or interpretations will be changed, or what the impact of such changes on the marketing approvals, if any, of our development candidates, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing conditions and other requirements.

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 EU, 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 EU and national regulatory burdens on those wishing to develop and market products, this could prevent or delay marketing approval of our investigational medicines, restrict or regulate post-approval activities, and affect our ability to commercialize any products for which we obtain marketing approval.

We expect that additional foreign, state, and federal healthcare reform measures or proposals will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our investigational medicines or additional pricing pressures. In the event that the pricing structures for healthcare products, such as the investigational medicines we are developing, change materially and limit payments for such investigational medicines, 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 strategic alliances may no longer be deemed

commercially viable to pursue based on our strategic 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 federal, state, and foreign 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 investigational medicines that we may successfully develop and for which we may obtain regulatory approval, and may affect our overall financial condition and ability to develop investigational medicines.

Due to the novel nature of our technology, we face uncertainty related to pricing and reimbursement for these investigational medicines.

Target patient populations for certain of our investigational medicines, such as those for rare genetic diseases, may be relatively small, and certain of our investigational medicines, like PCV, require customization on an individual scale. As a result, the pricing and reimbursement of our investigational medicines, if approved, must be adequate to support commercial infrastructure. If we are unable to obtain adequate levels of reimbursement, our ability to successfully market and sell our investigational medicines will be adversely affected. The manner and level at which reimbursement is provided for services related to our investigational medicines (e.g., for administration of our product to patients) is also important. Inadequate reimbursement for such services may lead to physician resistance and adversely affect our ability to market or sell our products.

****If the market opportunities for our development candidates or investigational medicines are smaller than we believe they are, our revenue may be adversely affected and our business may suffer. Because the target patient populations for some of our programs are difficult to ascertain or small, we must be able to successfully identify clinical trial participants and achieve a significant market share to maintain profitability and growth.***

An important area of focus of our research and product development activities is the development of treatments for severe rare genetic diseases. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with our programs are based on estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations, or market research, and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these diseases. The number of clinical trial participants or patients in the United States, Europe, and elsewhere may turn out to be lower than expected, potential clinical trial participants or patients may not be otherwise amenable to treatment with our products, or new clinical trial participants or patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our results of operations and our business.

The market opportunities of some of our programs may be limited to those patients who are ineligible for or have failed prior treatments and for which the market opportunities may be small.

The FDA often approves new therapies initially only for use by patients with relapsed or refractory advanced disease. We expect to initially seek approval of our PCV and intratumoral immuno-oncology investigational medicines in this context. Subsequently, for those products that prove to be sufficiently beneficial, if any, 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 investigational medicines, 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.

Our projections of both the number of people who have the cancers we may be targeting, as well as the subset of people with these cancers in a position to receive second or third line therapy, and who have the potential to benefit from treatment with our investigational medicines, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations, or market research, and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these cancers. The number of trial participants may turn out to be lower than expected. Additionally, the potentially addressable patient population for our investigational medicines may be limited or may not be amenable to treatment with our investigational medicines. Even if we obtain significant market share for our products, if approved, because the potential target populations are small, we may never achieve profitability without obtaining regulatory approval for additional indications.

Risks related to our business and operations

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

As of June 30, 2020, we had approximately 975 full-time employees and, in connection with the growth and advancement of our pipeline and operating as a public company, we expect to increase the number of employees and the scope of our operations. To manage our anticipated development and expansion, including expansion outside of the United States, we must continue to implement and improve our managerial, operational, and financial systems, expand our facilities, and continue to recruit and train additional qualified personnel. Also, 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 development candidates and investigational medicines 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 and early stage of growth, 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, 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 investigational medicines. 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 implement our business strategy. Our future financial performance and our ability to commercialize mRNA-1273 or our other investigational medicines, if approved, and compete effectively will depend, in part, on our ability to effectively manage the future development and expansion of our company.

Our future success depends on our ability to retain key employees, consultants, and advisors and to attract, retain, and motivate qualified personnel. We may not be able to retain employees or executives who have vested stock options.

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. Each of our executive officers and all of our employees, including key scientists and clinicians, are employed "at will," meaning we or each officer or employee may terminate the employment relationship at any time. 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. Many of our key employees, including members of our executive team, have been with us for a long period of time, and have valuable, fully vested stock options or other long-term equity incentives. We may not be able to retain these employees due to the competitive environment in the biotechnology industry, particularly in Cambridge, Massachusetts.

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, manufacturing 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, manufacturing 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, also will be critical to our success. Competition for skilled personnel, including in mRNA and LNP 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 or clinical trials or applications for marketing approval may make it more challenging to recruit and retain qualified personnel. Furthermore, we may not be successful commercializing our first product and as a result, we may be unable to attract and retain highly qualified sales and marketing professionals to support mRNA-1273 and our future products, if approved. 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 global 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.

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 EU 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; or 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. Sales, marketing, and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing, and other abusive practices. These laws and regulations restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs, and other business arrangements. 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 these 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.

Our employees may, from time to time, 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 have never recognized any revenue from product sales and may never be profitable.

