

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 September 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 October 20, 2020, there were 395,710,105 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 third-party and governmental arrangements and potential 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;
 - our ability to meet our obligations under supply agreements for 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.

ADDITIONAL INFORMATION

Our website, www.modernatx.com including the Investor Relations section, www.investors.modernatx.com; and corporate blog www.modernatx.com/moderna-blog; as well as our social media channels: Facebook, www.facebook.com/modernatx; Twitter, www.twitter.com/modernatx; and LinkedIn, www.linkedin.com/company/modernatx; contain a significant amount of information about us, including financial and other information for investors. We encourage investors to visit these websites and social media channels as information is frequently updated and new information is shared.

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Item 1. Financial Statements

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

	September 30, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	\$ 1,505,581	\$ 235,876
Investments	1,770,721	867,124
Accounts receivable	190,501	5,369
Prepaid expenses and other current assets	109,376	19,403
Restricted cash	1,032	1,032
Total current assets	3,577,211	1,128,804
Investments, non-current	691,969	159,987
Property and equipment, net	276,909	201,495
Right-of-use assets, operating leases	91,684	86,414
Restricted cash, non-current	11,053	10,791
Other non-current assets	2,047	1,931
Total assets	<u>\$ 4,650,873</u>	<u>\$ 1,589,422</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 20,521	\$ 7,090
Accrued liabilities	208,832	67,652
Deferred revenue	1,234,506	63,310
Other current liabilities	9,702	5,063
Total current liabilities	1,473,561	143,115
Deferred revenue, non-current	207,768	138,995
Operating lease liabilities, non-current	98,954	93,675
Financing lease liabilities, non-current	108,609	38,689
Other non-current liabilities	2,183	138
Total liabilities	1,891,075	414,612
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Preferred stock, par value \$0.0001; 162,000,000 shares authorized as of September 30, 2020 and December 31, 2019; no shares issued or outstanding at September 30, 2020 and December 31, 2019	—	—
Common stock, par value \$0.0001; 1,600,000,000 shares authorized as of September 30, 2020 and December 31, 2019; 395,390,672 and 336,536,985 shares issued and outstanding as of September 30, 2020 and December 31, 2019, respectively	40	34
Additional paid-in capital	4,726,007	2,669,426
Accumulated other comprehensive income	4,784	1,804
Accumulated deficit	(1,971,033)	(1,496,454)
Total stockholders' equity	<u>2,759,798</u>	<u>1,174,810</u>
Total liabilities and stockholders' equity	<u>\$ 4,650,873</u>	<u>\$ 1,589,422</u>

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 September 30,		Nine Months Ended September 30,	
	2020	2019 ⁽¹⁾	2020	2019 ⁽¹⁾
Revenue:				
Grant revenue	\$ 145,694	\$ 3,708	\$ 187,535	\$ 8,671
Collaboration revenue	12,216	13,338	45,115	37,483
Total revenue	157,910	17,046	232,650	46,154
Operating expenses:				
Research and development	344,486	119,637	611,479	378,355
General and administrative	48,541	28,173	109,277	83,913
Total operating expenses	393,027	147,810	720,756	462,268
Loss from operations	(235,117)	(130,764)	(488,106)	(416,114)
Interest income	5,571	9,252	20,515	30,546
Other expense, net	(3,226)	(1,881)	(5,910)	(5,689)
Loss before income taxes	(232,772)	(123,393)	(473,501)	(391,257)
Provision for (benefit from) income taxes	864	(178)	1,078	(526)
Net loss	\$ (233,636)	\$ (123,215)	\$ (474,579)	\$ (390,731)
Net loss per share, basic and diluted	\$ (0.59)	\$ (0.37)	\$ (1.26)	\$ (1.19)
Weighted average common shares used in net loss per share, basic and diluted	394,682,744	330,769,341	376,174,283	329,592,322

⁽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 September 30,		Nine Months Ended September 30,	
	2020	2019 ⁽¹⁾	2020	2019 ⁽¹⁾
Net loss	\$ (233,636)	\$ (123,215)	\$ (474,579)	\$ (390,731)
Other comprehensive income:				
Unrealized (loss) gain on available-for-sale debt securities, net of tax of \$0 and \$25, for the three months ended September 30, 2020 and 2019, respectively, and net of tax of \$0 and \$1,173 for the nine months ended September 30, 2020 and 2019, respectively	(3,683)	168	1,878	4,243
Less: amounts recognized for net realized loss (gain) included in net loss	211	(79)	1,102	(93)
Total other comprehensive (loss) income	(3,472)	89	2,980	4,150
Comprehensive loss	<u>\$ (237,108)</u>	<u>\$ (123,126)</u>	<u>\$ (471,599)</u>	<u>\$ (386,581)</u>

⁽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 NINE MONTHS ENDED SEPTEMBER 30, 2020 AND 2019
(Unaudited, in thousands except share data)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at June 30, 2020	393,277,267	\$ 39	\$ 4,675,987	\$ 8,256	\$ (1,737,397)	\$ 2,946,885
Vesting of restricted common stock units	43,374	—	—	—	—	—
Exercise of options to purchase common stock, net	2,070,031	1	26,814	—	—	26,815
Stock-based compensation	—	—	23,206	—	—	23,206
Unrealized loss on marketable securities	—	—	—	(3,472)	—	(3,472)
Net loss	—	—	—	—	(233,636)	(233,636)
Balance at September 30, 2020	<u>395,390,672</u>	<u>\$ 40</u>	<u>\$ 4,726,007</u>	<u>\$ 4,784</u>	<u>\$ (1,971,033)</u>	<u>\$ 2,759,798</u>
	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit ⁽¹⁾	Total Stockholders' Equity ⁽¹⁾
	Shares	Amount				
Balance at June 30, 2019	329,958,172	\$ 33	\$ 2,582,134	\$ 2,741	\$ (1,249,948)	\$ 1,334,960
Vesting of restricted common stock	33,678	—	—	—	—	—
Exercise of options to purchase common stock, net	2,502,927	—	15,554	—	—	15,554
Stock-based compensation	—	—	20,804	—	—	20,804
Unrealized gain on marketable securities	—	—	—	89	—	89
Net loss	—	—	—	—	(123,215)	(123,215)
Balance at September 30, 2019	<u>332,494,777</u>	<u>\$ 33</u>	<u>\$ 2,618,492</u>	<u>\$ 2,830</u>	<u>\$ (1,373,163)</u>	<u>\$ 1,248,192</u>

⁽¹⁾ Restated to conform to ASC 842. See accompanying Note 2.

	Common Stock			Additional Paid-In Capital	Accumulated Other Comprehensive Income	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	203,488	—	—	—	—	—	
Exercise of options to purchase common stock, net	10,613,303	2	133,367	—	—	133,369	
Purchase of common stock under employee stock purchase plan	173,738	—	2,917	—	—	2,917	
Stock-based compensation	—	—	67,542	—	—	67,542	
Unrealized loss on marketable securities	—	—	—	2,980	—	2,980	
Net loss	—	—	—	—	(474,579)	(474,579)	
Balance at September 30, 2020	395,390,672	\$ 40	\$ 4,726,007	\$ 4,784	\$ (1,971,033)	\$ 2,759,798	

	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	141,153		—	—	—	—	—
Exercise of options to purchase common stock, net	3,554,720		—	19,541	—	—	19,541
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	—		—	60,796	—	—	60,796
Unrealized gain on marketable securities	—		—	—	4,150	—	4,150
Net loss	—		—	—	—	(390,731)	(390,731)
Balance at September 30, 2019	332,494,777	\$	33	\$ 2,618,492	\$ 2,830	\$ (1,373,163)	\$ 1,248,192

⁽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)

	Nine Months Ended September 30,	
	2020	2019 ⁽¹⁾
Operating activities		
Net loss	\$ (474,579)	\$ (390,731)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	67,542	60,796
Depreciation and amortization	23,545	22,046
Amortization/accretion of investments	5,053	(3,428)
Loss on disposal of property and equipment	287	70
Changes in assets and liabilities:		
Accounts receivable	(185,132)	4,369
Prepaid expenses and other assets	(67,994)	1,813
Right-of-use assets, operating leases	(13,117)	(7,970)
Accounts payable	13,633	(19,185)
Accrued liabilities	132,374	(8,253)
Deferred revenue	1,239,969	(32,795)
Operating lease liabilities	14,417	13,475
Other liabilities	6,684	(153)
Net cash provided by (used in) operating activities	<u>762,682</u>	<u>(359,946)</u>
Investing activities		
Purchases of marketable securities	(2,326,141)	(949,277)
Proceeds from maturities of marketable securities	748,152	747,846
Proceeds from sales of marketable securities	140,337	81,030
Purchases of property and equipment	(44,147)	(24,892)
Net cash used in investing activities	<u>(1,481,799)</u>	<u>(145,293)</u>
Financing activities		
Proceeds from public offerings of common stock, net of issuance costs	1,852,759	—
Proceeds from issuance of common stock through equity plans, net	133,369	19,541
Proceeds from purchase of common stock under employee stock purchase plan	2,917	—
Charges to financing lease liabilities	39	741
Net cash provided by financing activities	<u>1,989,084</u>	<u>20,282</u>
Net increase (decrease) in cash, cash equivalents and restricted cash	<u>1,269,967</u>	<u>(484,957)</u>
Cash, cash equivalents and restricted cash, beginning of year	247,699	670,491
Cash, cash equivalents and restricted cash, end of period	<u>\$ 1,517,666</u>	<u>\$ 185,534</u>
Non-cash investing and financing activities		
Purchases of property and equipment included in accounts payable and accrued liabilities	<u>\$ 13,280</u>	<u>\$ 1,863</u>
Leasehold improvements included in prepaid and other current assets	<u>\$ —</u>	<u>\$ 6,310</u>

⁽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 September 30, 2020, we had an accumulated deficit of \$1.97 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, pre-launch inventory buildup, 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 September 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 nine months ended September 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 nine months ended September 30, 2019 (in thousands, except per share data):

	Three Months Ended September 30, 2019			Nine Months Ended September 30, 2019		
	ASC 842			ASC 842		
	Previously reported	Adjustments	As adjusted	Previously reported	Adjustments	As adjusted
Operating expenses:						
Research and development	\$ 119,715	\$ (78)	\$ 119,637	\$ 378,786	\$ (431)	\$ 378,355
General and administrative	28,188	(15)	28,173	83,994	(81)	83,913
Total operating expenses	147,903	(93)	147,810	462,780	(512)	462,268
Loss from operations	(130,857)	93	(130,764)	(416,626)	512	(416,114)
Other expense, net	(1,767)	(114)	(1,881)	(5,351)	(338)	(5,689)
Loss before benefit from income taxes	(123,372)	(21)	(123,393)	(391,431)	174	(391,257)
Net loss	(123,194)	(21)	(123,215)	(390,905)	174	(390,731)
Net loss per share attributable to common stockholders, basic and diluted	(0.37)	—	(0.37)	(1.19)	—	(1.19)

	Nine Months Ended September 30, 2019		
	Previously reported	ASC 842 Adjustment during the period	As adjusted
Operating activities			
Net loss	\$ (390,905)	\$ 174	\$ (390,731)
Depreciation and amortization	22,082	(36)	22,046
Prepaid expenses and other assets	(1,407)	3,220	1,813
Right-of-use assets, operating leases	—	(7,970)	(7,970)
Deferred lease obligation	3,844	(3,844)	—
Operating lease liabilities	—	13,475	13,475
Other liabilities	1,617	(1,770)	(153)
Net cash used in operating activities	(363,195)	3,249	(359,946)
Financing activities			
Reimbursement of assets under lease financing obligation	3,678	(3,678)	—
Charges to financing lease obligation	—	741	741
Payments on financing lease obligation	312	(312)	—
Net cash provided by financing activities	23,531	(3,249)	20,282

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 nine months ended September 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
Other comprehensive loss	(3,472)
Accumulated other comprehensive income, balance at September 30, 2020	\$ 4,784

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):

	September 30,	
	2020	2019
Cash and cash equivalents	\$ 1,505,581	\$ 173,711
Restricted cash	1,032	1,032
Restricted cash, non-current	11,053	10,791
Total cash, cash equivalents and restricted cash shown in the condensed consolidated statements of cash flows	\$ 1,517,666	\$ 185,534

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, intra-period 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. Grant Revenue

In September 2020, we entered into an agreement with the Defense Advanced Research Projects Agency (DARPA) for an award of up to \$56.4 million to fund development of a mobile manufacturing prototype leveraging our existing manufacturing technology that is capable of rapidly producing vaccines and therapeutics. As of September 30, 2020, the committed funding was \$5.0 million, with an additional \$51.4 million available if DARPA exercises additional contract options.

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 mRNA-1273, our vaccine candidate against the novel coronavirus. In July 2020, we amended our agreement 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. 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 September 30, 2020, the remaining available funding net of revenue earned was \$781.7 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 September 30, 2020, the remaining available funding net of revenue earned was \$71.9 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 (HIV). As of September 30, 2020, the available funding net of revenue earned was \$12.6 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 September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
BARDA	\$ 143,318	\$ 1,135	\$ 183,134	\$ 4,500
Other grant revenue	2,376	2,573	4,401	4,171
Total grant revenue	\$ 145,694	\$ 3,708	\$ 187,535	\$ 8,671

	September 30, 2020	December 31, 2019
Deferred grant revenue	\$ 5,670	\$ 1,496

4. Collaboration Revenue

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

Collaboration Revenue by Strategic Collaborator:	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
AstraZeneca	\$ 48	\$ 3,724	\$ 17,202	\$ 4,726
Merck	6,718	9,110	18,060	28,456
Vertex	5,450	504	9,698	4,301
Other	—	—	155	—
Total collaboration revenue	\$ 12,216	\$ 13,338	\$ 45,115	\$ 37,483

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

	December 31, 2019	Additions	Deductions	September 30, 2020
Contract Assets:				
Accounts receivable	\$ 1,972	\$ 115,037	\$ (85,354)	\$ 31,655
Contract Liabilities:				
Deferred revenue	\$ 199,528	\$ 117,002	\$ (50,320)	\$ 266,210

During the three and nine months ended September 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 September 30, 2020	Nine Months Ended September 30, 2020
Amounts included in contract liabilities at the beginning of the period ⁽¹⁾	\$ 13,263	\$ 50,320
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 September 30, 2020, the aggregated amount of the transaction price allocated to performance obligations under our collaboration agreements that are unsatisfied or partially unsatisfied was \$366.7 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 plc (AstraZeneca) to develop and commercialize potential therapeutic mRNA medicines directed at certain targets for the treatment of cardiovascular and cardiometabolic diseases and cancer, 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.

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.

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.

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 (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.

Please refer to our 2019 Form 10-K under the heading “Third-Party Strategic Alliances” for further description of each of the AstraZeneca collaboration agreements.

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	
	September 30, 2020	December 31, 2019
<i>Combined 2018 AZ Agreements:</i>		
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	<u>\$ 399,089</u>	<u>\$ 401,782</u>

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 nine months ended September 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 September 30, 2020 (in thousands):

	Transaction Price	
	September 30, 2020	
Combined 2018 AZ Agreements:		
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 September 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 September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Combined AZ Agreements	\$ 49	\$ 3,552	\$ 2,950	\$ 4,580

The revenue recognized for the three and nine months ended September 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):

	September 30, 2020	December 31, 2019
Combined AZ Agreements	\$ 72,266	\$ 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	
	September 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 September 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 nine months ended September 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 September 30, 2020 (in thousands):

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

As of September 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 September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
2016 VEGF Exercise	\$ —	\$ 172	\$ 14,253	\$ 146

The revenue recognized for the three and nine months ended September 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):

	September 30, 2020	December 31, 2019
2016 VEGF Exercise	\$ 29,335	\$ 41,266

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 nine month periods ended September 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 & Co., Inc (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. Subsequent to the end of the third quarter of 2020, the Master Collaboration and License Agreement between us and Merck related to our collaboration on RSV was terminated by mutual agreement on October 7, 2020.

Please refer to our 2019 Form 10-K under the heading “Third-Party Strategic Alliances” for further description of the 2015 Merck Agreement.

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 would be accounted for as a separate contract if exercised by the customer. We utilize the most likely amount method to estimate any development and regulatory milestone payments to be received. As of September 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 would be recognized when the related sales were to occur as they were determined to relate predominantly to the license granted and therefore have also been excluded from the transaction price. If a milestone payment were to be included in the transaction price in the future, it would 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	
	September 30, 2020	December 31, 2019
<i>2015 Merck Agreement:</i>		
Upfront payments	\$ 60,000	\$ 60,000
Development milestones	5,000	5,000
Reduction of reimbursements paid to Merck	(10,778)	(5,265)
Total	\$ 54,222	\$ 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 nine months ended September 30, 2020, there was a \$5.5 million deduction to the transaction price related to reimbursements paid to Merck for RSV vaccine Phase 1 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 September 30, 2020 (in thousands):

	Transaction Price September 30, 2020
2015 Merck Agreement	\$ 54,222
Remaining unsatisfied performance obligation	—

We utilize the most likely amount method to estimate any development and regulatory milestone payments to be received. As of September 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 September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Contra-revenue under the May 2019 Amendment	\$ (1,074)	\$ (1,657)	\$ (5,513)	\$ (3,796)
Collaboration revenue under the 2015 Merck Agreement	—	(188)	12	666
Total contra-revenue	\$ (1,074)	\$ (1,845)	\$ (5,501)	\$ (3,130)

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 September 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.

On October 7, 2020, the Master Collaboration and License Agreement between us and Merck related to our collaboration on RSV was terminated by mutual agreement. The termination did not have an impact to our condensed consolidated financial statements as of and for the three and nine months ended September 30, 2020.

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.

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).

Please refer to our 2019 Form 10-K under the heading "Third-Party Strategic Alliances" for further description of the Merck PCV/SAV Agreement.

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	
	September 30, 2020	December 31, 2019
<i>PCV/SAV Agreement:</i>		
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	<u>\$ 213,360</u>	<u>\$ 213,050</u>

We determined there are no other components of variable consideration that should be included in the transaction price as of September 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 nine months ended September 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 September 30, 2020 (in thousands):

	Transaction Price	
	September 30, 2020	
<i>PCV/SAV Agreement:</i>		
PCV performance obligation	\$ 206,356	
KRAS performance obligation	7,004	
Total	<u>\$ 213,360</u>	
Remaining unsatisfied performance obligation	\$ 60,548	

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 September 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 September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
PCV/SAV Agreement	\$ 7,792	\$ 10,944	\$ 23,561	\$ 31,575

The revenue recognized during the three and nine months ended September 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):

	September 30, 2020	December 31, 2019
PCV/SAV Agreement	\$ 60,548	\$ 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 cystic fibrosis transmembrane conductance regulator (CFTR) proteins.

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.

Please refer to our 2019 Form 10-K under the heading “Third-Party Strategic Alliances” for further description of the Vertex Agreement.

Accounting Treatment

As of September 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 September 30, 2020 (in thousands):

<i>Vertex Agreement - First Extended Research Term:</i>	Transaction Price	
	September 30, 2020	
Upfront payment	\$	4,000
Research and development		46,410
Total	\$	50,410

We utilize the most likely amount method to determine the amount of research and development funding to be received. As of September 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. There was a \$15.2 million increase to the transaction price during the nine months ended September 30, 2020, resulting from a change in the estimate of variable consideration.

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 September 30, 2020 (in thousands):

	Transaction Price September 30, 2020
First Extended Research Term transaction price	\$ 50,410
Remaining unsatisfied performance obligation	42,766

As of September 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 September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Vertex First Extended Research Term	\$ 5,449	\$ —	\$ 7,645	\$ —
Vertex Agreement/2019 Amendment	—	504	2,052	4,301
Total	\$ 5,449	\$ 504	\$ 9,697	\$ 4,301

The revenue recognized during the three and nine months ended September 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):

	September 30, 2020	December 31, 2019
Vertex Agreement ⁽¹⁾	\$ 4,061	\$ 793

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

Vertex—2020 Strategic Alliance in Cystic Fibrosis

In September 2020, we entered into a new Strategic Collaboration and License Agreement with Vertex (Vertex 2020 Agreement). The Vertex 2020 Agreement is aimed at the discovery and development of potential medicines to treat CF by delivering gene-editing therapies to lung cells to facilitate production of functional CFTR proteins.