Our ability to generate revenue and achieve profitability depends on our ability, alone or with strategic collaborators, to successfully complete the development of, and obtain the regulatory approvals necessary to commercialize our investigational medicines. We do not anticipate generating revenues from product sales for the foreseeable future, if ever. Our ability to recognize future revenues from product sales depends heavily on our success in:

- completing research, preclinical, and clinical development of our development candidates and investigational medicines;
- seeking and obtaining U.S. and foreign marketing approvals for investigational medicines for which we complete clinical trials;
- developing a sustainable, stable, consistent, and transferable manufacturing process or processes for our development candidates and investigational medicines;
- developing a sustainable, scalable, consistent, time sensitive, and transferable manufacturing process for our personalized cancer vaccine investigational medicine;
- 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 investigational medicines, if approved;
- obtaining market acceptance of our investigational medicines as a treatment option;
- launching and commercializing investigational medicines for which we obtain marketing approval and reimbursement, either by collaborating with a strategic collaborator 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, and expanding our portfolio of IP rights, including patents, trade secrets and know-how; and
- attracting, hiring, and retaining qualified personnel.

Even if one or more of the investigational medicines that we develop is approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved investigational medicine. Our expenses could increase beyond expectations if we are required by the FDA, the EMA, or other regulatory agencies to perform clinical and other studies or make changes to our manufacturing or quality systems in addition to those that we currently anticipate. Even if we are able to generate

revenues from the sale of any approved products, we may not become profitable and may need to obtain additional funding to continue operations.

Our internal computer systems and physical premises, or those of our strategic collaborators or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our product development programs and our manufacturing operations.

Our internal computer systems and those of our current and any future strategic 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. We have experienced, and may experience in the future, cyber-attacks on our information technology systems by threat actors of all types (including but not limited to nation states, organized crime, other criminal enterprises, individual actors and/or advanced persistent threat groups). In addition, we may experience intrusions on our physical premises by any of these threat actors. If any such cyber-attack or physical intrusion were to cause interruptions in our operations, such as a material disruption of our development programs or our manufacturing operations, whether due to a loss of our trade secrets or other proprietary information, it would have a material and adverse effect on us. 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 or physical premises 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, or claims for damages either under the GDPR and relevant member state law in the EU, other foreign laws, and the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, and other relevant state and federal privacy laws in the United States including the California Consumer Privacy Act, or the CCPA. On May 13, 2020, the Federal Bureau of Investigation, or FBI, and Cybersecurity and Infrastructure Security Agency, or CISA, announced that the FBI is investigating the targeting and compromise of U.S. organizations conducting COVID-19-related research by People's Republic of China, or PRC-affiliated cyber actors. Furthermore, on July 16, 2020, the National Security Agency and other U.S. and foreign agencies released a joint cybersecurity advisory regarding the Russian Intelligence Services' targeting of COVID-19 research and vaccine development. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, including but not limited to information related to our rapid manufacture of mRNA-1273, we could incur liability, our competitive and reputational position could be harmed, and the further development and commercialization of our investigational medicines could be delayed.

We may use our financial and human resources to pursue a particular research program or investigational medicine and fail to capitalize on programs or investigational medicines that may be more profitable or for which there is a greater likelihood of success.

Because we have limited resources, we must choose to pursue and fund the development of selected research programs or investigational medicines and may forego or delay pursuit of opportunities with other programs or investigational medicines that could later prove to have greater commercial potential. Our resource allocation decisions, or our contractual commitments to provide resources to our strategic collaborators under strategic alliance agreements, may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs for investigational medicines may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular investigational medicine, we may relinquish valuable rights to that investigational medicine through a strategic alliance, licensing, or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such investigational medicine, or we may allocate internal resources to an investigational medicine in a therapeutic area in which it would have been more advantageous to enter into a strategic alliance.

If we are not successful in discovering, developing, and commercializing additional products 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 investigational medicines, 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 discovery efforts, exploring potential strategic alliances for the development of new products, and in-licensing technologies. Identifying new investigational medicines requires substantial technical, financial, and human resources, whether or not any investigational medicines are ultimately identified. Even if we identify investigational medicines that initially show promise, we may fail to successfully develop and commercialize such products for many reasons, including the following:

- the research methodology used may not be successful in identifying potential investigational medicines;
- competitors may develop alternatives that render our investigational medicines obsolete;
- investigational medicines we develop may nevertheless be covered by third parties' patents or other exclusive rights;

- an investigational medicine 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;
- an investigational medicine 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 patients, the medical community or third-party payors.

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

Product liability lawsuits against us could cause us to incur substantial liabilities and could limit commercialization of any investigational medicine that we may develop, such as mRNA-1273.

We face an inherent risk of product liability exposure related to the development, testing, manufacturing and marketing of our current or future investigational medicines in clinical trials. Product liability claims and related cross-claims and claims for indemnification may be brought against us by patients, healthcare providers or others using, prescribing, selling or otherwise coming into contact with our investigational medicines. For example, we may be sued if any investigational medicine allegedly causes injury or is found to be otherwise unsuitable during clinical trials, manufacturing, or, if approved, marketing, sale or commercial use. If we cannot successfully defend ourselves against claims that our medicines caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any investigational medicine that we may develop;
- loss of revenue;
- substantial monetary awards to patients, healthy volunteers, or their family members;
- payments to indemnify clinical trial sites and other clinical trial partners;
- significant time and costs to defend the related litigation;
- withdrawal of clinical trial participants;
- the inability to commercialize any investigational medicine(s) that we may develop; and
- injury to our reputation and significant negative media attention.

Notwithstanding the risks undertaken by all persons who participate in clinical trials, and the information on risks provided to study investigators and patients participating in our clinical trials, including the mRNA-1273 studies, it is possible that product liability claims will be asserted against us relating to the worsening of a patient's condition, injury or death alleged to have been caused by one of our investigational medicines, including mRNA-1273. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, including as a result of interactions with alcohol or other drugs, knowledge of risks, negligence, strict liability and a breach of warranties. Claims could also be asserted under state consumer protection acts. Such claims might not be fully covered by product liability insurance. If we succeed in marketing products, including mRNA-1273, product liability claims could result in an FDA investigation of the safety and effectiveness of our products, our manufacturing processes and facilities or our marketing programs, and potentially a recall of our products or more serious enforcement action, limitations on the approved indications for which they may be used, suspension or withdrawal of approvals or license revocation. Regardless of the merits or eventual outcome, liability claims may also result in decreased demand for our products, injury to our reputation, costs to defend the related litigation, a diversion of management's time and our resources, substantial monetary awards to trial participants or patients and a decline in our stock price.

We carry product liability insurance which we believe to be sufficient in light of our current 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. If and when we obtain marketing approval for investigational medicines, we intend to expand our insurance coverage to include the sale of commercial products; however, we may be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts. On occasion, large judgments have been awarded in individual, mass tort and 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 our stock price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business.
If the costs of maintaining adequate insurance coverage increase significantly in the future, our operating results could be materially adversely affected. Likewise, if insurance coverage should become unavailable to us or become economically impractical, we would be required to operate our business without indemnity from commercial insurance providers. Additionally, even if we maintain insurance coverage for a type of liability, a particular claim may not be covered if it is subject to a coverage exclusion or we do not otherwise meet the conditions for coverage. If we operate our business without insurance, or with inadequate insurance, we could be responsible for paying claims or judgments against us, which could adversely affect our results of operations or financial condition.

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

If we obtain FDA approval for any of our investigational medicines 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 Physician Payments Sunshine Act and regulations. 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, to induce or reward, or in return for, either the referral of an individual for, or the for the purchase, order or recommendation or arranging of, any good, leasing, or furnishing of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs. The government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act or federal civil money penalties statute. 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. Although there are several statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution, they are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. 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, including the federal False Claims Act, prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid, or other government payors that are false or fraudulent. In addition, the government may assert that a claim including items or services resulting from a violation of the Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act or federal civil money penalties statute. Manufacturers can be held liable under the False Claims Act even when they do not submit claims directly to government payors if they are deemed to “cause” the submission of false or fraudulent claims. Companies that submit claims directly to payors may also be liable under the False Claims Act for the direct submission of such claims. The False Claims Act also permits a private individual acting as a “whistleblower” to bring actions on behalf of the federal government alleging violations of the False Claims Act and to share in any monetary recovery. 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 anti-inducement law prohibits, among other things, the offering or giving of remuneration, which includes, without limitation, any transfer of items or services for free or for less than fair market value (with limited exceptions), to a Medicare or Medicaid beneficiary that the person knows or should know is likely to influence the beneficiary’s selection of a particular supplier of items or services reimbursable by a federal or state governmental program.

- HIPAA and its implementing regulations, which create new federal criminal statutes that prohibit a person from knowingly and willfully executing, or attempting to execute, a scheme or making false or fraudulent statements to defraud any healthcare benefit program, regardless of the payor (e.g., public or private), or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity can be found guilty of violating HIPAA without actual knowledge of the statute or specific intent to violate it.

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their implementing regulations, 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 as well as their respective “business associates,” those independent contractors or agents of covered entities that create, receive, maintain, transmit or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys’ fees and costs associated with pursuing federal civil actions.

- The U.S. Federal Food, Drug and Cosmetic Act, which prohibits, among other things, the adulteration or misbranding of drugs, biologics, and medical devices.

- Federal transparency laws, including the federal Physician Payment Sunshine Act, which require disclosure of payments and other transfers of value provided by manufacturers of drugs, devices, biologicals and medical supplies to physicians (currently defined to include doctors, dentists, optometrists, podiatrists and chiropractors) 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. Effective January 1, 2022, these reporting obligations will extend to include transfers of value made to certain non-physician providers such as physician assistants and nurse practitioners.