The three-year research period of the Vertex 2020 Agreement will initially focus on the identification and optimization of novel LNPs and mRNAs that can deliver gene-editing therapies to cells in the lungs. Following the initial three-year period, 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. Vertex is also obligated to pay us for research services in connection with our

performance of certain activities in accordance with a jointly agreed research plan. Subject to customary “back-up” supply rights granted to Vertex, under the agreement, we are the exclusive manufacturer of related mRNA and LNPs for pre-clinical, clinical, and commercialization purposes.

Under the terms of the Vertex 2020 Agreement, we received a \$75.0 million upfront payment from Vertex. We are eligible to receive up to \$380.0 million in milestone payments upon the achievement of certain development, regulatory, and commercial milestone events with respect to any products that result from the strategic alliance, and Vertex will also pay us a tiered percentage of its gross profits derived from worldwide net sales of products arising from the strategic alliance.

During the term of the Vertex 2020 Agreement, we and Vertex have agreed to certain defined exclusivity obligations with respect to the development and commercialization of certain mRNA medicines.

Unless earlier terminated, the Vertex 2020 Agreement will continue until the expiration of all payment obligations. Vertex may terminate the Vertex 2020 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; in such case, Vertex must provide 180 days’ prior written notice. Either party may terminate the Vertex 2020 Agreement upon the other party’s material breach, subject to specified notice and cure provisions. Each party may also terminate the Vertex 2020 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

We determined that all aspects of the 2020 Vertex Agreement represent a transaction with a customer and therefore should be accounted for in accordance with ASC 606. We also determined that the 2020 Vertex Agreement should be accounted for separately from other Vertex Agreements as the agreements contemplate research on separate research candidates. 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, performed as part of the Initial Research Plan and the Additional Research Plan (collectively, the research period). We concluded that the license is not distinct from the research and development services, including manufacturing and supply of non-cGMP mRNA used in the performance of the research services, as Vertex 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 license has been combined with the research and development services, including manufacturing and supply of non-cGMP supply, into a single performance obligation. Additionally, we concluded the provision of clinical mRNA supply and/or non-cGMP mRNA supply provided to Vertex at their option represents a customer option and is considered a marketing offer as such options did not provide any discounts or other rights that would be considered a material right in the arrangement. Such options will be accounted for as a separate contract upon the customer’s election.

The total transaction price was determined to be \$75.0 million, comprised of the upfront payment. We utilize the most likely amount method to determine the amount of research and development funding to be received associated with the Additional Research Plan. Our funding estimate is based on our experience bringing research candidates to the point of nomination by our collaboration partners, including our experience with Vertex under separate transactions. We have fully constrained such amounts and will not include any expected funding in the transaction price until the scope of such services have been agreed to amongst the parties. We also utilize the most likely amount method to estimate any development and regulatory milestone payments to be received. Further, 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.

For the 2020 Vertex Agreement, the total transaction price was allocated entirely to a single performance obligation. 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.

For the three and nine months ended September 30, 2020, we did not recognize any revenue associated with the 2020 Vertex Agreement. As of September 30, 2020, the aggregate amount of the transaction price allocated to the remaining performance obligations that are unsatisfied is \$75.0 million, which is expected to be recognized as revenue through the third quarter of 2023. We

had deferred revenue of \$75.0 million as of September 30, 2020, which is classified as current and non-current in the consolidated balance sheets based on the term of the research period.

Chiesi—2020 Collaboration and License Agreement with Chiesi

In September 2020, we entered into a Collaboration and License Agreement with Chiesi Farmaceutici S.P.A. (Chiesi), which we refer to as the Chiesi Agreement. The Chiesi Agreement is aimed at the discovery and development of potential mRNA medicines for the treatment of Pulmonary Arterial Hypertension (PAH), a rare disease characterized by high blood pressure in the arteries of the lungs.

Pursuant to the Chiesi Agreement, we lead discovery efforts during a four-year research period, leveraging our Platform technology and mRNA delivery expertise along with Chiesi's scientific experience in PAH biology. Chiesi is responsible for conducting development and commercialization activities for candidates and products that arise from the collaboration, including the costs associated with such activities. Chiesi is also obligated to pay us for our performance of research activities during the research period in accordance with a jointly agreed research plan. Under the agreement, we are the exclusive manufacturer of related candidates and products for pre-clinical, clinical, and commercialization purposes.

Under the terms of the Chiesi Agreement, we are entitled to receive a \$25.0 million upfront payment from Chiesi. Chiesi has the right to extend the initial four-year research period by one additional year by making an additional payment to us. We are eligible to receive up to \$405.0 million in aggregate milestone payments upon the achievement of certain development, regulatory and commercial milestone events, and Chiesi will also pay us tiered double-digit royalties on worldwide net sales of products arising from the collaboration, subject to certain reductions, with an aggregate minimum floor.

During the term of the Chiesi Agreement, we and Chiesi have agreed to certain defined exclusivity with respect to the development and commercialization of certain mRNA medicines.

Accounting Treatment

We determined that all aspects of the Chiesi Agreement represent a transaction with a customer and therefore should be accounted for in accordance with ASC 606. We identified the following performance obligations in the Chiesi Agreement: (i) a research license and research and development services, including manufacturing and supply during the research period; (ii) a material right for the first product development and commercialization license; and (iii) a material right for the second product development and commercialization license. We concluded that the license is not distinct from the research and development services, including manufacturing and supply of non-cGMP mRNA, during the four-year research period, as Chiesi 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 license has been combined with the research and development services, including manufacturing and supply of non-cGMP supply, into a single performance obligation. Additionally, we concluded the provision of clinical mRNA supply and/or non-cGMP mRNA supply beyond the four-year research period and the right to extend the research period for one additional year represent customer options and are considered marketing offers as such options did not provide any discounts or other rights that would be considered a material right in the arrangement. 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	
	September 30, 2020	
<i>Chiesi Agreement:</i>		
Upfront payment	\$	25,000
Estimated reimbursement for research and development		17,656
Total	\$	42,656

We utilize the most likely amount method to determine the amount of research and development funding to be received associated with the research period. We also utilize the most likely amount method to estimate any development and regulatory milestone payments to be received. Further, 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 Chiesi'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 commercial milestone payments and 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.

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 services and manufacturing and supply included in the performance obligation, as applicable, primarily based on the nature of the services to be performed and the 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. We developed the estimated standalone selling prices for the licenses included in the associated performance obligations based on an analysis of our other transactions with collaboration partners and third party comparable transactions. In developing such estimates, 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. The estimated standalone selling price of the material rights to receive development and commercialization rights was developed by estimating the amount of discount that Chiesi 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 transaction price to the identified performance obligations under the arrangement, and the amount of the transaction price unsatisfied as of September 30, 2020 (in thousands):

	Transaction price	
	September 30, 2020	
<i>Chiesi Agreement:</i>		
Research and development	\$	17,656
Material right for the first product development and commercialization license		17,500
Material right for the second product development and commercialization license		7,500
Total	\$	42,656
Remaining unsatisfied performance obligation	\$	42,656

We recognize revenue related to amounts allocated to the combined research license and research and development services 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. We will recognize revenue associated with the material rights as revenue at the earlier of the exercise or expiry of the material rights.

For the three and nine months ended September 30, 2020, we did not recognize any revenue associated with the Chiesi Agreement. As of September 30, 2020, \$17.7 million of the remaining performance obligations that are unsatisfied is expected to be recognized as revenue through the third quarter of 2024 and \$25.0 million is expected to be recognized as revenue at the earlier of the exercise or expiry of the material rights.

We had deferred revenue of \$25.0 million as of September 30, 2020, classified as non-current in the consolidated balance sheets based on the term of the research period.

5. Contracts With Customers

U.S. Supply Agreement

In August 2020, we entered into a supply agreement with the U.S. Government, which we refer to as the U.S. Supply Agreement, for 100 million doses of our vaccine candidate against COVID-19, mRNA-1273, for a total award of up to \$1.525 billion. The total award amount includes approximately \$300.0 million of incentive payments which we will earn if an Emergency Use Authorization or a Biologics License Application, which we refer to as an EUA or a BLA, respectively, is received on or before January 31, 2021. We will receive such incentive payments as product is delivered to and accepted by the U.S. Government. Pursuant to the U.S. Supply Agreement, the U.S. Government made a \$601.4 million upfront payment to us which represents approximately 50% of the fixed price per dose that we are entitled to receive for the committed 100 million doses. We will receive the remaining 50% of the fixed price per dose upon delivery and acceptance of the 100 million doses to the U.S. Government. We will secure, manage and maintain storage for up to 100 million doses of mRNA-1273 based on the specific requirements of the contract and deliver the product to the designated government facility in accordance with the U.S. Supply Agreement. We will be reimbursed for such services at a negotiated price prior to the first product delivery. The U.S. Government has the option to purchase up to an additional 400 million doses at a fixed price of \$1.65 billion per 100 million doses by specified dates in the agreement. The U.S. Supply Agreement contains terms and conditions that are customary for U.S. Government agreements of this nature, including provisions giving the U.S. Government the right to terminate the agreement if the applicable Contracting Officer determines that a termination is in the U.S. Government's interest. Following any such termination, we and the U.S. Government may agree upon the amount to be paid or remaining to be paid to us because of the termination.

Accounting Treatment

We determined that the U.S. Supply Agreement represents a transaction with a customer and therefore should be accounted for in accordance with ASC 606. We concluded that the delivery of each dose pursuant to the U.S. Supply Agreement represents a separate performance obligation and therefore we have multiple performance obligations under the contract. The U.S. Government options to purchase additional doses are considered marketing offers and will be accounted for as a separate contract upon the customer's election.

The total transaction price for the U.S. Supply Agreement is \$1.225 billion, which represents the fixed price for the 100 million doses ordered. We have fully constrained the \$300.0 million incentive payments as such amounts are subject to our receipt of regulatory approval (an EUA or BLA). We have determined the upfront payment of \$601.4 million received from the U.S. Government is non-refundable as we have incurred costs to date related to the U.S. Supply Agreement that exceed such amount. We will recognize revenue based on the fixed price per dose when control of the product has transferred and customer acceptance has occurred, unless such acceptance provisions are deemed perfunctory.

For the three and nine months ended September 30, 2020, we did not recognize any revenue associated with the U.S. Supply Agreement. As of September 30, 2020, the aggregate amount of the transaction price allocated to the remaining performance obligations is expected to be recognized as revenue within a year. As of September 30, 2020, we had deferred revenue of \$601.4 million, classified as current deferred revenue in our condensed consolidated balance sheet. Timing of product manufacturing, delivery and receipt of marketing approval will determine the period in which revenue is recognized.

International Supply Agreements

In the third quarter of 2020, we entered into several supply agreements with international government agencies, including agencies from which we had previously received deposits in the second quarter of 2020, to supply such agencies with mRNA-1273, our vaccine candidate against COVID-19. Pursuant to the supply agreements, we have promised to provide a certain quantity of doses, which we refer to as the Ordered Amount, based on anticipated delivery schedules. Certain agreements provide the ability to increase an agency's Ordered Amount during specific periods of time. Each agency may have to pay an upfront for its Ordered Amount, and can receive a partial refund based on contractual provisions in such supply agreement that generally involve delivery delays, certain failures (delivery failures, clinical failures or failure to obtain market approvals) or the discontinuation of our worldwide clinical development of mRNA-1273. As of September 30, 2020, we had received cash of \$569.0 million associated with such international supply agreements. Each supply agreement contains delivery and acceptance instructions. We continue to work with each applicable agency to confirm our distribution channel to each territory covered by such agreement.

Accounting Treatment

We determined that each supply agreement represents a transaction with a customer and therefore should be accounted for in accordance with ASC 606. We concluded that the delivery of each dose pursuant to a supply agreement represents a separate

performance obligation and therefore we have multiple performance obligations under each contract. Options to increase the Ordered Amount are considered marketing offers and each will be accounted for as a separate contract upon the customer's election.

The total transaction price for each supply agreement equals the Ordered Amount multiplied by the fixed price per dose charged to the customer. Because the customer can reduce the Ordered Amount in certain circumstances based on the terms of the applicable supply agreement, we have concluded that the transaction price represents variable consideration. We have elected to not include sales and excise tax in the transaction price as an accounting election and any ancillary costs, to the extent billable to the customer, will be recorded as an offset to our related costs as such costs will be invoiced at cost. We will recognize revenue based on the fixed price per dose when control of the product has transferred to the customer and customer acceptance has occurred, unless such acceptance provisions are deemed perfunctory.

For the three and nine month periods ended September 30, 2020, we did not recognize any revenue associated with the international supply agreements. As of September 30, 2020, the aggregate amount of the transaction price allocated to the remaining performance obligations is expected to be recognized as revenue within a year. As of September 30, 2020, we had deferred revenue of \$569.0 million, classified as current deferred revenue in our condensed consolidated balance sheet. Timing of product manufacturing, delivery and receipt of marketing approval will determine the period in which revenue is recognized.

6. Financial Instruments

Cash and Cash Equivalents and Investments

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

September 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	\$ 1,505,579	\$ 2	\$ —	\$ 1,505,581	\$ 1,505,581	\$ —	\$ —
Available-for-sale:							
Level 2:							
Certificates of deposit	161,097	46	(1)	161,142	—	152,649	8,493
U.S. treasury securities	130,495	385	(1)	130,879	—	81,607	49,272
Debt securities of U.S. government agencies and corporate entities	2,165,133	6,043	(507)	2,170,669	—	1,536,465	634,204
	<u>\$ 3,962,304</u>	<u>\$ 6,476</u>	<u>\$ (509)</u>	<u>\$ 3,968,271</u>	<u>\$ 1,505,581</u>	<u>\$ 1,770,721</u>	<u>\$ 691,969</u>

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
	<u>\$ 1,259,980</u>	<u>\$ 3,047</u>	<u>\$ (40)</u>	<u>\$ 1,262,987</u>	<u>\$ 235,876</u>	<u>\$ 867,124</u>	<u>\$ 159,987</u>

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

September 30, 2020		
	Amortized Cost	Estimated Fair Value
Due in one year or less	\$ 1,766,834	\$ 1,770,721
Due after one year through five years	689,891	691,969
Total	<u>\$ 2,456,725</u>	<u>\$ 2,462,690</u>

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 nine months ended September 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 September 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 September 30, 2020:						
Certificates of deposit	\$ (1)	\$ 14,893	\$ —	\$ —	\$ (1)	\$ 14,893
U.S. treasury securities	(1)	15,341	—	—	(1)	15,341
Debt securities of U.S. government agencies and corporate entities	(507)	729,249	—	—	(507)	729,249
Total	<u>\$ (509)</u>	<u>\$ 759,483</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ (509)</u>	<u>\$ 759,483</u>
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	<u>\$ (40)</u>	<u>\$ 85,161</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ (40)</u>	<u>\$ 85,161</u>

At September 30, 2020 and December 31, 2019, we held zero and 19 individual 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.

7. Balance Sheet Components

Prepaid Expenses and Other Current Assets

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

	September 30, 2020	December 31, 2019
Down payments to manufacturing vendors	\$ 23,990	\$ —
Other prepaid expenses	62,434	8,475
Tenant incentives receivables	12,941	4,093
Interest receivable on marketable securities	10,011	6,835
Prepaid expenses and other current assets	<u>\$ 109,376</u>	<u>\$ 19,403</u>

Property and Equipment, Net

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

	September 30, 2020	December 31, 2019
Laboratory equipment	\$ 113,326	\$ 108,257
Leasehold improvements	163,793	152,426
Furniture, fixtures and other	4,613	3,316
Computer equipment and software	12,583	11,985
Internally developed software	7,020	7,020
Right-of-use asset, financing	56,348	9,853
Construction in progress	31,216	3,222
	<u>388,899</u>	<u>296,079</u>
Less: Accumulated depreciation	(111,990)	(94,584)
Property and equipment, net	<u>\$ 276,909</u>	<u>\$ 201,495</u>

Depreciation and amortization expense for the three months ended September 30, 2020 and 2019 was \$8.5 million and \$7.3 million, respectively. Depreciation and amortization expense for the nine months ended September 30, 2020 and 2019 was \$23.5 million and \$22.0 million, respectively.

Accrued Liabilities

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

	September 30, 2020	December 31, 2019
Clinical trials	\$ 44,554	\$ 6,291
Development operations	24,187	2,567
Manufacturing	14,029	5,872
Other external goods and services	64,439	21,465
Compensation-related	48,788	27,428
Property and equipment	12,835	4,029
Accrued liabilities	<u>\$ 208,832</u>	<u>\$ 67,652</u>

Deferred Revenue

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

	Deferred Revenue	
Balance at December 31, 2019	\$	202,305
Additions		1,293,370
Deductions		(53,401)
Balance at September 30, 2020	\$	1,442,274

In the third quarter of 2020, we entered into supply agreements with the U.S. Government and several other governmental agencies outside the United States related to the potential sale of doses of mRNA-1273. As of September 30, 2020, we had received deposits of \$1.17 billion based on the supply agreements, which were recorded to deferred revenue (see Note 5). Our remaining deferred revenue was related to our collaboration agreements and grants (see Note 3 and Note 4).

8. 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 (MTC), located in Norwood.

Operating Leases

Cambridge facility

We occupy a multi-building campus in Technology Square in Cambridge, Massachusetts 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, Massachusetts. 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. 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.

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 Norwood, Massachusetts. 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.

Moderna Technology Center North (MTC North)

In February 2019, we entered into a lease agreement for office and laboratory space of approximately 200,000 square feet, MTC North, located in Norwood, 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 the remainder of the space in July 2020 when the sublease expired. The 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 September 30, 2020 and December 31, 2019 were as follows (in thousands):

	September 30, 2020	December 31, 2019
Assets:		
Right-of-use assets, operating, net ⁽¹⁾⁽²⁾	\$ 91,684	\$ 86,414
Right-of-use assets, financing, net ⁽³⁾⁽⁴⁾	55,503	9,544
Total	\$ 147,187	\$ 95,958
Liabilities:		
Current:		
Operating lease liabilities ⁽⁵⁾	\$ 4,731	\$ 3,584
Non-current:		
Operating lease liabilities, non-current	98,954	93,675
Financing lease liabilities, non-current	108,609	38,689
Total non-current lease liabilities	207,563	132,364
Total	\$ 212,294	\$ 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 the three and nine months ended September 30, 2020 and 2019 were as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Operating lease costs	\$ 3,962	\$ 3,872	\$ 12,977	\$ 11,614
Financing lease costs:				
Amortization of right-of-use assets, financing leases	368	73	553	219
Interest expense for financing lease liabilities	2,843	1,644	6,385	4,901
Total financing lease costs	\$ 3,211	\$ 1,717	\$ 6,938	\$ 5,120
Variable lease costs	\$ 1,120	\$ 1,430	\$ 3,618	\$ 3,495

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

	Nine Months Ended September 30,	
	2020	2019
Cash paid for amounts included in measurement of lease liabilities:		
Operating cash flows used in operating leases	\$ (11,314)	\$ (11,396)
Operating cash flows used in financing leases	(5,383)	(4,161)
Operating lease non-cash items:		
Right-of-use assets reduced through lease modifications and reassessments	6,755	16,242
Right-of-use assets obtained in exchange for operating lease liabilities	17,107	26,839
Finance lease non-cash items:		
Right-of-use assets obtained through lease modifications and reassessments	46,495	—
Charges to financing lease obligation	39	741

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

Fiscal Year	Operating Leases ⁽¹⁾	Financing Leases ⁽¹⁾
2020 (remainder of the year)	\$ 2,770	\$ 1,858
2021	15,492	11,634
2022	15,913	11,848
2023	16,008	12,054
2024	16,168	12,279
Thereafter	110,167	440,552
Total minimum lease payments	176,518	490,225
Less amounts representing interest or imputed interest	(72,833)	(381,616) ⁽²⁾
Present value of lease liabilities	\$ 103,685	\$ 108,609

⁽¹⁾ Includes 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. Includes optional extensions in the MTC North lease term which represent a total of \$110.3 million un-discounted future lease payments in 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%.

9. 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 September 30, 2020 and December 31, 2019 (see Note 4).

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 counterparties 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 September 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 virus and additional Moderna products in the future. This agreement was reflected in the Global Long Term Agreement entered into between Moderna and Lonza on September 4, 2020. 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 September 30, 2020, as the leases had not yet commenced or the lease terms were less than 12 months. 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 \$613.9 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 September 30, 2020, we had \$16.9 million of non-cancelable purchase commitments for clinical services which are expected to be paid from 2020 to 2023. As of September 30, 2020, we had \$613.9 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 September 30, 2020 and December 31, 2019, we had cancelable open purchase orders of \$747.9 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 September 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.