- State, local and foreign law and their regulatory equivalents of each of the above federal laws, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payor, including private insurers and may be broader in scope than their federal equivalents; state and foreign laws that require biopharmaceutical companies to comply with the biopharmaceutical industry's voluntary compliance guidelines and other relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures, or drug pricing and state laws governing the privacy and security of health information in certain circumstances 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 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. 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. It is possible that governmental and enforcement authorities will conclude that our business practices, including our arrangements with physicians and other healthcare providers, some of whom receive stock options as compensation for services provided, may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. 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 significant sanctions, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, reputational harm, exclusion from participation in federal and state funded healthcare programs, contractual damages and the curtailment or restricting of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws. Further, if any of the physicians or other healthcare providers or entities with whom we expect to do business are found to be not in compliance with applicable laws, they may be subject to similar penalties. Any action for violation of these laws, even if successfully defended, could cause a biopharmaceutical manufacturer to incur significant legal expenses and divert management's attention from the operation of the business. In addition, the approval and commercialization of any product candidate we develop outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws. All of these could harm our ability to operate our business and our financial results.

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 EU Member States, such as the UK Bribery Act 2010. Infringement of these laws could result in substantial fines and imprisonment.

Payments made to physicians in certain European Union 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 European Union 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.

The collection and use of personal health data in the European Union had previously been governed by the provisions of the Data Protection Directive, which has been replaced by the GDPR which became effective on May 25, 2018. 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 EU. This expansion would incorporate our clinical trial activities in European Union member states. 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 data subjects residing in the EU. GDPR grants individuals the opportunity to object to the processing of their personal information, allows them to request deletion of personal information in certain circumstances, and provides the individual with an express right to seek legal remedies in the event the individual believes his or her rights have been violated. Further, the GDPR imposes strict rules on the transfer of personal data out of the European Union to the United States or other regions that have not been deemed to offer

"adequate" privacy protections. Failure to comply with the requirements of the GDPR and the related national data protection laws of the EU Member States, which may

deviate slightly from the GDPR, may result in significant fines. As a result of the implementation of the GDPR, we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules.

There is significant uncertainty related to the manner in which data protection authorities will seek to enforce compliance with GDPR. For example, it is not clear if the authorities will conduct random audits of companies doing business in the EU, 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 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 contract 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. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological or hazardous materials.

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.

Unfavorable U.S. or global economic conditions could adversely affect our business, financial condition, or results of operations.

Our results of operations could be adversely affected by general conditions in the global economy and financial markets, including by the current coronavirus pandemic, or any other health epidemic. The most recent global financial crisis caused extreme volatility and disruptions in the capital and credit markets. A severe or prolonged economic downturn, such as the most recent global financial crisis, could result in a variety of risks to our business, including weakened demand for our investigational medicines and our ability to raise additional capital when needed on favorable terms, if at all. A weak or declining economy could strain our suppliers, possibly resulting in supply disruption, or cause delays in payments for our services by third-party payors or our collaborators. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

We or the third parties upon whom we depend may be adversely affected by natural disasters, health epidemics or other business interruptions such as cybersecurity attacks and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Natural disasters or health epidemics could severely disrupt our operations, and have a material adverse impact on our business, results of operations, financial condition, and prospects. If a natural disaster, power outage, cybersecurity attack, health epidemic or other event occurred that prevented us from using all or a significant portion of our headquarters, damaged critical infrastructure, such as our manufacturing facilities or those of our third-party contract manufacturers, limited our ability to access or use our digital information systems or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place currently are limited and are unlikely to prove adequate in the event of a serious disaster or similar event. Cybersecurity liability insurance is difficult to obtain and may not cover any damages we would sustain based on any breach of our computer security protocols or other cybersecurity attack. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse impact on our business.

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

The FDA and similar foreign governmental authorities 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 of other quantity of the biologic product presents an imminent or substantial hazard to the public health. In addition, foreign governmental bodies have the authority to require the recall of any investigational medicine 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

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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 investigational medicines 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.

The investment of our cash, cash equivalents, and investments is subject to risks which may cause losses and affect the liquidity of these investments.

As of June 30, 2020, we had approximately $3.07 billion in cash, cash equivalents, and investments. These investments are subject to general credit, liquidity, market, and interest rate risks. We may realize losses in the fair value of these investments, which would have a negative effect on our consolidated financial statements. In addition, should our investments cease paying or reduce the amount of interest paid to us, our interest income would suffer. The market risks associated with our investment portfolio may have an adverse effect on our results of operations, liquidity, and financial condition.

Changes in tax law could adversely affect our business and financial condition.

The rules dealing with U.S. federal, state, and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our common stock. In recent years, many such changes have been made and changes are likely to continue to occur in the future. Future changes in tax laws could have a material adverse effect on our business, cash flow, financial condition or results of operations. We urge investors to consult with their legal and tax advisers regarding the implications of potential changes in tax laws on an investment in our common stock.

If the estimates we make, or the assumptions on which we rely, in preparing our consolidated financial statements prove inaccurate, our actual results may vary from those reflected in our projections and accruals.

Our consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of our assets, liabilities, revenues, and expenses, the amounts of charges accrued by us and related disclosure of contingent assets and liabilities. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. We cannot assure you, however, that our estimates, or the assumptions underlying them, will be correct.

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.