10. 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 options to purchase an additional 3,947,368 shares of common stock at the public offering price less underwriting discounts, 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 discounts, commissions and offering expenses.

11. 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 percent 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 September 30, 2020, we had a total of 67.5 million shares reserved for future issuance under our Equity Plans, of which 39.4 million shares were reserved for equity awards previously granted, and 28.1 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 nine months ended September 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 December 31, 2019	45,536,915	\$ 13.82	\$ 7.35	7.2 years	\$ 286,310
Granted	4,809,336	33.79	18.10		
Exercised	(10,613,303)	12.57	6.32		
Canceled/forfeited	(2,471,131)	17.78	10.39		
Outstanding at September 30, 2020	37,261,817	16.49	8.82	7.0 years	2,022,154
Exercisable at September 30, 2020	18,348,695	10.96	5.61	5.6 years	1,097,117
Expected to vest at September 30, 2020	18,913,122	21.86	11.94	8.3 years	926,598

⁽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 September 30, 2020.

For the nine months ended September 30, 2020, 10.6 million stock options were exercised. The total intrinsic value of options exercised was \$434.9 million for the nine months ended September 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 \$133.4 million for the nine months ended September 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 nine months ended September 30, 2020:

	Units	Weighted-Average Fair Value per Unit
Outstanding, non-vested at December 31, 2019	1,177,249	\$ 19.01
Issued	1,386,066	34.29
Vested	(203,488)	20.46
Canceled/forfeited	(187,650)	22.69
Outstanding, non-vested at September 30, 2020	2,172,177	28.37

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. The ESPP provides that the number of shares reserved and available for issuance under the plan will automatically increase each January 1, by the lesser of 3,240,000 shares of common stock, one percent 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. 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 nine months ended September 30, 2020. As of September 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 and share purchases under our ESPP are 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 nine months ended September 30, 2020 and 2019 are as follows:

	Weighted Average Nine Months Ended September 30,	
	2020	2019
Options:		
Risk-free interest rate	0.85 %	2.39 %
Expected term	6.11 years	6.07 years
Expected volatility	57.82 %	62 %
Expected dividends	— %	— %
Weighted average fair value per share	\$ 18.10	\$ 11.71
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 nine months ended September 30, 2020 and 2019 as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Options	\$ 18,924	\$ 18,994	\$ 57,365	\$ 56,475
Restricted common stock units	3,404	1,291	8,098	3,628
ESPP	878	519	2,079	693
Total	\$ 23,206	\$ 20,804	\$ 67,542	\$ 60,796
Research and development	\$ 14,022	\$ 12,616	\$ 40,761	\$ 36,268
General and administrative	9,184	8,188	26,781	24,528
Total	\$ 23,206	\$ 20,804	\$ 67,542	\$ 60,796

As of September 30, 2020, there was \$236.9 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 2.98 years at September 30, 2020.

12. Income Taxes

We recognize deferred tax assets and liabilities for the expected future tax consequences of temporary differences between the financial reporting and tax basis 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.

During the three and nine months ended September 30, 2020, we recorded an income tax provision of \$0.9 million and \$1.1 million, respectively, primarily related to withholding taxes on a foreign collaboration agreement upfront payment. There were no significant income tax provisions or benefits for the three and nine months ended September 30, 2019.

13. Net Loss per Share

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Numerator:				
Net loss	\$ (233,636)	\$ (123,215)	\$ (474,579)	\$ (390,731)
Denominator:				
Weighted average common shares used in net loss per share, basic and diluted	394,682,744	330,769,341	376,174,283	329,592,322
Net loss per share, basic and diluted	<u>\$ (0.59)</u>	<u>\$ (0.37)</u>	<u>\$ (1.26)</u>	<u>\$ (1.19)</u>

The following common stock equivalents, presented based on amounts outstanding as of September 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:

	September 30,	
	2020	2019
Stock options	37,261,817	48,962,655
Restricted common stock	—	21,564
Restricted common stock units	2,172,177	1,659,187
	<u>39,433,994</u>	<u>50,643,406</u>

14. Subsequent Events

Subsequent to September 30, 2020, we entered into an additional supply agreement with an international government agency to provide mRNA-1273 supply, our vaccine candidate against COVID-19, up to 50.0 million doses.

On October 7, 2020, the Master Collaboration and License Agreement between us and Merck related to our collaboration on RSV was terminated by mutual agreement. The termination did not have an impact to our condensed consolidated financial statements as of and for the three and nine months ended September 30, 2020.

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, or NIAID, part of the National Institutes of Health, or 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 equity offering, resulting in net proceeds of \$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, some of which are in collaboration with NIAID. 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 and completed on October 22, 2020.

We have entered into supply agreements with the United States government and several 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. Under these agreements, we have received upfront deposits for our future mRNA-1273 vaccine

supply, initially recorded as deferred revenue. As of September 30, 2020, we had approximately \$1.17 billion 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. We currently anticipate that our production of mRNA-1273 will be approximately 20 million doses by the end of 2020, and that our total production of mRNA-1273 will be in the range of between 500 million and 1 billion doses during 2021.

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. Through the end of the third quarter, we have entered into smaller volume agreements, primarily with governments outside the U.S., executed at \$32-\$37 per dose or \$64-\$74 per 2-dose course. In August 2020, we announced an agreement to supply the U.S. government with an initial supply of 100 million doses of mRNA-1273 at \$12.25 per dose or \$24.50 per 2-dose course (exclusive of the aforementioned BARDA funding and potential incentives, which together would bring the price per dose to \$24.80 per dose, or \$49.60 per 2-dose course if the incentives are achieved). The U.S. government also has an option to purchase up to an additional 400 million doses (in four 100 million dose increments) at \$16.50 per dose. Future larger volume agreements, if any, may result in a lower price per dose than the \$32-\$37 per dose previously negotiated with governments outside the U.S. 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 September 30, 2020, we had cash, cash equivalents, and investments of approximately \$3.97 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, pre-launch inventory buildup, expansion into global markets 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 \$233.6 million and \$474.6 million for the three and nine months ended September 30, 2020, respectively. As of September 30, 2020, our accumulated deficit was \$1.97 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.

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). We have restarted enrollment for the age de-escalation trial for mRNA-1653 and start-up activities for mRNA-3927 have resumed. We will continue to evaluate the status of other trials as the COVID-19 situation evolves, and we 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 (see further updates under “Key Development Updates for our Other Development Candidates” below). 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 21 development candidates. Since December 2015, we have dosed over 32,000 subjects in our clinical trials, including our Phase 3 trial of mRNA-1273, which started in late July and completed enrollment and dosing of 30,000 people with our vaccine or placebo on October 22, 2020.

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, Merck, and Vertex, and government-sponsored organizations and private foundations focused on global health initiatives, including BARDA, DARPA, the NIH, CEPI and the Bill & Melinda Gates Foundation, or the Gates Foundation.

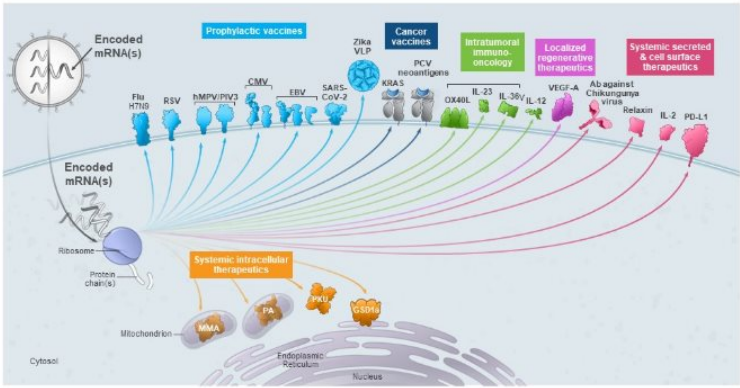
The following chart shows our current pipeline of 21 development candidates, grouped into modalities—first the two core modalities where we believe we have reduced the technology risk, followed by the four exploratory modalities in which we are continuing to investigate the clinical use of mRNA medicines.



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 21 development candidates. 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.

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 seven programs, six of which have entered into clinical trials. Across our historical vaccine development, 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 COVID-19 vaccine (mRNA-1273). We have ongoing Phase 1 trials for the Zika vaccine (mRNA-1893), pediatric RSV vaccine (mRNA-1345), hMPV/PIV3 vaccine (mRNA-1653) and Merck is conducting a Phase 1 trial for an additional RSV vaccine (mRNA-1172), which will be transitioned to Moderna after completion. Our COVID-19 vaccine (mRNA-1273) is described in detail below. In addition to the seven 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, PD-L1 (mRNA-6981) for autoimmune hepatitis and IL-2 (mRNA-6231) for autoimmune disorders. Our antibody against Chikungunya virus (mRNA-1944) has had positive Phase 1 readouts to date. In September 2020, we announced positive interim data from the Phase 1 study evaluating escalating doses of mRNA-1944 in the 0.6 mg/kg dose with steroid premedication cohort and two doses of 0.3 mg/kg (without steroid premedication) given one week apart cohort. mRNA-1944 was generally safe and well tolerated. No SAEs were reported; the most common adverse events were headache, nausea, myalgia, dizziness and chills. Administration of mRNA-1944 resulted in dose-dependent increases in levels of antibody against chikungunya (CHKV-24). Neutralizing antibodies were observed at all dose levels, indicating functional antibody production by mRNA-1944. Safety and increased CHKV-IgG production in the two-dose regimen shows the platform's ability for repeat dosing. 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, PD-L1 (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-36 γ (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 propionic acidemia, or PA (mRNA-3927), methylmalonic acidemia, or MMA (mRNA-3705), phenylketonuria, or PKU (mRNA-3283), and glycogen storage disorder type 1a, or GSD1a (mRNA-3745). We have an open IND for mRNA-3927 for a planned Phase 1/2 trial. During a COVID-19 related pause, we implemented changes that we believe will ultimately help to accelerate clinical development including a protocol amendment implementing a novel design to identify the optimal dose in the most efficient manner and to make the study less burdensome on patients, their families and clinical partners. Study start up activities and site initiation are ongoing. The FDA has designated the investigation of mRNA-3927 for the treatment of propionic acidemia as a Fast Track development program. In our MMA program, during a COVID-19 related pause, we implemented changes that we believe will ultimately help to accelerate clinical development including the introduction of a new drug product with better pharmacology (designated mRNA-3705) as well as a protocol revision to enhance operational performance and reflecting input from the patient and caregiver community. We plan to file new IND and CTA applications for mRNA-3705. mRNA-3705 received a Breakthrough Designation from the FDA. PKU (mRNA-3283) and GSD1a (mRNA-3745) are 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 μ g 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 μ g 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 μ g dose (231) in the same PsV assay. At the higher dose in the non-human primates (100 μ g), 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.

On September 29, 2020, we announced the publication in *The New England Journal of Medicine* of the second interim analysis of data from 40 healthy adult participants across two dose levels (25 and 100 µg) in two age cohorts (ages 56-70 and ages 71+), and reports results through Day 57 (1 month after the second dose).

Both the 25 µg and 100 µg dose levels of mRNA-1273 were generally well-tolerated, with no serious adverse events reported through Day 57. The most common solicited adverse events were headache, fatigue, myalgia, chills, and pain at the injection site, the majority of which were mild-to-moderate in severity and of self-limited duration. Local and systemic reactogenicity were more common and more frequently moderate in severity after the second dose. Two severe solicited systemic adverse events occurred following the second vaccination: fever in one participant in the ages 56-70 cohort who received the 25 µg dose and fatigue in one participant in the ages 71+ cohort who received the 100 µg dose. Clinical laboratory values of Grade 2 or higher revealed no pattern of concern. Participants will continue to be followed through 13-months to allow for a longer assessment of vaccine-related adverse events.

At both the 25 µg and 100 µg dose levels, after two vaccinations, mRNA-1273 induced dose-dependent binding antibody responses reaching the upper quartile of the distribution of convalescent sera. At Day 57 (1 month post-dose 2), geometric mean titers (GMT) exceeded the median of those seen in convalescent sera from 41 individuals with confirmed COVID-19 diagnosis.

Neutralizing activity was assessed with multiple assays, including a PsVNA against the two most common SARS-CoV-2 variants (614D and 614G) and three live-virus neutralization assays (SARS-CoV-2 nanoluciferase high-throughput neutralization assay [nLUC HTNA]), focus reduction neutralization test mNeonGreen [FRNT-mNG] and PRNT. No participants had detectable neutralizing responses by any assay prior to vaccination, and robust neutralizing activity was observed in all participants 14 days after the second vaccination.

Pseudovirus neutralization responses were observed as early as seven days after the second vaccination and were dose-dependent across all age groups (18-55, 56-70 and 71+). At Day 43 at the 100 µg dose level, PsVNA ID50 titers in the older adult cohorts ages 56-70 (GMT 402) and 71+ (GMT 317) were comparable to those seen in the age 18-55 cohort (GMT 360), and 3- to 4-fold higher than those seen in convalescent sera (GMT 106). Titers remained high through four weeks after the second dose in all age cohorts. Neutralizing activity against the 614G variant was also observed at the 100 µg dose in all age cohorts.

Results were consistent using three live virus assays. Neutralizing antibody titers as measured by nLUC HTNA and FRNT-mNG were similar across all age groups (18-55, 56-70 and 71+). At Day 43, PRNT80 GMT in the 100 µg dose groups was 878 in the 56-70 and 317 in the 71+ age cohort, representing 5.5 and 2.0-fold above convalescent sera respectively, and 4.1-fold above convalescent sera in the 18-55 age group (GMT 654).

The 25 µg dose in the 56-70 age cohort and the 100 µg dose level across all age groups (18-55, 56-70 and 71+) elicited a strong Th1-biased CD4 T cell response.

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, and the study was fully enrolled with 30,000 participants on October 22, 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.

On October 13, 2020, we announced the initiation of a rolling submission of data to Health Canada for mRNA-1273.

On October 14, 2020, we announced that we received written confirmation from the European Medicines Agency (EMA) that mRNA-1273 is eligible for submission of an application for a European Union Marketing Authorization under the EMA's centralized procedure.

On October 27, 2020, we announced the initiation of a rolling submission of data to the Medicines and Healthcare products Regulatory Agency in the United Kingdom for mRNA-1273.

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, and we subsequently entered into a Global Long Term Agreement with Lonza on September 4, 2020. 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):** Positive interim data from the Phase 2 study assessing the safety, reactogenicity, and immunogenicity of different dose levels of mRNA-1647 were announced in September 2020. mRNA-1647 was generally safe and well tolerated. After the first vaccination, injection site pain was the most commonly reported solicited local adverse reaction (AR). The most common solicited systemic ARs were headache, fatigue, and myalgia in both CMV-seronegative and CMV-seropositive mRNA-1647 treatment groups. No serious adverse events (SAEs) were reported and no unsolicited events leading to study discontinuation occurred. After the second vaccination, the rate and severity distribution of solicited ARs in the CMV-seronegative and CMV-seropositive mRNA-1647 treatment groups were generally similar. In CMV-seronegative participants, neutralizing antibody titers against epithelial cell infection were boosted to at least 12-fold over the baseline geometric mean titer (GMT) of CMV-seropositive participants. Neutralizing antibody titers against fibroblast infection were generally equivalent to the baseline GMT in CMV-seropositive participants. In CMV-seropositive participants, neutralizing antibody titers in the epithelial cell infection were boosted to GMTs at least 20-fold to greater than 32-fold over the respective baseline GMT after the second vaccination. Neutralizing antibody titers against fibroblast infection boosted to levels at least 2-fold over the respective baseline GMT. Based on the interim analysis of the Phase 2 study, the 100 µg dose has been chosen for the Phase 3 pivotal study, expected to begin in 2021. We own worldwide commercial rights for mRNA-1647.
- **hMPV/PIV3 vaccine (mRNA-1653):** The first 10 subjects in the Phase 1b age de-escalation clinical trial of mRNA-1653 were enrolled and dosed prior to a COVID-19 related pause. Further enrollment and dosing of pediatric participants has now restarted.
- **Pediatric respiratory syncytial virus (RSV) vaccine (mRNA-1345):** The Phase 1 age de-escalation clinical trial of mRNA-1345 is ongoing. On October 8, 2020, we announced that the initiation of dosing had begun. The first cohort was enrolled and dosed in October. We intend to combine mRNA-1345 with mRNA-1653, our vaccine against hMPV and PIV3, to create a combination vaccine against RSV, hMPV and PIV3. There is no approved vaccine for RSV. We own worldwide commercial rights to mRNA-1345.

- **Seasonal influenza (flu):** On September 17, 2020, we announced our intention to develop a seasonal flu vaccine. Seasonal flu (type A and type B) epidemics occur seasonally and vary in severity each year, causing respiratory illnesses and placing substantial burden on healthcare systems. Currently approved vaccines are approximately 40-60% effective in certain populations and face significant challenges from strain mismatch; high-risk groups would benefit from higher efficacy, which we believe our mRNA platform may be capable of delivering.
- **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 dosing patients.
- **Antibody against Chikungunya virus (mRNA-1944):** Positive interim data from the Phase 1 study evaluating escalating doses of mRNA-1944 in the 0.6 mg/kg dose with steroid premedication cohort and two doses of 0.3 mg/kg (without steroid premedication) given one-week apart cohort were announced in September 2020. mRNA-1944 was generally safe and well tolerated. No SAEs were reported; the most common adverse events were headache, nausea, myalgia, dizziness and chills. Administration of mRNA-1944 resulted in dose-dependent increases in levels of antibody against chikungunya (CHIKV-24). Neutralizing antibodies were observed at all dose levels, indicating functional antibody production by mRNA-1944. Safety and increased CHIKV-IgG production in the two-dose regimen shows the platform's ability for repeat dosing.
- **Propionic acidemia (PA) (mRNA-3927):** Due to the COVID-19 pandemic, we paused new enrollment and new site initiation for its Phase 1/2 study of mRNA-3927 to ensure the safety of pediatric patients and their caregivers. During the pause, we implemented changes that we believe will ultimately help to accelerate clinical development including a protocol amendment implementing a novel design to identify the optimal dose in the most efficient manner and to make the study less burdensome on patients, their families and clinical partners. Study start-up activities have resumed. mRNA-3927 uses the same LNP formulation as mRNA-1944.
- **Methylmalonic Acidemia (MMA) (mRNA-3705):** Due to the COVID-19 pandemic, we paused new enrollment and new site initiation for the Phase 1/2 study of our prior therapeutic candidate for MMA, mRNA-3704, in order to ensure the safety of pediatric patients and their caregivers. During the pause, we implemented changes that we believe will ultimately help to accelerate clinical development including the introduction of a new drug product with better pharmacology (designated mRNA-3705) as well as a protocol revision to enhance operational performance and reflecting input from the patient and caregiver community. We plan to file new IND and CTA applications for mRNA-3705 and will focus development efforts on that candidate going forward. mRNA-3705 uses the same LNP formulation as mRNA-1944. We own worldwide commercial rights to mRNA-3705.

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 government-sponsored and private organizations including BARDA, DARPA and the Gates Foundation and from strategic alliances with AstraZeneca, Merck and Vertex to discover, develop, and commercialize potential mRNA medicines.

Total revenue for the three and nine months ended September 30, 2020 was \$157.9 million and \$232.7 million, respectively. Total revenue for the three and nine months ended September 30, 2019 was \$17.0 million and \$46.2 million, respectively. In each period, total revenue was comprised of grant revenue and collaboration revenue.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Grant revenue:				
BARDA	\$ 143,318	\$ 1,135	\$ 183,134	\$ 4,500
Other	2,376	2,573	4,401	4,171
Total grant revenue	<u>\$ 145,694</u>	<u>\$ 3,708</u>	<u>\$ 187,535</u>	<u>\$ 8,671</u>

Collaborative revenue from our strategic alliances was comprised as follows for the periods presented (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Collaboration revenue:				
AstraZeneca	\$ 48	\$ 3,724	\$ 17,202	\$ 4,726
Merck	6,718	9,110	18,060	28,456
Vertex	5,450	504	9,698	4,301
Other	—	—	155	—
Total collaboration revenue	<u>\$ 12,216</u>	<u>\$ 13,338</u>	<u>\$ 45,115</u>	<u>\$ 37,483</u>

Cash received from strategic alliances was \$85.2 million and \$15.9 million for the nine months ended September 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 September 30, 2020 and December 31, 2019 was \$266.2 million and \$199.5 million, respectively.