As of December 31, 2019, we had federal and state net operating loss carryforwards of $981.8 million and $978.8 million, respectively, a portion of which will begin to expire in 2030. As of December 31, 2019, we also had federal and state research and development tax credit carryforwards of $45.6 million and $23.9 million, respectively, which begin to expire in 2030 and 2029, respectively. These net operating loss and tax credit carryforwards could expire unused and be unavailable to offset future income tax liabilities. Federal net operating losses generated in taxable years beginning after December 31, 2017 generally may not be carried back to prior taxable years, and while such federal net operating losses generated in taxable years beginning after December 31, 2017 will not be subject to expiration, the deduction for such net operating loss in any taxable year will be limited to 80% of our taxable income in such year, where taxable income is determined without regard to the net operating loss deduction itself. However, the Coronavirus Aid, Relief and Economic Security Act repeals the 80% limitation on the utilization of such federal net operating losses for taxable years beginning after December 31, 2017 and beginning before January 1, 2021 and allows for federal net operating losses generated in taxable years beginning after December 31, 2017 and before January 1, 2021 to be carried back to each of the five taxable years preceding the taxable year in which the loss arises. This change in law temporarily allowing for the carryback of federal net operating losses is not expected to produce any material benefit for the issuer. In general, under Sections 382 and 383 of the Code, a corporation that undergoes an “ownership change” is subject to limitations on its ability to utilize its pre-change net operating losses, or NOLs or tax credits, or credits, (including federal research and development tax credits) to offset future taxable income or taxes. For these purposes, an ownership change generally occurs where the aggregate stock ownership of one or more stockholders or groups of stockholders who owns at least 5% of a corporation’s stock increases its ownership by more than 50 percentage points over its lowest ownership percentage within a specified testing period. As of December 31, 2019, none of our NOLs or credits will expire due to Sections 382 and 383. However, future changes in our stock ownership, many of which are outside of our control, could result in an ownership change under Sections 382 and 383 of the Code and limit our ability to utilize our NOLs and credits. Our NOLs or credits may also be impaired under state law. Accordingly, we may not be able to utilize a material portion of our NOLs or credits. In addition, the rules regarding timing of revenue and expense recognition for tax purposes in connection with various transactions we have undertaken are complex and uncertain in various respects and could be subject to challenge by taxing authorities. In the event any such challenge is sustained, our net operating losses could be materially reduced and/or we could be determined to be a material cash taxpayer for one or more years. Furthermore, our ability to utilize our NOLs or credits is conditioned upon our attaining profitability

and generating U.S. federal and state taxable income. As described above we have incurred significant net losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future, and therefore, we do not know whether or when we will generate the U.S. federal or state taxable income necessary to utilize our NOL or credit carryforwards.

If we engage in future acquisitions, joint ventures, or strategic collaborations, this may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities, and subject us to other risks.

- We may evaluate various acquisitions and collaborations, including licensing or acquiring complementary products, IP 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, IP, 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 investigational medicines 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 strategic 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.

****The increasing use of social media platforms presents new risks and challenges.***

Social media is increasingly being used to communicate about our research, development candidates, investigational medicines, and the diseases our development candidates and investigational medicines are being developed to treat. Social media practices in the biopharmaceutical industry continue to evolve and regulations relating to such use are not always clear. This evolution creates uncertainty and risk of noncompliance with regulations applicable to our business, resulting in potential regulatory actions against us. For example, subjects may use social media channels to comment on their experience in an ongoing blinded clinical trial or to report an alleged adverse event. When such disclosures occur, there is a risk that we fail to monitor and comply with applicable adverse event reporting obligations or we may not be able to defend our business or the public's legitimate interests in the face of the political and market pressures generated by social media due to restrictions on what we may say about our development candidates and investigational medicines. There is also a risk of inappropriate disclosure of sensitive information or negative or inaccurate posts or comments about us on any social networking website. If any of these events were to occur or we otherwise fail to comply with applicable regulations, we could incur liability, face regulatory actions, or incur other harm to our business.

Risks related to ownership of our common stock

****The price of our common stock has been volatile and fluctuates substantially, which could result in substantial losses for stockholders.***

Our stock price has been, and in the future, may be, subject to substantial volatility. From December 7, 2018, our first day of trading on the Nasdaq Global Select Market, through July 31, 2020, our stock has traded within a range of a high price of $95.21 and a low price of $11.54 per share. In addition, since we began our development efforts with respect to mRNA-1273 earlier this year, our stock has experienced pronounced and extended periods of volatility. As a result of the volatility in our stock price, our stockholders could incur substantial losses.

Public statements by us, government agencies, the media or others relating to the coronavirus outbreak (including regarding our and others' efforts to develop a coronavirus vaccine) have in the past resulted, and may in the future result, in significant fluctuations in our stock price. Given the global focus on the coronavirus pandemic, information in the public arena on this topic, whether or not accurate, has had and will likely continue to have an outsized impact (positive or negative) on our stock price. Information related to our development, manufacturing, regulatory and commercialization efforts with respect to mRNA-1273, or information regarding such efforts by competitors with respect to their potential vaccines, may meaningfully impact our stock price.