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 us 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 may 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 nine months ended September 30, 2020 and 2019 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Program expenses by modality:				
Prophylactic vaccines	\$ 163,390	\$ 5,666	\$ 207,787	\$ 38,326
Cancer vaccines	8,047	10,346	24,166	33,807
Intratumoral immuno-oncology	3,486	4,205	6,962	11,398
Localized regenerative therapeutics	4	1	4	17
Systemic secreted and cell surface therapeutics	575	1,296	1,845	10,413
Systemic intracellular therapeutics	3,209	5,039	15,639	21,611
Total program-specific expenses by modality ⁽¹⁾	178,711	26,553	256,403	115,572
Other research and development expenses:				
Discovery programs	16,722	13,829	37,449	42,379
Platform research	23,856	21,940	64,101	70,693
Technical development and unallocated manufacturing expenses	78,605	29,294	137,027	68,800
Shared discovery and development expenses	32,570	15,405	75,738	44,643
Stock-based compensation	14,022	12,616	40,761	36,268
Total research and development expenses	\$ 344,486	\$ 119,637	\$ 611,479	\$ 378,355

⁽¹⁾ Include a total of 23 and 21 development candidates at September 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 continue 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 BARDA agreement to accelerate development of mRNA-1273, our revenue and expenses are expected to continue 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 establishment of commercial activities both within and outside the United States. We have already incurred additional expenses related to building out a regulatory, sales and marketing team to support the sale, marketing and distribution of mRNA-1273 in anticipation of its potential approval. If we obtain regulatory approval for mRNA-1273 or any of our other investigational medicines, and do not enter into one or more third-party commercialization collaboration and manufacturing arrangements, we will incur significant additional expenses related to building out these functions.

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 \$48.5 million and \$109.3 million for the three and nine months ended September 30, 2020, respectively. General and administrative expenses, including IP-related expenses, were \$28.2 million and \$83.9 million for the three and nine months ended September 30, 2019, respectively. IP-related expenses, including our internal personnel-related costs, were \$4.1 million and \$9.7 million for the three and nine months ended September 30, 2020,

respectively. IP-related expenses, including our internal personnel-related costs, were \$3.7 million and \$10.9 million for the three and nine months ended September 30, 2019, respectively.

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 leases related to our Moderna Technology Center manufacturing facility, or MTC South, and Moderna Technology Center North, or MTC North.

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 and nine months ended September 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 September 30,		Change 2020 vs. 2019	
	2020	2019	\$	%
Revenue:				
Grant revenue	\$ 145,694	\$ 3,708	\$ 141,986	3829%
Collaborative revenue	12,216	13,338	(1,122)	(8)%
Total revenue	157,910	17,046	140,864	826%
Operating Expenses:				
Research and development	344,486	119,637	224,849	188%
General and administrative	48,541	28,173	20,368	72%
Total operating expenses	393,027	147,810	245,217	166%
Loss from operations	(235,117)	(130,764)	(104,353)	80%
Interest income	5,571	9,252	(3,681)	(40)%
Other expense, net	(3,226)	(1,881)	(1,345)	72%
Loss before income taxes	(232,772)	(123,393)	(109,379)	89%
Provision for (benefit from) income taxes	864	(178)	1,042	(585)%
Net loss	\$ (233,636)	\$ (123,215)	\$ (110,421)	90%

	Nine Months Ended September 30,		Change 2020 vs. 2019	
	2020	2019	\$	%
Revenue:				
Grant revenue	\$ 187,535	\$ 8,671	\$ 178,864	2063%
Collaboration revenue	45,115	37,483	7,632	20%
Total revenue	232,650	46,154	186,496	404%
Operating Expenses:				
Research and development	611,479	378,355	233,124	62%
General and administrative	109,277	83,913	25,364	30%
Total operating expenses	720,756	462,268	258,488	56%
Loss from operations	(488,106)	(416,114)	(71,992)	17%
Interest income	20,515	30,546	(10,031)	(33)%
Other expense, net	(5,910)	(5,689)	(221)	4%
Loss before income taxes	(473,501)	(391,257)	(82,244)	21%
Provision for (benefit from) income taxes	1,078	(526)	1,604	(305)%
Net loss	\$ (474,579)	\$ (390,731)	\$ (83,848)	21%

Revenue

Total revenue increased by \$140.9 million, or 826%, for the three months ended September 30, 2020 compared to the same period in 2019, primarily due to an increase in grant revenue, slightly offset by a decrease in collaboration revenue. Grant revenue increased by \$142.0 million for the three months ended September 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. Collaboration revenue decreased by \$1.1 million for the three months ended September 30, 2020 compared to the same period in 2019, primarily driven by decreases in revenue from AstraZeneca and Merck as the delivery of drug materials and costs incurred under the collaboration agreements decreased in the third quarter of 2020, partially offset by an increase in revenue from Vertex attributable to increased reimbursable costs during the period.

Total revenue increased by \$186.5 million, or 404%, for the nine months ended September 30, 2020 compared to the same period in 2019, due to increases in both collaboration revenue and grant revenue. Grant revenue increased by \$178.9 million for the nine months ended September 30, 2020 compared to the same period in 2019, mainly driven by an increase in revenue from BARDA related to our mRNA-1273 vaccine candidate development. Collaboration revenue increased by \$7.6 million for the nine months ended September 30, 2020 compared to the same period in 2019, mainly attributable to increases in revenue from AstraZeneca and Vertex, partially offset by a decrease in revenue from Merck as the delivery of drug materials and costs incurred under the collaboration agreements decreased in 2020.

Operating expenses

Research and development expenses

Research and development expenses increased by \$224.8 million, or 188%, for the three months ended September 30, 2020 compared to the same period in 2019. The increase was primarily attributable to an increase in clinical trial expenses of \$104.5 million, an increase in raw materials and manufacturing costs of \$50.2 million, an increase in personnel-related costs of \$27.4 million, an increase in consulting and outside services of \$23.0 million and an increase of information technology (IT) and facility-related costs of \$14.4 million.

Research and development expenses increased by \$233.1 million, or 62%, for the nine months ended September 30, 2020 compared to the same period in 2019. The increase was primarily attributable to an increase in clinical trial expenses of \$104.4 million, an increase in personnel-related costs of \$42.9 million, an increase in consulting and outside services of \$34.2 million, an increase in raw materials and manufacturing costs of \$30.5 million, an increase in IT and facility-related expenses of \$16.5 million and an increase in stock-based compensation of \$4.5 million.

The increases for both the three- and nine-month periods in 2020 were largely attributable to increased mRNA-1273 clinical development and headcount and pre-launch inventory buildup.

General and administrative expenses

General and administrative expenses increased by \$20.4 million, or 72%, for the three months ended September 30, 2020 compared to the same period in 2019. The increase was mainly due to an increase in personnel-related costs of \$9.8 million, an increase in legal-related costs of \$6.4 million and an increase in consulting and outside services of \$5.1 million. These increases were partially offset by a decrease in IT and facility-related expenses of \$2.4 million.

General and administrative expenses increased by \$25.4 million, or 30%, for the nine months ended September 30, 2020 compared to the same period in 2019. The increase was mainly due to an increase in personnel-related costs of \$13.6 million, an increase in legal-related costs of \$8.4 million, an increase in consulting and outside services of \$2.8 million and an increase in stock-based compensation of \$2.3 million. These increases were partially offset by a decrease in IT and facility-related expenses of \$2.6 million.

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

Interest income

Interest income decreased by \$3.7 million, or 40%, for the three months ended September 30, 2020 compared to the same period in 2019. Interest income decreased by \$10.0 million, or 33%, for the nine months ended September 30, 2020 compared to the same period in 2019. The decreases in interest income from our investments in marketable securities for both the three- and nine-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 September 30,		Change 2020 vs. 2019	
	2020	2019	\$	%
Gain on investments	\$ 211	\$ 79	\$ 132	167%
Interest expense	(2,834)	(1,657)	(1,177)	71%
Other expense, net	(603)	(303)	(300)	99%
Total other expense, net	<u>\$ (3,226)</u>	<u>\$ (1,881)</u>	<u>\$ (1,345)</u>	72%

	Nine Months Ended September 30,		Change 2020 vs. 2019	
	2020	2019	\$	%
Gain on investments	\$ 1,102	\$ 93	1,009	1085%
Interest expense	(6,378)	(4,955)	(1,423)	29%
Other expense, net	(634)	(827)	193	(23)%
Total other expense, net	<u>\$ (5,910)</u>	<u>\$ (5,689)</u>	<u>\$ (221)</u>	4%

Total other expense, net remained relatively flat for the three and nine months ended September 30, 2020, compared to the same periods in 2019. Our interest expense is primarily related to our finance leases.

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 September 30, 2020, we had cash, cash equivalents and investments of \$3.97 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 September 30, 2020, we had current and non-current investments of approximately \$1.77 billion and \$692.0 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 \$34.6 million and \$3.9 million for the nine months ended September 30, 2020 and 2019, respectively. Cash disbursements related to our MTC facilities were \$30.1 million and \$14.4 million for the nine months ended September 30, 2020 and 2019.

In February 2020, we completed a public equity offering of 30,263,158 shares of common stock, including the underwriters' exercised over-allotment option, at a price of \$19.00 per share. The aggregate net proceeds from the offering were \$549.5 million, net of underwriting discounts, commissions and offering expenses.

In May 2020, we completed a public equity offering of 17,600,000 shares of common stock, at a price of \$76.00 per share. The aggregate net proceeds from the offering were \$1.30 billion, net of underwriting discounts, commission and offering expenses.

We have used and intend to use the net proceeds from these equity offerings: (i) to fund working capital needs (raw materials, labor and capital equipment purchases) related to the manufacturing of mRNA-1273 for distribution in the United States and outside the United States, assuming necessary regulatory approvals are obtained and the remainder, if any, (ii) to fund clinical development and drug discovery in existing and new therapeutic areas, (iii) to fund further development of our mRNA technology platform and the creation of new modalities, or (iv) to fund working capital and other general corporate purposes.

In the third quarter of 2020, we entered into supply agreements with the U.S. Government and several other governmental agencies outside the United States related to the potential sale of doses of mRNA-1273, our vaccine candidate against COVID-19. To date, we have received deposits of \$1.17 billion based on these agreements.

As we pursue the rapid clinical testing and manufacture of mRNA-1273, we continue to commit financial resources and personnel to the development of this vaccine.

Cash flow

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

	Nine Months Ended September 30,	
	2020	2019
Net cash provided by (used in):		
Operating activities	\$ 762,682	\$ (359,946)
Investing activities	(1,481,799)	(145,293)
Financing activities	1,989,084	20,282
Net increase (decrease) in cash, cash equivalents and restricted cash	\$ 1,269,967	\$ (484,957)

Operating activities

We derive cash flows from operations primarily from cash collected from certain government-sponsored and private organizations and 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 may 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 provided by operating activities for the nine months ended September 30, 2020 was \$762.7 million and consisted of net loss of \$474.6 million and non-cash adjustments of \$96.4 million, plus a net change in assets and liabilities of \$1.14 billion. Non-cash items primarily included stock-based compensation of \$67.5 million, depreciation and amortization of \$23.5 million, and amortization of investment premium and discount of \$5.1 million. The net change in assets and liabilities was due to an increase in deferred revenue of \$1.24 billion, an increase in accrued liabilities of \$132.4 million, an increase in operating lease liabilities of \$14.4 million, an increase in accounts payable of \$13.6 million and an increase in other liabilities of \$6.7 million, partially offset by an increase in accounts receivable of \$185.1 million, an increase in prepaid expenses and other assets of \$68.0 million, and an increase in right-of-use assets related to operating leases of \$13.1 million.

Net cash used in operating activities for the nine months ended September 30, 2019 was \$359.9 million and consisted of net loss of \$390.7 million and non-cash adjustments of \$79.4 million, minus a net change in assets and liabilities of \$48.7 million. Non-cash items primarily included stock-based compensation of \$60.8 million, depreciation and amortization of \$22.0 million and amortization of investment premium and discount of \$3.4 million. The net change in assets and liabilities was primarily due to a decrease in deferred revenue of \$32.8 million, a decrease in accounts payable of \$19.2 million, a decrease in accrued liabilities of \$8.3 million and an increase of right-of-use assets relating to operating leases of \$8.0 million, partially offset by an increase in operating lease liabilities of \$13.5 million, a decrease in accounts receivable of \$4.4 million, and a decrease in prepaid expense and other assets of \$1.8 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 nine months ended September 30, 2020 was \$1.48 billion, which included purchases of marketable securities of \$2.33 billion and purchases of property and equipment of \$44.1 million, partially offset by proceeds from maturities of marketable securities of \$748.2 million and proceeds from sales of marketable securities of \$140.3 million.

Net cash used in investing activities for the nine months ended September 30, 2019 was \$145.3 million, which included purchases of marketable securities of \$949.3 million and purchases of property and equipment of \$24.9 million, partially offset by proceeds from maturities of marketable securities of \$747.8 million and proceeds from sales of marketable securities of \$81.0 million.

Financing activities

We generated cash from financing activities of \$1.99 billion for the nine months ended September 30, 2020, primarily from net proceeds from equity offerings of \$1.85 billion, net proceeds from the issuance of common stock through our equity plans of \$133.4 million and proceeds from purchase of common stock under employee stock purchase plan of \$2.9 million.

We generated cash from financing activities of \$20.3 million for the nine months ended September 30, 2019, primarily from net proceeds from the issuance of common stock through our equity plans of \$19.5 million.

Operation and funding requirements

Since our inception, we have incurred significant losses and negative cash flows from operations due to our significant research and development expenses. We have an accumulated deficit of \$1.97 billion as of September 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 September 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 September 30, 2020, other than disclosed at Note 8 and Note 9 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 September 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 September 30, 2020 and December 31, 2019, we had cash, cash equivalents, and investments in marketable securities of \$3.97 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 September 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 September 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 September 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 September 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 August 6, 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 been adversely affected, including 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) (for which we are pursuing a new IND), propionic acidemia (mRNA-3927) and in our infectious disease candidate, hMPV/PIV3 (mRNA-1653). 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, most of our administrative employees are continuing their work outside of our offices, and on-site staff has largely been restricted to those employees whose presence in the office is required to execute their job responsibilities. Certain of our employees conducting non-essential research and development or manufacturing activities also continue to perform their work remotely outside our laboratory or manufacturing space. Our employees' productivity, collaboration and effectiveness may be negatively impacted to the extent they are not able to return to the workplace 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 have difficulty meeting 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, prospects, 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 against which our vaccine, if developed, may not be partially or fully effective, and may ultimately prove unsuccessful or unprofitable. Furthermore, notwithstanding our entry into supply agreements for mRNA-1273 with the U.S. and foreign governments, there are no assurances that our vaccine will be approved for distribution and commercial use, 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 AstraZeneca, GlaxoSmithKline/Sanofi, Johnson & Johnson, Novavax and Pfizer/BioNTech. 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 continue 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 or emergency approval of any vaccine against COVID-19 remains uncertain, 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, 2 or 3 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 interim analyses of the limited number of subjects in three age strata (ages 18-55, 56-70 and >71) enrolled in 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 immunogenicity as compared to the interim Phase 1 study results or that the neutralizing antibodies are not sufficiently durable without repeated boosting. In addition, the correlation between levels of neutralizing antibodies and the level of vaccine efficacy is currently unknown. We also may observe new, more frequent or adverse events of greater severity in subjects participating in these ongoing clinical studies. In addition, the interpretation of the data from our clinical trials of mRNA-1273 by the 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 estimate the effectiveness of vaccine candidates being developed to prevent COVID-19 have only recently been developed and are continuing to evolve. The validity and standardization of these assays has not yet been established. 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 our 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 by the FDA for mRNA-1273, we would be able to distribute mRNA-1273 under the conditions set forth in the Emergency Use Authorization 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 21 development candidates with 13 having entered clinical studies. 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 September 30, 2020, we had approximately \$3.97 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 September 30, 2020, we had an accumulated deficit of \$1.97 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, Basel, Switzerland, and in other global regions where we have established and may continue to 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 contract research organizations, or 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. In addition, as we did in our Phase 3 clinical study of mRNA-1273 in September 2020, we may slow enrollment in a trial to focus on achieving greater diversity in the subject population. 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 (MED11191) 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 hMPV/PIV3 vaccine (mRNA-1653), pediatric RSV vaccine (mRNA-1345), PA development candidate (mRNA-3927) and MMA development candidate (mRNA-3705). The first pediatric subjects in the Phase 1b age de-escalation clinical trial of mRNA-1653 have been enrolled and dosed. During the COVID-19 related pause, the Safety Monitoring Committee reviewed a preliminary data set on these small initial group of pediatric patients and recommended continuation of the study with no modification in the planned trial execution. Our PA development candidate (mRNA-3927) for which we are conducting a first-in-human Phase 1/2 trial in patients between one and eighteen years of age has resumed study start up activities. If participants are enrolled in the trial and successfully dosed, they 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 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, most of which are 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. Most of 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 or in the commercialization of any approved product.

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, including mRNA-1273. 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 or other strategic collaborators, 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 personalized cancer vaccine, or 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 we are in the process of establishing infrastructure for sales, marketing, and 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 and for our manufacturing processes. 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 relief 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.

In addition, we may choose not to enforce our intellectual property rights in certain circumstances or for certain periods of time. For example, in October 2020 we announced that while the COVID-19 pandemic continues, we will not enforce our COVID-19 related patents against those making vaccines intended to combat the pandemic. We also noted that to eliminate any perceived intellectual property barriers to vaccine development during the pandemic period, upon request we are also willing to license our intellectual property for COVID-19 vaccines to others for the post pandemic period. However, we may never enter into such licenses of our intellectual property for the post-pandemic period, and our business may be otherwise adversely impacted by our decision not to enforce this intellectual property during the pandemic.

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 governmental 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 the commercialization of our pipeline

****We have no sales, distribution, or marketing experience, and may invest significant financial and management resources to establish these capabilities, particularly as we prepare for the potential commercialization of mRNA-1273. 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.***

mRNA-1273 represents the first product that we might sell, distribute and market. To enable the potential successful commercialization of mRNA-1273 and other products that may result from our development programs, we are investing in the development of sales, marketing, distribution, managerial and other non-technical capabilities in the United States, Europe, and other regions, both on our own and 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. For example, we announced in September 2020 that we plan to develop a vaccine for the seasonal flu. Although we believe there is an unmet need for a highly effective seasonal flu vaccine, this is a well-developed market and we may not be successful in either developing a successful product or achieving a market share for our product that justifies our investment. 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 or will lose employer-based insurance coverage, which may adversely affect our ability to commercialize our products. 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. Additionally, on July 24, 2020, President Trump signed four Executive Orders aimed at lowering drug prices. The Executive Orders direct the Secretary of HHS to: (1) eliminate protection under an Anti-Kickback Statute safe harbor for certain retrospective price reductions provided by drug manufacturers to sponsors of Medicare Part D plans or pharmacy benefit managers that are not applied at the point-of-sale; (2) allow the importation of certain drugs from other countries through individual waivers, permit the re-importation of insulin products, and prioritize finalization of the FDA's December 2019 proposed rule to permit the importation of drugs from Canada; (3) ensure that payment by the Medicare program for certain Medicare Part B drugs is not higher than the payment by other comparable countries (depending on whether pharmaceutical manufacturers agree to other measures); and (4) allow certain low-income individuals receiving insulin and epinephrine purchased by a Federally Qualified Health Center, or FQHC, as part of the 340B drug program to purchase those drugs at the discounted price paid by the FQHC. On September 13, 2020, President Trump signed an Executive Order directing HHS to implement a rulemaking plan to test a payment model, pursuant to which Medicare would pay, for certain high-cost prescription drugs and biological products covered by Medicare Part B, no more than the most-favored-nation price (i.e., the lowest price) after adjustments, for a pharmaceutical product that the drug manufacturer sells in a member country of the Organization for Economic Cooperation and Development that has a comparable per-capita gross domestic product. Although a number of these, and other proposed measures will require authorization through additional legislation to become effective, Congress and the current administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. 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 federal, 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, or MMA, contains provisions that call for the promulgation of regulations that expand pharmacists' and wholesalers' ability to import cheaper versions of an approved drug and competing products from Canada, where there are government price controls. Further, the MMA provides that these changes to U.S. importation laws will not take effect unless and until the Secretary of 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 September 23, 2020, the Secretary of HHS made such certification to Congress, and on October 1, 2020, the FDA published a final rule that allows for the importation of certain prescription drugs from Canada. Under the final rule, States and Indian Tribes, and in certain future circumstances pharmacists and wholesalers, may submit importation program proposals to the FDA for review and authorization. On September 25, 2020, CMS stated drugs imported by States under this rule will not be eligible for federal rebates under Section 1927 of the Social Security Act and manufacturers would not report these drugs for "best price" or Average Manufacturer Price purposes. Since these drugs are not considered covered outpatient drugs, CMS further stated it will not publish a National Average Drug Acquisition Cost for these drugs. Separately, the FDA also issued a final guidance document outlining a 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 market implications of the final rule and 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 inseparable 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 scheduled oral arguments for November 10, 2020. 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 Bipartisan Budget Act of 2018, 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 September 30, 2020, we had approximately 1,100 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 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. 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 personally identifiable data, including health data and medical data (personal data) in the European Union is regulated by the GDPR, which became effective on May 25, 2018. The GDPR applies to personal data processed in connection with clinical trial activities in EU 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. The GDPR grants individuals the opportunity to object to the processing of their personal data, allows them to exercise certain data subject requests, including to request deletion of personal data in certain circumstances, and provides the individual with an express right to seek legal recourse 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 may result in monetary penalties of up to €20 million or 4% of annual worldwide revenue, whichever is higher. In addition to risking such fines for any failure to comply with the GDPR, we may require substantial costs in connection with our efforts to put in place additional mechanisms ensuring compliance with European data protection requirements.

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 government-mandated or voluntary recall by us or our strategic collaborators 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 September 30, 2020, we had approximately \$3.97 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 Internal Revenue 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 Internal Revenue 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 September 30, 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.” Our management and other personnel will need to continue 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 Quarterly Report.

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 21.2% 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 on May 24, 2020, June 16, 2020, July 25, 2020, August 31, 2020 and September 15, 2020
10.2*†	Global Long Term Agreement, by and among ModernaTX Inc., Lonza Sales Ltd., and Lonza Ltd., dated September 4, 2020
10.3*†	Award Contract No. W911QY20C0100, by and between Moderna US Inc. and the Army Contracting Command of the U.S. Department of Defense, dated August 9, 2020, as amended September 8, 2020 and September 11, 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.

Date:
October 30, 2020

Date:
October 30, 2020

MODERNA, INC.

By: /s/ Stéphane Bancel

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

By: /s/ David W. Meline

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

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PART I – THE SCHEDULE

B. SUPPLIES/SERVICES AND COST/PRICE

B.1 Brief Description of Supplies/Services

The Department of Health and Human Services (HHS), Office of the Assistant Secretary for Preparedness and Response (ASPR), Biomedical Advanced Research and Development Authority (BARDA) requires the contractor(s) to develop a mRNA vaccine to licensure for the prevention of COVID-19. The project will entail pre-clinical and Phase 2 and Phase 3 clinical studies sufficient to demonstrate the safety and efficacy of the proposed vaccine(s); CMC development, scale-up, scale-out and validation of manufacturing capacities, including bulk drug substance and fill and finished drug product, with a capacity of 100 million doses by 2021 and all program management and regulatory activities necessary to achieve FDA licensure of the vaccine. The project shall be accomplished on an accelerated timeline, with parallel activity WBS, aggressive manufacturing scale-up, risk management, and taking advantage of any regulatory flexibilities. Contract terms include a requirement for domestic production of vaccine and assurance of material sourcing for vaccine production during execution of the project.

B.2 Price/Cost

This contract contains the price/cost provisions agreed upon by the Government and the Contractor.

B.2.1 Contract Budget Ceiling

The contract has a cost/price ceiling that the Contractor exceeds at its own risk. The Contractor is responsible for managing its performance in accordance with the final scope of work and costs/prices incorporated into the contract. The Government is not obligated to reimburse the Contractor for costs incurred in excess of costs/prices agreed upon at time of award. The contract ceiling is \$483,298,520.00.

B.2.2 Contract Periods

This contract consists of pre-award cost (CLIN 0001), a base period for the Development of mRNA vaccine to BLA (CLIN 0002) and one (1) option period for the Domestic Manufacturing Scale-Out (CLIN 0003).

B.3 Contract Line Item Numbers (CLINs) Schedule

This is a Cost-Plus-Fixed-Fee (CPFF), contract.

B.3.1 Base Period of Performance

The base period of performance (POP) includes pre-award cost (CLIN 0001) and the Development of mRNA vaccine to BLA (CLIN 0002).

- a. CLIN 0001 costs shall be pre-award cost incurred by Moderna, with a do not exceed cost of [***].
- b. CLIN 0002 costs shall cover the base period statement of work that consists of the development of mRNA vaccine to BLA.
- c. These are cost-plus-fixed-fee CLINs with a CPFF structure, [***].
- d. Monies shall be provided for the total cost of performance from the Department of Health and Human Services.
- e. The Contractor shall maintain records of all contract costs and such records shall be subject to the Audit and Records-Negotiation clause.
- f. It is estimated that the amount currently allotted will cover performance of the contract through [***] for the base period.

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Pre-Award Period of Performance: [***]

Table 1

CLIN	Estimated Period of Performance	Supplies/Services	Estimated USG Cost	Management Fee (Profit)	Total
0001		Pre-Award Cost	[***]	[***]	[***]

Base Period of Performance: [***]

Table 2

CLIN	Estimated Period of Performance	Supplies/Services	Estimated USG Cost	Management Fee (Profit)	Total
0002		Development of mRNA vaccine to BLA	[***]	[***]	[***]

B.3.2 Option Period 1

This option period includes all Kit Build-Out activities for the facility under CLIN 0003, and may overlap with the base period.

CLIN 0003 is under a CPFF structure, [***]

CLIN	Estimated Period of Performance	Supplies/Services	Estimated USG Cost	Management Fee (Profit)	Total
0003		Domestic Manufacturing Scale-Out	[***]	[***]	[***]

B.3.3 Total Contract Value

The total potential value of this contract, including all CLINs 0001, 0002 and option CLIN 0003 is \$483,298,520.00.

B.4 Advanced Understandings

This contract contains advanced understandings between the Government and the Contractor. Specific elements of cost, which normally require prior written approval of the Contracting Officer before incurrence of the cost, will be included in this Section if the Contracting Officer has granted approval prior to contract award.

B.4.1 Rights of first refusal – mRNA Vaccines

[***]

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B.4.2 HHS reserves the right to exercise priorities and allocations authority with respect to this contract, to include rating this order in accordance with 45 CFR Part 101, Subpart A—Health Resources Priorities and Allocations System

B.4.3 Earned Value Management (EVM) Lite Requirements

The Contractor shall use an Earned Value Management (EVM) System for all retrofit and development activities of the anticipated requirement, that is consistent with the "7 Principles of Earned Value Management Tier 2 System Implantation Intent Guide" attached to this contract. Alternative systems may be submitted to the Contracting Officer for consideration and approval.

B.4.4 Public Readiness and Emergency Preparedness Act ("PREP ACT") Coverage

The Federal Government may not use, or authorize the use of, any products or materials provided under either this agreement or any future purchase from Recipient's domestic manufacturing capacity unless such use occurs in the United States and is protected from liability under a declaration issued under the Public Readiness and Emergency Preparedness Act, 42 U.S.C. § 247d-6d.

B.4.5 Provisions to Applicable Costs

This section prohibits or restricts the use of contract funds which includes the following items (costs unallowable unless otherwise approved by the Contracting Officer):

- a. Acquisition, by purchase or lease, of any interest in real property;
- b. Purchase or lease of any item of general purpose office furniture or office equipment regardless of dollar value;
- c. Accountable Government Property (as defined by HHS Government property policies)
- d. Overtime;
- e. General scientific meetings/conferences;
- f. Travel costs including foreign travel;
- g. Costs incurred in the performance of any cost-reimbursement type subcontract (including consulting agreements);
- h. Costs to be paid for the performance of a fixed-price subcontract that exceeds \$250,000.00 (for equipment purchases, \$25,000.00 per unit);
- i. Refreshments and Meal Expenditures;
- j. Promotional Items Printing;
- k. Payment of regulatory submission fees to the FDA or other U.S. regulatory agency;
- l. BLA licensing or renewal fees;
- m. Pre-contract costs (other than those expressly set forth herein).

B.4.6 Facility, Equipment and Product Ownership

In the event the USG terminates this contract for other than default, all Contractor-acquired Government Furnished Property (GFP) [as defined by 52.245-1], to include process equipment, is to be assessed by a reputable third party firm that specializes in assigning fair market value of biopharmaceutical materials, supplies and equipment for the resale market. The USG will use this fair market value assessment in settlement, around the disposition of the GFP.

Ownership and applicable usage rights of all materials/product (e.g. vaccines, validated lots) manufactured and/or acquired with Government funds, throughout the Contract's entire period of performance, shall be retained by the USG. The Contracting Officer will direct the Contractor on the disposition (i.e. storage, transfer, disposal, etc.) of all Contractor-acquired/manufactured USG materials/product.

B.4.7 [reserved] .

B.4.8 **Advanced Understanding: Milestone Review: the development of a COVID-19 vaccine is an** accelerated program. Progress for vaccine development will be continually assessed for go/no go decisions so that funding is properly allocated across the MCM development effort to those candidates most likely to be available in time to impact the COVID-19 public health emergency. Formal 'go/no go' assessments will be made at multiple points, including:
[***]

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B.4.9 Contractor Responsibility for Major Site Service & Utility System

BARDA acknowledges that Moderna is offering to undergo potential upgrades to its manufacturing processes as outlined in the Technical Proposal. A preliminary assessment of major site service and utility systems of Contractor's existing facility has deemed them adequate in supply and fitness to meet stated scope. However, if, during the course of executing this contract, Moderna discovers that major site service or utility replacement/upgrades at such facility are required to accomplish the scope of work, then the costs for said replacement/upgrades shall be covered by Moderna. As with any significant renovation Moderna has implied duty to disclose superior knowledge of site conditions. As contract work is performed, Moderna will ensure that the BARDA Contracting Officer's Representative (COR) is fully informed of all issues that could affect cost or schedule. BARDA commits to work with Moderna to assess specific complex situations.

Examples of major site-wide service/utility systems outside the envelope of Buildings to be warranted by Moderna:

- Plant steam supply;
- Potable water/ Non-potable water supply (depending on the site, non-potable water could be fire hydrants);
- Sewer line/Sanitation line (post inactivation/ treatment) ;
- Site chiller/ chilled water supply;
- High and Low voltage Electrical feed(s) ;
- Network Infrastructure;
- Site-wide automation capacity;
- Perimeter fencing/ site security;
- Storm water;
- Gas (natural gas, site gas feeds);
- Fuel (generator fuel piping, this may be out of scope);
- Earthwork required to relocate, improve, or maintain site infrastructure such as manholes, duct banks, etc.

All NEPA, state and local government environmental requirements are met for this project; any concerning issues have been disclosed to the USG before award.

B.4.10 Evaluating the Expansion of Surge Vaccine Manufacturing Capacity

The parties agree to develop and evaluate plans to further expand and diversify US-based domestic vaccine manufacturing capacity to respond to the pandemic. A draft framework will be completed within 60 days. This CMC domestic build-out/scale-out will further ensure that the United States has sufficient manufacturing capacity in response to the pandemic.

B.4.11 Subcontracts

Prior written consent from the Contracting Officer in the form of Contracting Officer Authorization (COA) is required for any subcontract that:

- Is of the cost-reimbursement type; or
- Is Fixed-Price and exceeds \$250,000 or 5% of the total estimated cost of the Contract, whichever value is greater.

The Contracting Officer shall request appropriate supporting documentation in order to review and determine authorization, pursuant with FAR Clause 52.244-2, Subcontracts. After receiving written consent of the subcontract by the Contracting Officer, the Contractor shall provide a copy of the signed, executed subcontract and consulting agreement to the Contracting Officer.

On March 13, 2020, the U.S. President declared a national emergency due to the outbreak of the coronavirus. The subcontractors and consultants listed below are currently engaged in the mRNA-1273 development program and are tentatively approved to continue work. These subcontractors must complete the COA process per FAR Clause 52.244-2 within 90 days. New vendors initiating work within the first 60 days of the contract will be allowed to start, and COA requests will be submitted within 90 days.

Note: Consulting services are treated as subcontracts and subject to the 'consent to subcontract' provisions set forth in this Article.

[***]

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[***]

B.4.12 Performance Standard

The contractor will not be in default under this agreement to the extent that it makes reasonable efforts to perform the services and produce and provide the items described in this contract.

B.4.13 Limited Rights Data

Notwithstanding any contrary representation by the Contractor on the System for Award Management or any contrary provision in this contract, the following categories of information developed at private expense will, if provided to the Government, be considered limited rights data subject to the restrictions specified in FAR 52.227-14, Alternate II. These restrictions apply to any component of information covered by this provision, regardless of whether a component is included in a contract deliverable. The Government will not reverse engineer or otherwise evaluate materials provided under this Contract to reproduce the type of information described below without Moderna's prior written consent.

[***]	[***]	[***]
[***]	[***]	[***]
[***]		
[***]		
[***]		
[***]		
[***]		
[***]		
[***]		

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C. DESCRIPTION / SPECIFICATIONS / WORK STATEMENT

C.1 Background

Coronaviruses are potential epidemic threats and have been recognized on the World Health Organization's list of top emerging diseases likely to cause major epidemics and Coalition for Epidemic Preparedness Innovations priority pathogens list. No vaccines to prevent Coronavirus infection are currently available. The emergence of the SARS-CoV-2 virus creates an urgent need to rapidly develop vaccines to prevent COVID-19 disease. Developing and delivering a vaccine for highly transmissible, emerging diseases such as the SAR-CoV-2 virus requires breaking from traditional approaches. It requires parallel development activities, aggressive manufacturing scale-up, risk management and implementation of regulatory flexibilities. Many of these requirements are met by manufacturing 'platforms' that are capable of producing vaccines against different agents using essentially the same manufacturing systems. Suitable platforms are constituted by defined product production processes that allow significant planning for manufacturing scale and time to vaccine availability and will be supported by human safety and immunogenicity data targeting an one or more infectious agents. To meet the purposes of this contract, it is critical that the vaccine be produced in the United States. Domestic production of the vaccine is the only assurance that Americans will have access to the finished product.

Moderna's mRNA-based vaccine platform has been used to rapidly prepare vaccine candidates against Cytomegalovirus, Zika, Respiratory Syncytial Virus, Influenza, Human Metapneumovirus and Parainfluenza virus. Four of these candidates have been evaluated in Phase 1 clinical studies and shown to be safe and immunogenic. Moderna collaborated with the Vaccine Research Center, NIAID ("VRC/NIAID") to design a lead SARS-CoV-2 vaccine candidate encoding a stabilized pre-fusion, SARS-CoV-2 Spike protein, which is more immunogenic than wild-type or subunit proteins. Moderna's mRNA vaccine is currently being evaluated in pre-clinical studies and Phase 1 trials sponsored by the NIAID. For the purposes of this contract, Moderna will perform all work required to support the advanced development, scale-up manufacturing and FDA licensure of their lead SARS-CoV-2 vaccine candidate(s). This work includes preclinical development of mRNA vaccines to demonstrate safety and efficacy against COVID-19, mRNA vaccine process and manufacturing scale-up development, product lot release assay development and process validation, production of clinical material and consistency lots clinical evaluation studies for safety, immunogenicity and efficacy; and fill/finish capacity evaluation, expansion, and validation.

The Governments has determined a bona fide need for each non-severable discrete work segment which will conclude upon the completion of a defined task(s) that provides independent merit and value to the Government. The Contractor must achieve a defined end-point required in each discrete work segment, as outlined in Section F of this contract, before the Government will consider exercising any of the follow-on option segment(s). The Contractor's success in completing the required tasks under each work segment must be demonstrated through the Deliverables and Milestones specified under Section B and F of this contract. Those deliverables will support the GO/NO GO Contract Milestones and Decision Gates specified therein. The GO/NO GO Contract Milestones and Decision Gates will constitute the basis for the Government's decision, at its sole discretion, to exercise any follow-on option segment(s).

The base and option segments under Contract Line Items (CLINs) 0001 through 0003 are event driven work segments rather than time driven CLINs. The funds for each independent, non-severable discrete work segment (requirement), regardless of duration, are separated by CLIN, and shall only be used for the scope of work covered in each discrete work segment. The periods of performance listed under each of the CLINs under Article B.2 and Article B.3 are estimated time periods. Those individual time periods may be extended by mutual agreement of the parties to complete the tasks required under each work segment. It is possible that more than one independent, non-severable discrete work segment (requirement), may be awarded at one time and that individual CLINs may overlap and/or proceed concurrently

C.2 Statement of Work

Independently, and not as an agent of the United States Government, the contractor shall furnish all necessary services, qualified professional, technical, and administrative personnel, material, equipment and facilities, not otherwise provided by the Government under the terms of this contract, as needed to perform the tasks set forth below.

mRNA Vaccine Development (WBS 1.0)

The Contractor, Moderna, Inc. ("Moderna") shall execute the preclinical, clinical, and chemistry, manufacturing and controls (CMC) activities required to license a vaccine against the SARS-CoV-2 virus (herein referred to as "mRNA vaccine"). Building upon early clinical development already underway, this proposal will support the late stage development, including the demonstration of clinical efficacy and generation of a dataset supportive of licensure. Moderna will additionally evaluate the platform manufacturing capabilities relative to the needs for supply in response to a pandemic.

Program Management (WBS 1.1)

mRNA Program Management (WBS 1.1.1)

Moderna's mRNA program team is composed of a multidisciplinary, highly matrixed, group of functional leads with experience in, and responsibility for, integrating plans and operationalizing strategies across Research, Toxicology, CMC, Regulatory Affairs,

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Clinical Development and Quality. Collectively, the team has advanced ten programs to first-in-human studies within five years. The group will be led by a program lead (PL) who will oversee and coordinate the activities necessary to meet program objectives. The PL will be the point of accountability for the development of mRNA vaccine. [***]. A program management office (PMO) will be responsible for managing the cost and schedule constraints of the contract via an integrated master schedule and corresponding budget, identifying and managing program risk, and ensuring contract compliance. With the input from the mRNA project team, the PMO will be responsible for coordinating the drafting of and management to an integrated development plan. Upon execution of the contract, weekly meetings with BARDA will be held to monitor program performance and monthly and annual reports will be delivered to BARDA for the record.

Nonclinical Toxicology (WBS 1.2)

Development and Reproductive Toxicology of mRNA (WBS 1.2.2.1)

To assess the risk of administering the vaccine to pregnant women, a complete GLP rat developmental and reproductive toxicology (DART) study is planned. Female Sprague Dawley rats will be dosed at the highest anticipated clinical dose level and include a control arm of phosphate-buffered saline (PBS). As is typical for DART evaluations for vaccines, the animals will be immunized three times prior to mating and two times during gestation. Each group will have two cohorts (one group will undergo Cesarean section with examination of the uteri and embryos; the other group will have natural delivery and will be terminated at weaning).

Nonclinical (WBS 1.3)

For the purposes of this proposal it is assumed that the VRC continues to support nonclinical activities to develop murine and non-human primate efficacy studies, and animal models to assess the potential of vaccine-enhanced disease. The scope of work below will execute additional robustness experiments in these developed models.

Assess Disease Enhancement (WBS 1.3.3.1)

[***]

We plan to perform studies in mouse and NHPs to assess the theoretical risk of vaccine induced disease enhancement triggered by CoV infection following vaccination with imRNA vaccine. [***]

[***]

[***]

Establish a Surrogate of Protection (WBS 1.3.3.2)

The primary endpoint for accelerated approval of a SARS-CoV-2 vaccine would be a neutralization assay. This endpoint must be supported with a body of pre-clinical work that demonstrates a correlation between neutralizing titers and efficacy and that quantifies a protective serologic threshold titer using the same neutralization assay. Murine and NHP efficacy models are being developed in parallel to the Phase 1 clinical study. Building on data from these preliminary models and studies, Moderna will conduct NHP efficacy and murine passive transfer studies to confirm and refine the surrogate of protection.

Clinical (WBS 1.4)

[***]

Phase 2 Safety and Immunogenicity Study (WBS 1.4.2.1)

[***]

Phase 3 Pivotal Study:(WBS 1.4.3.1)

I. Scenario in which SARS-CoV-2 virus is circulating: In this scenario a randomized controlled trial with prevention of disease endpoint would serve to demonstrate effectiveness of the vaccine.