The stock market in general, and the market for biopharmaceutical companies in particular, has experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, you may not be able to sell your common stock at or above your initial purchase price. The market price for our common stock may be influenced by many factors, including:

- results of clinical trials of our investigational medicines or those of our competitors;
- the success of competitive products or technologies;
- commencement or termination of strategic alliances;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents, or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our investigational medicines or clinical development programs;
- the results of our efforts to discover, develop, acquire, or in-license additional investigational medicines;
- actual or anticipated changes in estimates as to financial results, development timelines, or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry, and market conditions;
- the numerous programs in our pipeline, the development of which could each generate news or significant adverse events that could impact financial results or recommendations by securities analysts; and
- public announcements by us or our strategic collaborators regarding the progress of our development candidates or investigational medicines or similar public announcements by our competitors.

If our quarterly or annual results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly or annual fluctuations in our results may, in turn, cause the price of our stock to fluctuate substantially. We believe that period-to-period comparisons of our results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

Our stock price is likely to continue to be volatile and subject to significant price and volume fluctuations in response to market and other factors, including the other factors discussed in our filings incorporated by reference herein or in future periodic reports; variations in our quarterly operating results from our expectations or those of securities analysts or investors; downward revisions in securities analysts' estimates; and announcement by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments.

In the past, following periods of volatility in the market price of a company's securities, securities class-action litigation often has been instituted against that company. Such litigation, if instituted against us, could cause us to incur substantial costs to defend such claims and divert management's attention and resources, which could seriously harm our business, financial condition, and results of operations, and prospects.

We have broad discretion in the use of our cash, cash equivalents, and investments, and may not use them effectively.

Our management will have broad discretion in the application of our cash, cash equivalents, and investments, and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our common stock. Furthermore, our operating expenses have significantly increased due to development and manufacturing activities for our mRNA-1273 program, and we may not deploy our expanded capital base effectively. The failure by our management to apply these funds effectively could result in financial losses that could have a material adverse impact on our business, cause the price of our common stock to decline, and delay the development of our investigational medicines. Pending their use, we may invest our cash, cash equivalents, and investments in a manner that does not produce income or that loses value.

We have incurred and will continue to incur increased costs as a result of operating as a public company, and our management is 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.

As a public company, we incur significant legal, accounting, and other expenses that we did not incur as a private company. In addition, the federal securities laws, including the Sarbanes-Oxley Act of 2002 and rules subsequently implemented by the Securities and Exchange Commission, or SEC, and Nasdaq have imposed various requirements on public companies, including requirements to file annual, quarterly, 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 devote a

substantial amount of time to these compliance initiatives. Moreover, these rules and regulations increase our legal and financial compliance costs and make some activities more time consuming and costly. For example, these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance. 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 the 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 of 2002, or Section 404, we are required to furnish a report by our management on our internal control over financial reporting, including an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. However, while we were an "emerging growth company" as defined in the Jumpstart Our Business Startups Act, our auditors were not required to formally attest to the effectiveness of our internal control over financial reporting. As of the end of our fiscal year ended December 31, 2019, we qualified as a "large accelerated filer" as defined in the Securities Exchange Act of 1934, as amended, or the Exchange Act and, as a result, ceased to qualify as an emerging growth company. Accordingly, commencing with our Annual Report on Form 10-K for the year ended December 31, 2019, we were required to have our auditors formally attest to the effectiveness of our internal control over financial reporting pursuant to Section 404. Our compliance with Section 404 necessitates that we incur substantial accounting expense and expend significant management efforts. We will continue to dedicate internal resources, potentially engage outside consultants, and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue 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 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.

In July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act. or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas such as "say on pay" and proxy access. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives.

We are in the early stages of developing our policies and practices regarding pre-approval access and any policy we develop and implement may result in a negative perception of our Company and have a material adverse impact on our business.

As we advance our pipeline, patients and their physicians have sought access to our investigational medicines outside of sponsored clinical trials and prior to regulatory approval. While we will continue to review and respond to these early access requests, at this stage in our development of a new class of medicines, we are not providing access to our investigational medicines outside of the clinical trial setting. As our development programs progress further, we will continue our dialogue with patients and their families, advocacy leaders, physicians, and others on this and other topics. We will post our pre-approval access policies in accordance with regulatory guidelines.

As a general matter, we do not currently plan on providing forward-looking guidance regarding the expected timing of milestones for most of our development programs. We plan to report on the status of most of our programs, including the achievement of milestones and related data, on a retrospective basis, or as otherwise required by U.S. federal securities laws applicable to us, which may lead to speculation about our prospects that could have a material adverse effect on our business. If we do provide forward-looking guidance on the expected timing of milestones, we may not meet those timelines which may have a material adverse effect on our business.

We believe the early stage nature of most of our portfolio is not suitable to providing forward-looking guidance on the expected timing of individual program milestones, particularly data readout timing. While as a general matter we intend to periodically report on the status of our development programs, including articulating anticipated next steps in the form of development plans or potential data readouts, for the majority of our programs, we do not currently plan to provide forward-looking guidance on the timing of those next steps. We have provided forward looking guidance as to the expected timing of certain milestones and clinical steps in our mRNA-1273 (SARS-CoV-2) and mRNA-1647 (CMV) programs, our most advanced clinical programs. If we are unable to meet the timelines established in this guidance our business may be materially and adversely impacted. In addition, we do not control the timing of disclosure of any such milestones related to any of our programs that are managed by our strategic collaborators. Any disclosure by our strategic collaborators of data that is 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 our stock price or overall valuation. Not providing forward-looking guidance on the expected timing of program milestones may lead to speculation by investors, shareholders, analysts, and other market participants and in the media as to the progress of our individual development candidates, investigational medicines, or our programs as a whole, which may have a material adverse impact on our stock price or valuation. In the event that we do choose to provide forward looking guidance on the expected timing of milestones in our business, we may be required to later update any movement in the timing of such

milestones, including delays, which may have the effect of investors speculating in our stock or otherwise have a material adverse impact on our business. The ability to predict with accuracy the timing of clinical readouts or progress in clinical trials is difficult and subject to change based on many factors, most of which are out of our control, including other risks and uncertainties included in this prospectus supplement.

Sales of a substantial number of shares of our common stock by our existing stockholders in the public market could cause our stock price to fall.

Sales of a substantial number of shares of our common stock in the public market could occur at any time, subject to certain restrictions described below. These sales, or the perception in the market that holders of a large number of shares intend to sell shares, could reduce the market price of our common stock.

The holders of up to 61.6 million shares of our common stock are entitled to rights with respect to the registration of their shares under the Securities Act. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares held by affiliates, as defined in Rule 144 under the Securities Act. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock.

Additionally, the number of shares of our common stock reserved for issuance under our 2018 Stock Option and Incentive Plan automatically increased on January 1, 2020 and will automatically increase each January 1 thereafter by 4% of the number of shares of common stock outstanding on the immediately preceding December 31 or such lesser number of shares determined by our compensation committee. Unless our board of directors elects not to increase the number of shares available for future grant each year, our stockholders may experience additional dilution.

In addition, certain of our employees, executive officers, and directors have entered or may enter into Rule 10b5-1 trading plans providing for sales of shares of our common stock from time to time. Under a Rule 10b5-1 trading plan, a broker executes trades pursuant to parameters established by the employee, director, or officer when entering into the plan, without further direction from the employee, officer, or director. A Rule 10b5-1 trading plan may be amended or terminated in some circumstances. Our employees, executive officers, and directors also may buy or sell additional shares outside of a Rule 10b5-1 trading plan when they are not in possession of material, nonpublic information.

Raising additional capital may cause dilution to our existing stockholders, restrict our operations, or require us to relinquish rights to our technologies or development candidates or investigational medicines.

We may seek additional capital through a combination of public and private equity offerings, debt financings, strategic alliances, and licensing arrangements. To the extent that we raise additional capital through the sale of equity or debt securities, your ownership interest will be diluted and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. The incurrence of indebtedness would result in increased fixed payment obligations and could involve restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license IP rights, and other operating restrictions that could adversely impact our ability to conduct our business. If we raise additional funds through collaborations and alliances and licensing arrangements with third parties or through asset sales, we may have to relinquish valuable rights to our technologies or development candidates or investigational medicines, or grant licenses on terms unfavorable to us.

If securities analysts do not publish research or reports about our business or if they publish negative evaluations of our stock, the price of our stock could decline.

The trading market for our common stock relies, in part, on the research and reports that industry or financial analysts publish about us or our business. If one or more of the analysts who covers us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price may decline. If one or more of these analysts ceases coverage of us or fails to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

Our executive officers, directors, five percent stockholders, and their affiliates beneficially own approximately 23.3% of our outstanding common stock. Therefore, these stockholders will have the ability to influence us through their ownership positions. For example, these stockholders, 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 common stock that you may believe are in your best interest as one of our stockholders.

Provisions in our amended and restated certificate of incorporation and by-laws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us or increase the cost of acquiring us, even if doing so would benefit our stockholders or remove our current management.

Our amended and restated certificate of incorporation, by-laws, and Delaware law contain provisions that may have the effect of delaying or preventing a change in control of us or changes in our management. Our amended and restated certificate of incorporation and amended and restated by-laws include provisions that:

- authorize "blank check" preferred stock, which could be issued by our board of directors without stockholder approval and may contain voting, liquidation, dividend, and other rights superior to our common stock;
- create a classified board of directors whose members serve staggered three-year terms;
- specify that special meetings of our stockholders can be called only by our board of directors, the chairperson of our board of directors, our chief executive officer, or our president;
- prohibit stockholder action by written consent;
- establish an advance notice procedure for stockholder approvals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our board of directors;
- provide that our directors may be removed only for cause;
- provide that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum;
- specify that no stockholder is permitted to cumulate votes at any election of directors;
- expressly authorize our board of directors to modify, alter, or repeal our amended and restated by-laws; and
- require supermajority votes of the holders of our common stock to amend specified provisions of our amended and restated certificate of incorporation and amended and restated by-laws.

These provisions, alone or together, could delay or prevent hostile takeovers and changes in control or changes in our management.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which limits the ability of stockholders owning in excess of 15% of our outstanding voting stock to merge or combine with us.