[***]

II. Scenario in the absence of SARS-CoV-2 virus: In this scenario an efficacy study becomes infeasible.

[***]

Lot to Lot Consistency (WBS 1.4.3.2)

[***]

Pediatrics (WBS 1.4.3.3)

[***]

Regulatory (WBS 1.5)

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IND Preparation and Filing (WBS 1.5.1.1)

Moderna's Regulatory Affairs group, in close collaboration with BARDA, will work to draft a comprehensive regulatory master plan to guide the preclinical, CMC and clinical development of mRNA within the first 90 days of the contract. An original investigational new drug application (IND) will be filed with the United States Food and Drug Administration (FDA) to support the clinical development of the Moderna product from Phase 2 onwards.

IND Maintenance (WBS 1.5.1.2)

The Moderna-owned IND will be maintained to support the desired clinical development plan. As needed, meetings will be conducted to receive feedback and gain concurrence on the specifics of the development activities with the FDA.

BLA Submission (WBS 1.5.2.1)

Moderna will submit a Biologics License Application (BLA) and seek approval for the mRNA vaccine.

CMC (WBS 1.6)

CTM Manufacture for Phase 2 (WBS 1.6.3.2)

[***]

Process Development for Late Stage Clinical Supply (WBS 1.6.3.3)

mRNA Process Development

Technical Development will confirm and optimize the process parameters for mRNA manufacture. [***]

[***]

BLA Readiness (WBS 1.6.3.8)

In support of the Biologics License Application (BLA) due to the nature of the proposed timeline, it is likely that Moderna will need to complete some of process validation activities, primarily process characterization, after the completion of process performance qualification and before BLA filing. Moderna intends to rapidly develop a robust process for clinical manufacturing and PPQ, and then fully describe the acceptable design space for the process prior to BLA filing. Other activities to support this BLA filing, such as completing raw material qualification activities; if not included in the BLA submission, will require a supplement to the initial BLA. In the initial BLA filing Moderna will describe its control strategy to cover the gap between initial BLA filing and the BLA supplement.

Process Development for Full Commercial Scale (WBS 1.6.4.1)

The following section outlines the process development activities [***]. The goal of this work is to demonstrate the capability to produce mRNA at a scale that can support clinical demand.

[***]

[***]

Analytical Method Development and Validation (WBS 1.6.5.2)

[***]

Characterization Assay Development and Implementation (WBS 1.6.5.3)

[***]

Stability Studies (WBS 1.6.5.4)

Throughout the program, many studies will be undertaken [***] This includes studies using development bench scale material, engineering lot material, and GMP material. This body of data will be used to apply interim and long-term shelf life to the drug product and process intermediates.

1. Intellectual Property

The parties agree that data generated prior to entering into or outside the scope of the agreement will, when delivered to the USG, be considered to be limited rights data subject to the restrictions covered under FAR Clause 52.227-14 Alt II paragraph (g)(3). The government will obtain unlimited rights to data funded under this contract pursuant to FAR Clause 52.227-14. The parties rights to subject inventions developed during performance of this contract will be governed by the terms of FAR Clause 52.227-11

2. Use of Select Agents

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As Moderna selects programs for demonstration of the platform, Moderna will defer to an HHS chaired committee of contracting, security, safety and scientific program management to assess the applicability of the facilities, regulations, policies, and procedures for meeting the U.S. requirements described in 42 CFR part 73, 7 CFR part 331, and/or 9 CFR part 121.

3. Laboratory Licenses Requirements

Moderna will comply with all applicable requirements of Section 353 of the Public Health Service Act (CLIA, as amended). This requirement shall also be included in any relevant subcontract for services under the contract.

4. Target Product Profile

[***]			
	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]		
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
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CONTRA-INDICATION	None
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D. PACKAGING AND MARKING (if applicable)

Unless otherwise specified by the Contracting Officer, all deliverable items to be furnished to the Government under this contract (including invoices) shall be made by first class mail, overnight carrier, or email, as described in Section F.

All physical deliverables shall be preserved, packaged, and marked in accordance with normal commercial practices to meet the packaging requirements of the carrier, including that which is necessary to prevent deterioration and damages due to the hazard of shipping, handling, and storing. The Contractor shall guarantee that all required materials shall be delivered in immediate usable and acceptable condition.

E. INSPECTION AND ACCEPTANCE

E.1 Federal Acquisition Regulation Clauses Incorporated by Reference

This contract incorporates one or more clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this address: <http://acquisition.gov/far/>

The following FAR clauses, pertinent to Section E, are hereby incorporated by reference:

FAR Clause	Title	Date
52.246-2	Inspection of Supplies – Fixed Price	Aug 1996
52.246-5	Inspection of Services – Cost Reimbursement	Apr 1984
52.246-9	Inspection of Research and Development	May 2001

All work under this contract may be subject to inspection and final acceptance by the Contracting Officer or the duly authorized representative of the Government. The Contracting Officer's Representative (COR) is a duly authorized representative of the Government and is responsible for the inspection and acceptance of all items/activities to be delivered and or completed under this contract.

F. DELIVERABLES / PERFORMANCE

F.1 Federal Acquisition Regulation Clauses Incorporated by Reference

This contract incorporates one or more clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this address: <http://acquisition.gov/far/>

The following FAR clause, pertinent to Section F, is hereby incorporated by reference:

FAR Clause	Title	Date
52.242-15	Stop-Work Order, Alternate I (Apr 1984)	Aug 1989

F.1.1 A pandemic facility and/or operational management plan including change procedures from normal to pandemic operations. Prepare an operational plan to continue operations in the event of a declared pandemic emergency (Draft within 15 days of award, Final within 30 days of award).

F.1.2 Data Management Plan

The Contractor shall develop and implement data management and quality control systems/procedures, including transmission, storage, confidentiality, and retrieval of all contract data; provide for the statistical design and analysis of data resulting from the research; provide raw data or specific analyses of data generated with contract funding to the Project Officer, upon request.

F.1.3 Standard Operating Procedures

The Contractor shall make internal and, to the extent possible, Subcontractor Standard Operating Procedures (SOPs) available for review by the Government on-site at Contractor's facility, upon request from the COR or CO. At Contractor's election, SOPs may be provided electronically.

F.1.4 Evaluation of Fill Finish Alternatives

The Contractor shall submit a Draft Final and Final Report describing the fill finish alternatives evaluated, the evaluation method and criteria used, cost comparison, and recommendation for which fill finish alternative to move forward. The draft report shall be due within thirty (30) days after completion of analysis. Subcontractor-prepared reports, on behalf of the Contractor, shall be submitted to the COR and CO for review and comment, no later than five (5) business days after receipt by the Contractor. BARDA shall provide written comments to the Draft Final Report within fifteen (15) days after the submission. The Final Report shall be due thirty (30) days after receiving comments on the Draft Final Report from BARDA. If corrective action is recommended, the Contractor must address, in written, all concerns raised by the Government.

F.1.5 Supply Chain Resiliency Plan

The partner contractor shall have a comprehensive Supply Chain Resiliency Program that provides for identification and reporting of critical components associated with the secure supply of drug substance, drug product, and work-in-process through to finished goods. A critical component is any material that is essential to the product or the manufacturing process associated with that product. Included in the definition are consumables and disposables associated with manufacturing. NOT included in the definition are facility and capital equipment.

Consideration of critical components includes the evaluation and potential impact of raw materials, excipients, active ingredients, substances, pieces, parts, software, firmware, labeling, assembly, testing, analytical and environmental componentry, reagents, or utility materials which are used in the manufacturing of a drug, cell banks, seed stocks, devices and key processing components and equipment. A clear example of a critical component is one where a sole supplier is utilized.

Identification of key equipment suppliers and their locations, local resources and the associated planning and control processes at the time of award is important to the security of the medical countermeasure supply chain. These processes shall address planning and scheduling for active pharmaceutical ingredients, upstream, downstream, component assembly, finished drug product and delivery events as necessary for the delivery of product. Where multi-site manufacturing is integral to the delivery of contractual materials, it should be included as part of the planning and scheduling process. Communication for these requirements shall be updated as part of an annual review, or as necessary, as part of regular contractual communications.

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The focus on the aspects of resiliency shall be on critical components and aspects of complying with the contractual delivery schedule. Delivery methods shall be addressed, inclusive of items that are foreign-sourced, both high and low volume, which would significantly affect throughput and adherence to the contractually agreed deliveries.

For upstream and downstream processing, both single-use and re-usable in-place processing equipment, and manufacturing disposables also shall be addressed. For finished goods, the inspection, labeling, packaging, and associated machinery shall be addressed taking into account capacity capabilities.

The partner contractor shall communicate the methodology for inventory control, production planning, scheduling processes and ordering mechanisms, as part of those agreed deliveries. For critical items these processes should provide visibility for key items over an adequate planning horizon that ensures effective control of the established supply chain for contractual deliveries. Production rates and lead times shall be understood and communicated to the HHS/ASPR/BARDA Contracting Officer or the Contracting Officer's Representative as necessary.

Production throughput critical constraints should be well understood by activity and by design, and communicated to contractual personnel. As necessary, communication should focus on identification, exploitation, elevation, and secondary constraints of throughput, as appropriate.

Reports for critical items may be summarized with the following template:

Critical Material Name	Vendor	Supplier, Manufacturing / Distribution Location	Supplier Lead Time	Shelf Life	Transportation / Shipping restrictions
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The CO and COR reserve the right to request unredacted copies of technical documents, during the period of performance, for distribution within the Government, and Contractor will reasonably consider any such requests. Documents shall be provided within ten (10) days after CO issues the request. The Contractor may arrange for additional time if deemed necessary, and agreed to by the CO.

F.2 Deliverables Schedule

Successful performance of the final contract shall be deemed to occur upon performance of the work set forth in the Statement of Work attached to this contract as Attachment 1 (SECTION J-List of Attachments), and upon delivery and acceptance, as required by the Statement of Work, by the Contracting Officer, or the duly authorized representative pursuant to SECTION E-Inspection and Acceptance, of the following items listed below under heading 1 "Summary of Contract Deliverables" in accordance with the stated delivery schedule.

The items specified below under heading 1 "Summary of Contract Deliverables", as described in the Statement of Work which is Attachment 1 to this contract will be required to be delivered by the date(s) specified below and in accordance with any specifications stated in SECTION D- PACKAGING, MARKING AND SHIPPING, of this contract. All reports identified below relate solely to the development activity funded under this contract:

1. Summary of Contract Deliverables

Unless otherwise stated, each deliverable in the table below shall be provided as one (1) electronic copy to the COR, CS, and CO as set forth in SECTION D.

In addition to or in replacement of electronic copies, the CO may direct the Contractor to submit the below deliverables via BARDA Digital Resources Portal in machine readable format.

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Table 5

CDRL#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
01	Meetings		
01.1	Post Award Teleconference	The contractor shall complete an initial teleconference after contract award 1. Outline activities for the next 30 days 2. Discuss agenda items for the post-award Kickoff Meeting (01.2)	• Within one week of contract award • Contractor shall provide agenda and establish a teleconference number at least 3 business days in advance of the teleconference unless notified that BARDA will supply one • COR edits/approves and instructs contractor to distribute agenda prior to meeting by at least 2 business days • Contractor provides meeting minutes to COR within 3 business days after the meeting • COR reviews, comments and approves minutes within 10 business days
01.2	Kickoff Meeting	The Contractor shall complete a Kickoff meeting after contract award	• Within a month of contract award, pending concurrence by the contracting officer • Contractor shall provide itinerary and agenda at least 5 business days in advance of site visit or virtual meeting • COR edits/approves and instructs contractor to distribute agenda prior to meeting by at least 3 business days • Contractor provides meeting minutes to COR within 3 business days after the meeting • COR reviews, comments, and approves minutes within 10 business days
01.3	Every 2 weeks Teleconference	The Contractor shall participate in teleconferences every 2 weeks, with BARDA to discuss the performance on the contract. Meeting frequency can be increased as needed during the course of the project	• Contractor provides agenda to COR no later than 2 business days in advance of meeting • COR edits/approves and instructs contractor to distribute agenda prior to meeting • Contractor distributes agenda and presentation materials at least 24 hours in advance • Contractor provides meeting minutes to COR within 3 business days of the meeting • COR reviews, comments, and approves minutes within 6 business days
01.4	Quarterly Meetings	At the discretion of the government the Contractor shall hold recurring teleconference or face-to-face Project Review Meetings up to four per year either in Washington D.C or at work sites of the Contractor or sub-contractors. Face-to-face meetings shall alternate between Washington DC and Contractor, sub-contractor sites. The meetings will be used to discuss contract progress in relation to the Program Management deliverables described below as well as study designs, technical, regulatory, and ethical aspects of the program.	• Contractor shall provide itinerary and agenda at least 5 business days, and presentation materials at least 3 business days in advance of site visit • COR edits/approves and instructs contractor to distribute agenda prior to meeting by at least 3 business days • Contractor provides meeting minutes to COR within 3 business days after the meeting • COR reviews, comments, and approves minutes within 10 business days
01.5	FDA Meetings	The Contractor shall forward the dates and times of any meeting with the	• Contractor shall notify BARDA of upcoming FDA meeting within 24 hours of scheduling

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CDRL#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		FDA to BARDA and make arrangements for appropriate BARDA staff to attend the FDA meetings. BARDA staff shall include up to a maximum of four people (typically COR and up to 3 subject matter experts)	Type A, B or C meetings OR within 24 hours of meeting occurrence for ad hoc meetings The Contractor shall forward initial Contractor and FDA-issued draft minutes and final minutes of any meeting with the FDA to BARDA within 2 business days of receipt
01.6	Daily check in with project staff for COVID-19 Contract	Upon request of the Government, the Contractor shall participate in a daily check-in update with the project staff (via teleconference or email). The updates will address key cost, schedule and technical updates. Daily updates may be shared with senior Government leaders during the COVID- 19 response and should be provided on a non-confidential basis, unless the update includes confidential information in which case Contractor shall provide the update in both confidential and non-confidential formats. Daily check-ins may occur on weekdays, excluding federal holidays. Upon request of the Government, check-ins may also occur on weekends and on federal holidays, provided at least 24 hours' notice.	- No agenda will be required for the meeting - No meeting minutes are required - Contractor will provide bulleted email updates following any call or in lieu of a call by 2PM for that day

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02	Technical Reporting		
02.1 (Monthly)	Monthly & Annual Technical Progress Reports/Annual Meeting	1. The Integrated Program Management Report (IPMR) is a contractually required report prepared by the contractor. IPMR Formats 1, 3, 5, and 6 are required. These formats will contain performance data and information derived from the contractor's internal Earned Value Management System (EVMS) and Integrated Master Schedule (IMS). The Contractor's EVMS shall comply with Earned Value Management's Seven (7) Principles.	• Monthly Reports shall be submitted on the 20th day of the month covering the preceding month; Annual Reports submitted on the 30th calendar day of the month after each contract anniversary. Monthly progress reports are not required for the months when the Annual Report(s) are due, and Monthly/Annual Report(s) are not due during a month when the Final Report (final version, not draft) is due (see deliverable 02.4). The COR and CO will review the monthly reports with the Contractor and provide feedback • Contractor shall provide FINAL versions of reports within 10 business days after receiving BARDA comments/edits • Integrated Performance Management Report (IPMR) shall be developed according to the instructions of Data Item Description (DiD) #81861A • The CPR shall be provided on the 20th day of the month covering the preceding month, including the same month as the Annual Report(s) is due • The IPMR required formats for this Contract shall be Formats 1 (WBS), 3 (Performance Measurement Baseline Changes and Reconciliation), 5 (Variance Analysis Report – Narrative Form), and 6 (Integrated Master Schedule)
02.2 (Annual)		2. An Executive Summary highlighting the progress, issues and relevant manufacturing, non-clinical, clinical and regulatory activities. The Executive Summary should highlight only critical issues for that reporting period and resolution approach; limited to 2 pages 3. BARDA Contractor Clinical Trials Information Sheet – covering ongoing BARDA-sponsored clinical studies. This form shall provide data on relevant activities during the period covered, by study site, including: cumulative enrollment; new enrollments; screen failures; patients dropped from study; AE and SAEs; activation or inactivation of study sites; investigator appointments or changes; and status of IRB/IEC review/approval/renewal 4. Progress in meeting contract milestones organized by WBS, overall project assessment, problems encountered and recommended solutions. The reports shall detail the planned and actual progress during the period covered, explaining any differences between the two and the corrective steps 5. A three-month rolling forecast of the key planned activities, referencing the WBS/IMS 6. A tracking log of progress on regulatory submissions with the FDA number, description of submission, date of submission, status of submission and next steps 7. Estimated and Actual Expenses a. This report shall also contain a narrative or table detailing whether there is a significant discrepancy (>10%) at this time between the %	

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		of work completed and the cumulative costs incurred to date. Monthly and actual expenses should be broken down to the appropriate WBS level. This section of the report should also contain estimates for the Subcontractors' expenses from the previous month if the Subcontractor did not submit a bill in the previous month. If the subcontractor(s) was not working or did not incur any costs in the previous month, then a statement to this effect should be included in this report for those respective subcontractors. If the COR and CO are satisfied that the contractor's reporting is sufficient to convey this information, this section may be waived.	
02.3 (Draft) 02.4 (Final)	Draft and Final Technical Progress Report	A draft Final Technical Progress Report containing a summation of the work performed and the results obtained over the entire contract. This report shall be in sufficient detail to fully describe the progress achieved under all milestones. Report should contain a timeline of originally planned and baselined activities and milestones overlaid with actual progress attained during the contract. Descriptions and rationale for activities and milestones that were not completed as planned should be provided. The draft report shall be duly marked as 'Draft'. The Final Technical Progress Report incorporating feedback received from BARDA and containing a summation of the work performed and the results obtained for the entire contract PoP. The final report shall document the results of the entire contract. The final report shall be duly marked as 'Final'. A cover letter with the report will contain a summary (not to exceed 200 words) of salient results achieved during the performance of the contract.	•The Draft Technical Progress Report shall be submitted 75 calendar days before the end of the PoP and the Final Technical Progress Report on or before the completion date of the PoP •COR will provide feedback on draft report within 15 calendar days of receipt, which the Contractor shall consider incorporating into the Final Report
02.5 (Draft) 02.6 (Final)	Draft and Final Study Reports, Clinical and Non-Clinical	Contractor shall provide Draft and Final Clinical/Non-Clinical Study Reports to BARDA for review and comment.	•Draft report due within 45 calendar days after completion of analysis and at least 15 business days prior to submission to FDA •Subcontractor prepared reports received by the Contractor shall be submitted to the COR and CO for review and comment no later than 5 business days after receipt by Contractor •The Government will provide written comments to the Draft Report for Clinical / Non-Clinical Study reports within 15 business days after the submission •Final report due 30 calendar days after receiving comments on the Draft Final

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			Report for Clinical and Non-Clinical Studies; If corrective action is recommended, Contractor must address all concerns raised by BARDA in writing Contractor shall consider revising reports to address BARDA's recommendations prior to FDA submission
02.7	FDA Manufacturing Reports	At BARDA's request, Contractor shall provide Manufacturing Reports to BARDA for review and comment prior to submission to FDA The COR and CO reserve the right to request within the PoP a non-proprietary Manufacturing Report for distribution within the USG	- Contractor will submit Manufacturing Reports at least 15 business days prior to FDA submission - The Government will provide written comments to the manufacturing report within 15 business days after the submission - If corrective action is recommended, Contractor must address all concerns raised by BARDA in writing - Contractor shall consider revising reports to address BARDA's concerns and/or recommendations prior to FDA submission
02.8	Product Development Source Material and Manufacturing Report	The Contractor shall submit a detailed spreadsheet regarding critical project materials that are sourced from a location other than the United States, sources, and manufacturing sites, including but not limited to: physical locations of sources of raw and processed material by type of material; location and nature of work performed at manufacturing sites; and location and nature of non-clinical and clinical study sites.	- Contractor will submit Product Development Source Material Report - Within month of contract award - Within 30 days of substantive changes are made to sources and/or materials - Or on the 6th month contract anniversary. - The Government will provide written comments to the Product Development Source Material and Manufacturing Report within 15 business days after the submission - If corrective action is recommended, Contractor must address all concerns raised by BARDA in writing
02.9	Contractor Locations	The contractor shall submit detailed data regarding locations where work will be performed under this contract, including addresses, points of contact, and work performed per location, to include sub-contractors.	Contractor will submit Work Locations Report: - Within 5 business days of contract award - Within 30 business days after a substantive location or capabilities change - Within 2 business days of a substantive change if the work performed supports medical countermeasure development that addresses a threat that has been declared a Public Health Emergency by the HHS Secretary or a Public Health Emergency of International Concern (PHEIC) by the WHO
02.10	Clinical Report during Active Enrollment Periods	The contractor shall submit detailed clinical reports during active clinical trial enrollment to include at a minimum number of subjects screened and enrolled, site activation status, safety reporting (SAEs), deviation reports and database management. Exact format TBD by COR and contractor.	Contractor shall submit Clinical Reports on a weekly basis starting when first patient is enrolled and ending when last patient is enrolled.