Any provision of our amended and restated certificate of incorporation or amended and restated by-laws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock, and could also affect the price that some investors are willing to pay for our common stock.

An active trading market for our common stock may not be sustained.

Our shares of common stock began trading on the Nasdaq Global Select Market on December 7, 2018. Given the limited trading history of our common stock, there is a risk that an active trading market for our shares will not be sustained, which could put downward pressure on the market price of our common stock and thereby affect the ability of our stockholders to sell their shares.

Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain.

We do not currently intend to declare or pay cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the terms of any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

****Our amended and restated by-laws designate the Court of Chancery of the State of Delaware or the United States District Court for the District of Massachusetts as the exclusive forum for certain litigation that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us.***

Pursuant to our amended and restated by-laws, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware is the sole and exclusive forum for state law claims for (1) any derivative action or proceeding brought on our behalf, (2) any action asserting a claim of or based on a breach of a fiduciary duty owed by any of our current or former directors, officers, or other employees to us or our stockholders, (3) any action asserting a claim against us or any of our current or former directors, officers, employees, or stockholders arising pursuant to any provision of the Delaware General Corporation Law or our amended and restated by-laws, or (4) any action asserting a claim governed by the internal affairs doctrine (the "Delaware Forum Provision"). The Delaware Forum Provision will not apply to any causes of action arising under the Securities Act, or the Exchange Act. Our amended and restated by-laws further provide that the United States District Court for the District of Massachusetts is the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act (the "Federal Forum Provision"). We have chosen the United States District Court for the District of Massachusetts as the exclusive forum

for such causes of action because our principal executive offices are located in Cambridge, Massachusetts. In addition, our amended and restated by-laws provide that any person or entity purchasing or otherwise acquiring any interest in shares of our common stock is deemed to have notice of and consented to the Delaware Forum Provision and the Federal Forum Provision; provided, however, that stockholders will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder.

We recognize that the Delaware Forum Provision and the Federal Forum Provision may impose additional litigation costs on stockholders in pursuing any such claims, particularly if the stockholders do not reside in or near the State of Delaware or the Commonwealth of Massachusetts, as applicable. Additionally, the forum selection clauses in our amended and restated by-laws may limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees, which may discourage the filing of lawsuits against us and our directors, officers, and employees, even though an action, if successful, might benefit our stockholders. 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 courts will enforce our Federal Forum Provision. The Federal Forum Provision may also impose additional litigation costs on stockholders who assert that the provision is unenforceable or invalid, and if the Federal Forum Provision is found to be unenforceable, we may incur additional costs in resolving such matters. The Court of Chancery of the State of Delaware and the United States District Court for the District of Massachusetts may also reach different judgments or results than would other courts, including courts where a stockholder considering an 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 stockholders.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

Recent Sales of Unregistered Securities

None.

Use of Proceeds from Public Offering of Common Stock

There has been no material change in the planned use of proceeds from our initial public offering as described in our final prospectus filed with the SEC pursuant to Rule 424(b) of the Securities Act. We are holding the balance of the net proceeds in cash, cash equivalents, and investments. We invested the funds received in short-term, interest-bearing investment-grade securities and government securities.

Item 5. Other Information.

As we have entered the Phase 3 pivotal testing of our mRNA-1273 vaccine against COVID-19, our first potential commercial product, and to avoid any distraction as we pursue our mission, all members of our executive team and board of directors have agreed not to enter into new 10b5-1 trading plans, nor add new shares to existing trading plans, nor engage in additional unscheduled sales of Moderna stock in the open market, until the earlier of the filing with the FDA of our Biologics License Application (BLA) with respect to mRNA-1273 or the discontinuation of the program. We do not undertake any obligation to update or otherwise comment further on this matter.

Item 6. Exhibits

The Exhibits listed below are filed or incorporated by reference as part of this Form 10-Q.

Exhibit No.	Exhibit Index
10.1*†	Agreement No. HHSO100201600029C, by and between the Company and the Biomedical Advanced Research and Development Authority, dated as of April 16, 2020, as amended
10.2*	Offer Letter by and between the Company and David W. Meline, dated as of June 3, 2020
31.1*	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1+	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Taxonomy Extension Calculation Document
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	XBRL Taxonomy Extension Presentation Link Document
104*	Cover Page Interactive Data File (formatted as Inline XBRL with applicable taxonomy extension information contained in Exhibits 101.*)

* Filed herewith

\+ The certification furnished in Exhibit 32.1 hereto is deemed to accompany this Form 10-Q and will not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended. Such certification will not be deemed to be incorporated by reference into any filings under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, except to the extent that the Registrant specifically incorporates it by reference.

† Portions of this exhibit (indicated by asterisks) have been omitted in accordance with the rules of the Securities and Exchange Commission.

SIGNATURES

Pursuant to the requirements of the Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

MODERNA, INC.

Date:
August 6, 2020

By: /s/ Stéphane Bancel

Stéphane Bancel
Chief Executive Officer and Director
(*Principal Executive Officer)*

Date:
August 6, 2020

By: /s/ David W. Meline

David W. Meline
Chief Financial Officer
(*Principal Financial Officer)*