Contract No. 75A50120C00034 Development of an mRNA Vaccine for SARS-CoV-2

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02.11	Study Protocols	The contractor shall submit draft and final nonclinical and clinical study protocols to CO and COR	Draft study protocols will be submitted to COR electronically prior to finalization. - BARDA will provide comments within 10 days of receipt of draft protocol - Contractor shall respond in writing to BARDA comments and recommendations prior to finalization of protocol. Final study protocols will be submitted to COR electronically no later than 10 business days prior to FDA submission
02.12	Final Data Submission Package	Contractor must submit a data package consisting of all raw data produced under this contract. Data may be used by BARDA for analysis, evaluation, shared with other agencies, or shared outside of the government consistent with FAR 52.227-14. This submission package must be delivered in a non-proprietary format. If clinical trial data is included, that data must be provided consistent with applicable privacy laws to protect personally identifiable information (PII).	Contractor will submit at least 15 days prior to contract end date. Partial data-sets may also be requested for delivery prior to submission of the Final Data Submission Package.
02.13	Supplemental Technical Documents, Raw Data, or Data Analysis	Upon request and also as part of deliverables the Contractor shall provide raw data, data analysis, or data report to BARDA.	Contractor shall provide the Technical Documents upon request from the CO or COR
03	Audits		
03.1	BARDA Audit	Contractor shall accommodate periodic or ad hoc site visits by BARDA. If BARDA, the Contractor, or other parties identifies any issues during an audit, the Contractor shall capture the issues, identify potential solutions, and provide a report to BARDA	- If issues are identified during the audit, Contractor shall submit a report to BARDA detailing the finding and corrective action(s) within 10 business days of the audit - COR and CO will review the report and provide a response to the Contractor with 10 business days - Once corrective action is completed, the Contractor will provide a final report to BARDA
03.2	FDA Audits	In the event of an FDA inspection that occurs in relation to this contract and for the product, or for any other FDA inspection that has the reasonable potential to impact the performance of this contract, the Contractor shall provide the USG with an exact copy (non-redacted) of the FDA Form 483 and the Establishment Inspection Report (EIR). The Contractor shall provide the COR and CO with copies of the plan for addressing areas of non-conformance to FDA regulations for GLP, GMP, or GCP guidelines as identified in the audit report, status	- Contractor shall notify CO and COR within 10 business days of a scheduled FDA audit or within 24 hours of an ad hoc site visit/audit if the FDA does not provide advanced notice - Contractor shall provide copies of any FDA audit report received from subcontractors that occur as a result of this contract or for this product within 1 business day of receiving correspondence from the FDA or third party - Within 10 business days of audit report, Contractor shall provide CO with a plan for

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		updates during the plans execution and a copy of all final responses to the FDA. The Contractor shall also provide redacted copies of any FDA audits received from subcontractors that occur as a result of this contract or for this product. The Contractor shall make arrangements for BARDA representative(s) to be present during the final debrief by the regulatory inspector	addressing areas of nonconformance, if any are identified
03.3	QA Audits	BARDA reserves the right to participate in QA audits performed by the contractor. Upon completion of the audit/site visit the Contractor shall provide a report capturing the findings, results and next steps in proceeding with the subcontractor. If action is requested of the subcontractor, detailed concerns for addressing areas of non-conformance to FDA regulations for GLP, GMP, or GCP guidelines, as identified in the audit report, must be provided to BARDA. The Contractor shall provide responses from the subcontractors to address these concerns and plans for corrective action	- Contractor shall notify CO and COR a minimum of 10 business days in advance of upcoming, audits/site visits of subcontractors - Contractor shall notify the COR and CO within 5 business days of report completion. - COR and CO will review the report and provide a response to the Contractor with 10 business days
03.4	Risk Management Plan (RMP)	The Contractor shall provide an RMP that outlines the impacts of each risk in relation to the cost, schedule, and performance objectives. The plan shall include risk mitigation strategies. Each risk mitigation strategy will capture how the corrective action will reduce impacts on cost, schedule and performance	- A Draft is due 90 business days within contract award; updates to the RMP are due concurrent with Monthly Technical Progress Reports. The contractor may choose to notify the government up to two times every three months if there are no changes from the prior submission, and not submit an update - BARDA will provide Contractor with a list of concerns in response plan submitted - Contractor must address, in writing, all concerns raised by BARDA within 20 business days of Contractor's receipt of BARDA's concerns
03.5	Integrated Master Schedule (IMS)	The contractor shall provide an IMS that illustrates project tasks, dependencies, durations throughout the period of performance, and milestones (GO/NO-GO). The IMS must map to the WBS, and provide baseline, and actual or forecast dates for completion of tasks	- The IMS is to be submitted in both PDF and Microsoft Project Form to the COR - The first Draft of the IMS is due 30 business within contract award - The Government will request revisions within 10 business days, at which point the schedule baseline for the period of performance will be set - Thereafter an updated IMS is due concurrent with Monthly Technical Progress Reports
03.6	Deviation Notification and Mitigation Strategy	Process for changing IMS activities associated with cost and schedule as baselined. Contractor shall notify BARDA of significant proposed changes the IMS defined as increases in cost above 5% or schedule slippage of more than 30 days, which would require a PoP extension. Contractor	Due at least 10 business days prior to the Contractor anticipating the need to implement changes

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		shall provide a high level management strategy for risk mitigation	
03.7	Incident Report	Contractor shall communicate to BARDA and document all critical programmatic concerns, issues, or probable risks that have or are likely to significantly impact project schedule and/or cost and/or performance. "Significant" is frequently defined as a 10% or greater cost or schedule variance within a control account, but should be confirmed in consultation with the COR. Incidents that present liability to the project even without cost/schedule impact, such as breach of GCP during a clinical study, must also be reported	• Due within 48 hours of activity or incident or within 24 hours for a security activity or incident • Email or telephone with written follow-up to COR and CO • Additional updates due to COR and CO within 48 hours of additional developments • Contractor shall submit within 5 business days a Corrective Action Plan (if deemed necessary by either party) to address any potential issues • If corrective action is deemed necessary, Contractor must address in writing, its consideration of concerns raised by BARDA within 5 business days of receiving such concerns
09	Advanced R&D Products		
09.1	Technical Documents	Upon request, Contractor shall provide CO and COR with deliverables from the following contract funded activities: quality agreements between contractors and sub-contractors, process Development Reports, Assay Qualification Plan/Report, Assay Validation Plan/Report, Assay Technology Transfer Report, Batch Records, SOPs, Master Production Records, Certificate of Analysis, Clinical Studies Data or Reports. The CO and COR reserve the right to request within the PoP a non-proprietary technical document for distribution within the Government	• Contractor shall provide technical document within 10 business days of CO or COR request. Contractor can request additional time on an as needed basis • If corrective action is recommended, the Contractor must address, in writing, concerns raised by BARDA in writing
09.2	Animal Model or Other Technology Transfer Package	Contractor shall provide Animal Model or Other Technology Transfer Package containing relevant methodology and data sufficient to enable other practitioners in the field to successfully replicate experimental conditions developed and tested with BARDA support	• Contractor shall provide a draft package within 20 business days of COR or CO request • Contractor shall revise the package to address BARDA's concerns, recommendations and/or requests for additional detail
09.3	Raw Data or Data Analysis	Contractor shall provide raw data or data analysis to BARDA upon request	• Contractor shall provide raw data or data analysis to CO and COR within 20 business days of request
09.4	Publications	Any manuscript or scientific meeting abstract containing data generated under this contract must be submitted to BARDA for review prior to submission. Acknowledgment of BARDA funding must be included as noted in contract articles H.9 and H.24	• Contractor must submit all manuscript or scientific meeting abstract to PO and CO prior to submission/presentation by 30 business days for manuscripts and 15 business days for abstracts or posters • Contractor must address in writing all concerns raised by BARDA in writing • Final submissions shall be submitted to BARDA concurrently or no later than one (1) calendar day of its submission
10	Regulatory Documents		

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10.1	FDA Correspondence	The Contractor shall memorialize any correspondence between Contractor and FDA and submit to BARDA	Contractor shall provide copies of any FDA correspondence within 2 business days of correspondence
10.2	FDA Submissions	The Contractor shall provide BARDA the opportunity to review and comment upon all draft submissions before submission to the FDA. Contractor shall provide BARDA with an electronic copy of the final FDA submission. All documents shall be duly marked as either "Draft" or "Final"	- Contractor shall submit draft FDA submissions to BARDA at least 15 business days prior to FDA submission - BARDA will provide feedback to Contractor within 10 business days of receipt - The Contractor must address, in writing, its consideration of all concerns raised by BARDA prior to FDA submission - Final FDA submissions shall be submitted to BARDA concurrently or no later than 1 calendar day of submission
11	Press Releases	Contractor agrees to accurately and factually represent the work conducted under this contract in all press releases	- Contractor shall ensure that the CO has received and approved an advanced copy of any press release to this contract not less than 5 business days prior to the issuance of the press release - If corrective action is required, the Contractor agrees to accurately and factually represent the work conducted under this contract in all press releases - Any final press releases shall be submitted to BARDA no later than one (1) calendar day prior to its release

2. Detailed Description of Select Contract Deliverables

A. Monthly and Annual Progress Reports

In addition to those reports required by the other terms of this contract, the Contractor shall prepare and submit the following reports in the manner stated below and in accordance with this Article F of this contract, and in the Statement of Work, attached to this contract as Attachment 1 (SECTION J-List of Attachments).

i. Monthly Progress Report

This report shall include a description of the activities during the reporting period, and the activities planned for the ensuing reporting period. The first reporting period consists of the first full month of performance plus any fractional part of the initial month. Thereafter, the reporting period shall consist of each calendar month.

The Contractor shall submit a Monthly Progress Report according to the dates set forth in the summary table ("Summary of Contract Deliverables") under this article. The progress report shall conform to the requirements set forth in the DELIVERIES Article in SECTION F of this contract.

The format should include:

- A cover page that includes the contract number and title; the type of report and period that it covers; the Contractor's name, address, telephone number, fax number, and e-mail address; and the date of submission;
- SECTION I – EXECUTIVE SUMMARY
- SECTION II - PROGRESS
- SECTION II Part A: OVERALL PROGRESS - A description of overall progress.
- SECTION II Part B: MANAGEMENT AND ADMINISTRATIVE UPDATE - A description of all meetings, conference calls, etc. that have taken place during the reporting period. Include progress on administration and management issues (e.g., evaluating, and managing subcontractor performance, and personnel changes).
- SECTION II Part C: TECHNICAL PROGRESS - For each activity related to Gantt chart, document the results of work completed and cost incurred during the period covered in relation to proposed progress, effort and budget. The report shall be in sufficient detail to explain comprehensively the results achieved. The description shall include pertinent data and/or graphs in sufficient detail to explain any significant results achieved and preliminary conclusions resulting from analysis and scientific evaluation of data accumulated to

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date under the contract. The report shall include a description of problems encountered and proposed corrective action; differences between planned and actual progress, why the differences have occurred and what corrective actions are planned; preliminary conclusions resulting from analysis and scientific evaluation of data accumulated to date under the project.

- SECTION II Part D: PROPOSED WORK - A summary of work proposed related to Gantt chart for the next reporting period and preprints/reprints of papers and abstracts.
- SECTION III: Estimated and Actual Expenses.
 - a. This section of the report shall contain a narrative or table detailing whether there is a significant discrepancy (>10%) at this time between the % of work completed and the cumulative costs incurred to date. Monthly and actual expenses should be broken down to the appropriate WBS level.
 - b. This section of the report should also contain estimates for the Subcontractors' expenses from the previous month if the Subcontractor did not submit a bill in the previous month. If the subcontractor(s) was not working or did not incur any costs in the previous month, then a statement to this effect should be included in this report for those respective subcontractors.

A Monthly Progress Report will not be required in the same month that the Annual Progress Report is submitted.

ii. **Annual Progress Report**

This report shall include a summation of the results of the entire contract work for the period covered. Monthly Progress Reports shall not be submitted in the same month when an Annual Progress Report is due. Furthermore, an Annual Progress Report will not be required for the period when the Final Report is due.

The first Annual Progress Report shall be submitted in accordance with the date set forth in the table ("Summary of Contract Deliverables") under ARTICLE F.2. of this contract. The progress report shall conform to the requirements set forth in the DELIVERIES Article in SECTION F of this contract.

Each Annual Progress Report shall include:

- A Cover page that includes the contract number and title; the type of report and period that it covers; the Contractor's name, address, telephone number, fax number, and email address; and the date of submission;
- SECTION I: EXECUTIVE SUMMARY - A brief overview of the work completed, and the major accomplishments achieved during the reporting period.
- SECTION II: PROGRESS
 - SECTION II Part A: OVERALL PROGRESS - A description of overall progress.
 - SECTION II Part B: MANAGEMENT AND ADMINISTRATIVE UPDATE - A high level summary of critical meetings, etc. that have taken place during the reporting period. Include progress on administration and management to critical factors of the project (e.g. regulatory compliance audits and key personnel changes).
 - SECTION II Part C: TECHNICAL PROGRESS - A detailed description of the work performed structured to follow the activities and decision gates outlined at the Integrated Baseline Review and as described in the Integrated Master Plan. The Report should include a description of any problems (technical or financial) that occurred or were identified during the reporting period, and how these problems were resolved.
 - SECTION II Part D: PROPOSED WORK - A summary of work proposed for the next year period to include an updated Gantt Chart.
 - SECTION III: Estimated and Actual Expenses.
 - a. This section of the report shall contain a narrative or table detailing whether there were discrepancies between estimated and actual expenses over the past year. Actual expenses should be broken down to the appropriate WBS level. This section of the report should also contain estimates for outstanding costs for the previous year which may have been incurred, but not yet billed.

Contractor also should include the following in the Annual Progress Report:

1. Copies of manuscripts (published and unpublished), abstracts, and any protocols or methods developed specifically under the contract during the reporting period; and
2. A summary of any Subject Inventions per the requirements under FAR Clause 52.227-11.

iii. **Draft Final Report and Final Report**

These reports are to include a summation of the work performed and results obtained for the entire contract period of performance. This report shall be in sufficient detail to describe comprehensively the results achieved. The Draft Final Report and Final Report shall be submitted in accordance with the DELIVERIES Article in SECTION F of the contract. An Annual Progress Report will not be required for the period when the Final Report is due. The Draft Final

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Report and the Final Report shall be submitted in accordance with the dates set forth in the table ("Summary of Contract Deliverables") under ARTICLE F.2. of this contract. The report shall conform to the following format:

1. Cover page to include the contract number, contract title, performance period covered, Contractor's name and address, telephone number, fax number, email address and submission date.
2. SECTION I: EXECUTIVE SUMMARY - Summarize the purpose and scope of the contract effort including a summary of the major accomplishments relative to the specific activities set forth in the Statement of Work.
3. SECTION II: RESULTS - A detailed description of the work performed related to WBS and Gantt chart, the results obtained, and the impact of the results on the scientific and/or public health community including a listing of all manuscripts (published and in preparation) and abstracts presented during the entire period of performance and a summary of all inventions.

Draft Final Report: The Contractor is required to submit the Draft Final Report to the Contracting Officer's Representative and Contracting Officer. The Contracting Officer's Representative and Contracting Officer will review the Draft Final Report and provide the Contractor with comments in accordance with the dates set forth in ARTICLE F.2. of this contract.

Final Report: The Contractor will deliver the final version of the Final Report on or before the completion date of the contract. The final version shall include or address the COR's and CO's written comments on the draft report. Final Report shall be submitted on or before the completion date of the contract.

iv. Summary of Salient Results

The Contractor shall submit, with the Final Report, a summary (not to exceed 200 words) of salient results achieved during the performance of the contract.

v. Audit Reports

Within thirty (30) calendar days of an audit related to conformance to FDA regulations and guidance, including adherence to GLP, GMP, GCP guidelines, the Contractor shall provide copies of the audit report (so long as received from the FDA) and a plan for addressing areas of nonconformance to FDA regulations and guidelines for GLP, GMP, or GCP guidelines as identified in the final audit report.

vi. Other Technical Reports

1. Draft Report for Clinical and Non-Clinical Studies and Final Report for Clinical and Non-Clinical Studies

- The clinical trial reports shall follow the format of International Conference on Harmonization document ICH E3 "Guideline for Industry on Structure and Content of Clinical Study Reports"
- Draft Final Report for Clinical and Non-Clinical Studies funded by this contract will be submitted to the Contracting Officer's Representative and Contracting Officer (CO) for review and comment within the time frames set forth in the table ("Summary of Contract Deliverables") under ARTICLE F.2.
- Subcontractor prepared reports received by the Contractor shall be submitted to the Contracting Officer's Representative and Contracting Officer (CO) for review and comment as set forth by the table in this Article. Contractor shall consider revising reports to address BARDA's recommendations prior to FDA submission.
- The Government shall provide written comments to the Draft Final Report for Clinical and Non-Clinical Studies in accordance with the dates set forth by the table in this Article.
- The comprehensive Final Report for Clinical and Non-Clinical Studies will be submitted to the Contracting Officer and the Contracting Officer's Representative set forth by the table in this Article.

2. Supplemental Technical Documents

Upon request, Contractor shall provide CO and COR with the following contract funded documents as specified below but not limited to: Process Development Reports; Assay Qualification Plan/Report, Assay Validation Plan/Report, Assay Technology Transfer Report, Batch Records, Contractor/Subcontractor Standard Operating Procedures (SOP's), Master Production Records, Certificate of Analysis, Clinical Studies Data or Reports. The CO and COR reserve the right to request within the Period of Performance a non-proprietary technical document for distribution within the USG. Contractor shall provide technical document within 10 business days of CO or COR request. Contractor can request additional time on an as needed basis. If edits are recommended, the Contractor must address, in writing, concerns raised by BARDA.

B. Deliverables Arising from FDA Correspondence

i. FDA Meetings

The Contractor shall forward the dates and times of any meeting with the FDA to BARDA and make arrangements for appropriate BARDA staff to attend the FDA meetings. BARDA staff shall include up to a maximum of four people.

- Contractor shall notify BARDA of upcoming FDA meeting within 24 hours of scheduling Type A, B or C meetings OR within 24 hours of meeting occurrence for ad hoc meetings.
- The Contractor shall forward initial Contractor and FDA-issued draft minutes and final minutes of any meeting with the FDA to BARDA within 5 business days of receipt. All documents shall be duly marked as either "Draft" or "Final."

ii. FDA Submissions

The Contractor shall provide BARDA all documents submitted to the FDA.

Contractor shall provide BARDA with an electronic copy of the final FDA submission. All documents shall be duly marked as either "Draft" or "Final."

- When draft documents are submitted for BARDA review, BARDA will provide feedback to Contractor within 3 business days of receipt.
- When BARDA reviews draft documents, the Contractor shall revise their documents to address BARDA's written concerns and/or recommendations prior to FDA submission.
- Final FDA submissions shall be submitted to BARDA concurrently or no later than 1 calendar day of their submission to FDA.

iii. FDA Audits

In the event of an FDA inspection which occurs as a result of this contract and for the product, or for any other FDA inspection that has the reasonable potential to impact the performance of this contract, the Contractor shall provide the USG with an exact copy (non-redacted) of the FDA Form 483 and the Establishment Inspection Report (EIR) within five (5) business days after the Contractor's receipt of those documents. The Contractor shall provide the COR and CO with copies of the plan for addressing areas of non-conformance to FDA regulations for GLP, GMP, or GCP guidelines as identified in the audit report, status updates during the plans execution and a copy of all final responses to the FDA. The Contractor shall also provide redacted copies of any FDA audits received from subcontractors that occur as a result of this contract or for this product. The Contractor shall make arrangements for BARDA representative(s) to be present during the final debrief by the regulatory inspector.

- Contractor shall notify CO and COR within 10 business days of a scheduled FDA audit or within 24 hours of an ad hoc site visit/audit if the FDA does not provide advanced notice.
- Contractor shall provide copies of any FDA audit report received from subcontractors that occur as a result of this contract or for this product within 5 business days of receiving correspondence from the FDA, Subcontractor, or third party.
- Within 10 business days of audit report, Contractor shall provide CO with a plan for addressing areas of nonconformance, if any are identified.

iv. Manufacturing Campaign Reports

Contractor shall provide Manufacturing Campaign Reports to BARDA for review and comment prior to submission to FDA.

The COR and CO reserve the right to request within the Period of Performance (PoP) a non-proprietary Manufacturing Campaign Report for distribution within the USG.

- Contractor will submit Manufacturing Campaign Reports at least 15 business days prior to FDA submission.
- If corrective action is recommended, Contractor shall address, in writing, the concerns raised by BARDA.
- Contractor shall revise the reports to address BARDA's concerns and/or recommendations prior to FDA submission.
- Final FDA submission shall be submitted to BARDA concurrently or no later than 1 business day after submission to the FDA.

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v. Other FDA Correspondence

The Contractor shall memorialize any correspondence between Contractor and FDA and submit to BARDA. All documents shall be duly marked as either "Draft" or "Final." Contractor shall provide written summary of any FDA correspondence within 5 business days of correspondence.

i. Risk Management Plan

The Contractor shall provide a Risk Management Plan that outlines the impacts of each risk in relation to the cost, schedule, and performance objectives. The plan shall include risk mitigation strategies. Each risk mitigation strategy will capture how the corrective action will reduce impacts on cost, schedule and performance.

- Due within 90 days of contract award
- Contractor provides updated Risk Management Plan in Monthly Progress Report
- BARDA shall provide Contractor with a written list of concerns in response plan submitted
- Contractor must address, in writing, all concerns raised by BARDA within 20 business days of Contractor's receipt of BARDA's concerns.

Work Breakdown Structure and Option Periods

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Contract No. 75A50120C00034 Development of an mRNA Vaccine for SARS-CoV-2

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Integrated Program Gantt Chart

Gantt Chart of Moderna's Proposal "Development of an mRNA Vaccine mRNA vaccine"

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Deliverables

The primary deliverable of this proposal is a licensed mRNA vaccine. In addition, the team, in partnership with BARDA, will also design a plan to enhance Moderna's ability to rapidly respond to a Coronavirus pandemic by leveraging our mRNA platform. Interim deliverables are presented below.

WBS	Title	Deliverable	[***]
1	mRNA Vaccine Development		
1.1	Program Management		
1.1.1	Program and Alliance Management	-Management Plans; Routine Reporting Deliverables	[***]
1.2	Nonclinical Toxicology		
1.2.2	Safety		
1.2.2.1	Development and Reproductive Toxicology	- Final Study Report	[***]
1.3	Nonclinical		
1.3.1	Model Development (reserved)		
1.3.1.2	NHP Efficacy Study	- Final Study Report	[***]
1.3.1.3	Mouse Efficacy Study	- Final Study Report	[***]
1.4	Clinical		
1.4.2	Phase 2		
1.4.2.1	Phase 2 Safety and Immunogenicity Study	- Clinical Study Protocol	[***]
		- Final Clinical Study Report	[***]
1.4.3	Phase 3		
1.4.3.1	Phase 3 Efficacy or Safety and Immunogenicity	- Clinical Study Protocol	[***]
		- Final Clinical Study Report	[***]
1.4.3.2	Phase 3 Lot-to-Lot	- Clinical Study Protocol	[***]
		- Final Clinical Study Report	[***]
1.4.3.3	Phase 3 Adolescents	- Clinical Study Protocol	[***]
		- Final Clinical Study Report	[***]
1.5	Regulatory		
1.5.1	IND		
1.5.1.1	IND Filing	- NA	
1.5.1.2	IND Maintenance	- Record of FDA Communications	[***]
1.5.2	BLA		[***]
1.5.2.1	BLA Submission	- NA	
1.6	CMC		
1.6.3	Pilot Scale Manufacturing		
1.6.3.2	CTM Manufacture for P201	- CoA for Clinical Lots	[***]
1.6.3.4	CTM Manufacture for P301	- CoA for Clinical Lots	[***]
1.6.3.6	CTM Manufacture for P302/P303	- CoA for Clinical Lots	[***]

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G. CONTRACT ADMINISTRATION

G.1 Contracting Officer

The Contracting Officer (CO) is the only individual who can legally commit the Government to the expenditure of public funds. No person other than the Contracting Officer can make any changes to the terms, conditions, general provisions or other stipulations of this Contract.

The Contracting Officer is the only individual with authority to act as agent of the Government under this Contract, with authority to (1) direct or negotiate any changes in the statement of work, (2) modify or extend the period of performance, (3) authorize reimbursement to the Contractor for any costs incurred during the performance of this Contract and/or (5) otherwise change any terms and conditions of this Contract.

No information, other than that which may be contained in an authorized modification to this contract duly issued by the Contracting Officer, which may be received from any person employed by the United States Government, or otherwise, shall be considered grounds for deviation from any stipulation of this contract.

Wendell Conyers – (202) 692-4784 – wendell.conyers@hhs.gov – Office No. 21K13
Supervisory Contract Specialist Division of Contracts Management & Acquisition (CMA)
Biomedical Advanced Research & Development Authority (BARDA)

G.2 Contracting Officer's Representative

As delegated by the CO, the Contracting Officer's Representative (COR) is responsible for: (1) monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements; (2) assisting the CO in interpreting the statement of work and any other technical performance requirements; (3) performing technical evaluation as required; (4) performing technical inspections required by this contract; and (5) assisting in the resolution of technical problems encountered during performance.

Chuong Huynh – (202) 260-2177 – chuong.huynh@hhs.gov – Office No.
Project Officer / COR for Development Activities
Influenza and Emerging Infectious Diseases Division
Biomedical Advanced Research & Development Authority (BARDA)

G.3 Deliveries

All deliveries of physical documents, shall be addressed in the following format:

UPS/FedEx/USPS
U.S. Department of Health & Human Services <i>Insert Recipient's Name</i> HHS/ASPR/BARDA <i>Insert Office Number</i> – O'Neill House Office Building, 2 nd Floor Washington, DC 20515 <i>Insert Recipient's Telephone Number</i>

G.4 Invoicing Instructions

Invoices for payment shall be submitted to the Contracting Officer and Contracting Officer's Representative, as one (1) hard copy and one (1) electronic copy addressed in the format indicated in G.3, shall follow the detailed invoicing instructions listed in Section J, and include an SF-1034.

CO	COR	Alternate COR	PSC
Wendell Conyers (Contracting Officer) HHS/ASPR/BARDA/CMA O'Neill House Office Building Room Number 21C06 Washington, DC 20515 Email: wendell.conyers@hhs.gov	Chuong Huynh (COR) HHS/ASPR/BARDA O'Neill House Office Building Room Number 24K24 Washington, DC 20515 TBD	TBD Alt COR HHS/ASPR/BARDA O'Neill House Office Building Room Number 24K13 Washington, D.C.20515 TBD	PSC_Invoices@psc.hhs.gov & "HHS e-Room" (shared access may be provided to

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			the Contractor after award).
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- a. Contractor invoices/financial reports shall conform to the form, format, and content requirements of the instructions for Invoice/Financing requests and Contract Financial Reporting.
- b. Monthly invoices must include the cumulative total expenses to date, adjusted (as applicable) to show any amounts suspended by the Government.
- c. The Contractor agrees to immediately notify the CO in writing if there is an anticipated overrun (any amount) or unexpended balance (greater than 10%) of the estimated costs for the base period or any option period(s) (See estimated costs under Section B) and the reasons for the variance. These requirements are in addition to the specified requirements of FAR 52.232-20, Limitation of Cost that is incorporated by reference under Section I.1 which states;

Limitation of Cost (Apr 1984)

The parties estimate that performance of this contract, exclusive of any fee, will not cost the Government more than (1) the estimated cost specified in the Schedule or, (2) if this is a cost-sharing contract, the Government's share of the estimated cost specified in the Schedule. The Contractor agrees to use its best efforts to perform the work specified in the Schedule and all obligations under this contract within the estimated cost, which, if this is a cost-sharing contract, includes both the Government's and the Contractor's share of the cost.

The Contractor shall notify the Contracting Officer in writing whenever it has reason to believe that—

The costs the Contractor expects to incur under this contract in the next 60 days, when added to all costs previously incurred, will exceed 75 percent of the estimated cost specified in the Schedule; or

The total cost for the performance of this contract, exclusive of any fee, will be either greater or substantially less than had been previously estimated.

As part of the notification, the Contractor shall provide the Contracting Officer a revised estimate of the total cost of performing this contract. Except as required by other provisions of this contract, specifically citing and stated to be an exception to this clause—

- The Government is not obligated to reimburse the Contractor for costs incurred in excess of (i) the estimated cost specified in the Schedule or, (ii) if this is a cost-sharing contract, the estimated cost to the Government specified in the Schedule; and
- The Contractor is not obligated to continue performance under this contract (including actions under the Termination clause of this contract) or otherwise incur costs in excess of the estimated cost specified in the Schedule, until the Contracting Officer (i) notifies the Contractor in writing that the estimated cost has been increased and (ii) provides a revised estimated total cost of performing this contract. If this is a cost-sharing contract, the increase shall be allocated in accordance with the formula specified in the Schedule.
- No notice, communication, or representation in any form other than that specified in paragraph (d)(2) of this clause, or from any person other than the Contracting Officer, shall affect this contract's estimated cost to the Government. In the absence of the specified notice, the Government is not obligated to reimburse the Contractor for any costs in excess of the estimated cost or, if this is a cost-sharing contract, for any costs in excess of the estimated cost to the Government specified in the Schedule, whether those excess costs were incurred during the course of the contract or as a result of termination.
- If the estimated cost specified in the Schedule is increased, any costs the Contractor incurs before the increase that are in excess of the previously estimated cost shall be allowable to the same extent as if incurred afterward, unless the Contracting Officer issues a termination or other notice directing that the increase is solely to cover termination or other specified expenses.
- Change orders shall not be considered an authorization to exceed the estimated cost to the Government specified in the Schedule, unless they contain a statement increasing the estimated cost.
- If this contract is terminated or the estimated cost is not increased, the Government and the Contractor shall negotiate an equitable distribution of all property produced or purchased under the contract, based upon the share of costs incurred by each.

d. The Contractor shall submit an electronic copy of the payment request to the approving official instead of a paper copy. The payment request shall be transmitted as an attachment via e-mail to the address listed above in one of the following formats: MSWord, MS Excel, or Adobe Portable Document Format (PDF). Only one payment request shall be submitted per e-mail and the subject line of the e-mail shall include the Contractor's name, contract number, and unique invoice number.

- e. An electronic copy of the payment request shall be uploaded into the designated eRoom (as defined in Section F.3

Electronic Submission) and an e-mail notification of the upload will be provided to the CO and COR.

- f. All invoice submissions shall be in accordance with FAR 52.232-25, Prompt Payment (Oct 2008).
- g. Invoices - Cost and Personnel Reporting, and Variances from the Negotiated Budget.
- h. Invoices - Cost and Personnel Reporting, and Variances from the Negotiated Budget.

The Contractor agrees to provide a detailed breakdown on invoices of the following cost categories:

- 1. Direct Labor - List individuals by name, title/position, hourly/annual rate, level of effort (actual hours or % of effort), and amount claimed.
- 2. Fringe Benefits - Cite rate and amount
- 3. Overhead - Cite rate and amount
- 4. Materials & Supplies - Include detailed breakdown when total amount is over \$100,000
- 5. Travel - Identify travelers, dates, destination, purpose of trip, and total breaking out amounts for transportation (plane, car, etc.), lodging, M&IE. Cite COA, if appropriate. List separately, domestic travel, general scientific meeting travel, and foreign travel.
- 6. Consultant Fees - Identify individuals, amounts and activities. Cite appropriate COA
- 7. Subcontracts - Attach subcontractor invoice(s). Cite appropriate COA
- 8. Equipment - Cite authorization and amount. Cite appropriate COA
- 9. Other Direct Costs - Include detailed breakdown when total amount is over \$100,000.
- 10. G&A - Cite rate and amount.
- 11. Total Cost (and applicable cost-shared ratio)
- 12. Fixed Fee (if applicable)
- 13. Total Cost Plus Fixed Fee

Monthly invoices must include the cumulative total expenses to date, adjusted (as applicable) to show any amounts suspended by the USG. Nothing in this section discharges the contractor's responsibility to comply with any applicable FAR Parts 30 or 31 clauses' relating to cost reimbursement subcontracts. In order to verify allowability, further breakdown of costs may be requested at the USG's discretion. The Contractor shall subcontract with Firm Fixed Price Contracts to the maximum extent practicable.

Additional instructions and an invoice template are provided in Section J-List of Attachments, Invoice/Financing Request Instructions and Contract Financial Reporting Instructions for Cost- Reimbursement Contracts. All invoices must be signed by a representative of the contractor authorized to certify listed charges are accurate and comply with government regulations. Invoices shall be signed and submitted electronically (in accordance with Section F.3 Electronic Submission).

If applicable, the Contractor shall convert any foreign currency amount(s) in the monthly invoice to U.S. dollars each month, on the 1st of the month, using the foreign exchange rate index published on www.federalreserve.gov. Payment of invoices is subject to the U.S. dollar limits within the Total Costs of CLIN 0001 and 0002 in Section B of the contract.

The Government shall use electronic funds transfer to the maximum extent possible when making payments under this contract. FAR 52.232-33, Payment by Electronic Funds Transfer-System for Award Management, in Section I requires the Contractor to designate in writing a financial institution for receipt of electronic funds transfer payments.

The electronic version of the invoice can be submitted via e-mail or uploaded through HHS' eRoom (shared access may be provided to the Contractor after award).

The Government may request additional information (timecards, receipts, etc.) to support costs claimed in the Contractor's invoices. Incomplete invoices may be suspended by the Contracting Officer if the Contractor's claimed costs cannot be substantiated.

G.5 REIMBURSEMENT OF COST

The Government shall reimburse the Contractor the cost determined by the Contracting Officer to be allowable (hereinafter referred to as allowable cost) in accordance with FAR 52.216-7, Allowable Cost and Payment incorporated by reference in Section I, Contract Clauses, of this contract, and FAR Subpart 31.2. Examples of allowable costs include, but are not limited to, the following:

- a) All direct materials and supplies that are used in performing the work provided for under the contract, including those purchased for subcontracts and purchase orders.
- b) All direct labor, including supervisory, that is properly chargeable directly to the contract, plus fringe benefits.

- c) All other items of cost budgeted for and accepted in the negotiation of this basic contract or modifications thereto.
- d) Travel costs including per diem or actual subsistence for personnel while in an actual travel status in direct performance of the work and services required under this contract subject to the following:
 - (i) Air travel shall be by the most direct route using "air coach" or "air tourist" (less than first class or business class) unless it is clearly unreasonable or impractical (e.g., not available for reasons other than avoidable delay in making reservations, would require circuitous routing or entail additional expense offsetting the savings on fare, or would not make necessary connections).
 - (ii) Rail travel shall be by the most direct route, first class with lower berth or nearest equivalent.
 - (iii) Costs incurred for lodging, meals, and incidental expenses shall be considered reasonable and allowable to the extent that they do not exceed on a daily basis the per diem rates set forth in the Federal Travel Regulation (FTR).
 - (iv) Travel via privately owned automobile shall be reimbursed at not more than the current General Services Administration (GSA) FTR established mileage rate.

G.6 Providing Accelerated Payment to Small Business Subcontractors, FAR 52.232-40 (Dec. 2013)

- (a) Upon receipt of accelerated payments from the Government, the Contractor shall make accelerated payments to its small business subcontractors under this contract, to the maximum extent practicable and prior to when such payment is otherwise required under the applicable contract or subcontract, after receipt of a proper invoice and all other required documentation from the small business subcontractor.
- (b) The acceleration of payments under this clause does not provide any new rights under the prompt Payment Act.
- (c) Include the substance of this clause, include this paragraph c, in all subcontracts with small business concerns, including subcontracts with small business concerns for the acquisition of commercial items.

G.7 Contract Communication/Correspondence

The Contractor shall identify all correspondence, reports, and other data pertinent to this contract by imprinting thereon the contract number from Page 1 of the contract.

[***]

- 3. In accordance with FAR Part 5.216-7(d), the contractor shall submit an adequate final indirect cost rates proposal to the contracting officer within the 6-months period following the end of its fiscal years during the period of contract performance

G.8 Post-Award Evaluation of Contractor Performance

- (a) *Purpose:* In accordance with FAR 42.1502(a), past performance evaluations shall be prepared at least annually and at the time the work under a contract or order is completed, via CPARS, the Government-wide evaluation tool (www.cpars.gov).
- (b) *Evaluators:* The performance evaluation will be completed jointly by the Contracting Officer's Representative and the Contracting Officer.
- (c) *Performance Evaluation Factors:* Per FAR 42.1503(b)(2), evaluation factors for each assessment shall include, at a minimum: technical (quality of product or service); cost control; schedule/timeliness; management and business relations; small business subcontracting; other (as applicable).
- (d) *Contractor Review:* A copy of the evaluation will be electronically sent to the Contractor as soon as practicable after completion of the evaluation. The Contractor shall submit comments, rebutting statements, or additional information to the Contracting Officer within 14 calendar days after receipt of the evaluation.
- (e) *Resolving Disagreements between the Government and the Contractor:* Disagreements between the parties regarding the evaluation will be reviewed at a level above the Contracting Officer. The ultimate conclusion on the performance evaluation is a decision of the contracting agency. Copies of the evaluation, Contractor's response, and review comments, if any, will be retained as part of the evaluation.

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- (f) *Release of Contractor Performance Evaluation Information:* The completed evaluation will not be released to other than Government personnel and the Contractor whose performance is being evaluated. Disclosure of such information could cause harm both to the commercial interest of the Government and to the competitive position of the Contractor being evaluated, as well as impede the efficiency of Government operations.
- (g) *Source Selection Information:* Departments and agencies may share past performance information with other Government departments and agencies when requested to support future award decisions. The information may be provided through interview and/or by sending the evaluation and comment document to the requesting source selection official.
- (h) *Retention Period:* The agency will retain past performance information for a maximum period of 3 years after completion of contract performance for the purpose of providing source selection information for future contract awards.

H. SPECIAL CONTRACT REQUIREMENTS

H.1 Access and Disposition of Data

The Government shall have physical and electronic access to all documentation and data generated under this contract, including: all Contractor efforts; Subcontractor efforts; communications and correspondence with regulatory agencies and bodies to include all audit observations, inspection reports, meeting minutes, and all Contractor commitments and responses.

H.2 Interactions with the Food and Drug Administration (FDA)

The Contractor shall memorialize any interactions between the Contractor and the FDA, and submit documentation to the COR and CO. All documents shall be duly marked as either "Draft" or "Final."

H.2.1 FDA Correspondence

Contractor shall provide written summary of any FDA correspondence within five (5) business days of correspondence.

H.2.2 FDA Meetings

The Contractor shall forward the dates and times of any meeting with the FDA to the COR and CO, and make arrangements for appropriate BARDA staff to attend the FDA meetings. BARDA staff shall include up to a maximum of four people (COR, CO and up to 2 subject matter experts).

- (1) Contractor shall notify the COR and CO of upcoming FDA meeting within 24 hours of scheduling Type A, B or C meetings, or within 24 hours of meeting occurrence for ad hoc meetings.
- (2) The Contractor shall forward initial Contractor and FDA-issued draft and final minutes of any meeting with the FDA, to the COR and CO, within 2 business days of receipt. All documents shall be duly marked as either "Draft" or "Final."

H.2.3 FDA Pre-Submissions, Submissions, and Other Related Correspondence

The Contractor shall provide the COR and CO the opportunity to review and comment upon all draft submissions directly related to this contract before submission to the FDA. Contractor shall provide the COR and CO with an electronic copy of the final FDA submission. All documents shall be duly marked as either "Draft" or "Final".

- (1) Contractor shall submit draft FDA submissions to the COR and CO at least 15 business days prior to FDA submission.
- (2) The COR and CO will provide feedback to Contractor within 5 business days of receipt.
- (3) If corrective action is recommended, the Contractor must address, in writing, its consideration of all concerns raised by the COR and CO.
- (4) The Contractor shall consider revising their documents to address the COR and CO's concerns and/or recommendations prior to FDA submission.
- (5) Final FDA submissions shall be submitted to the COR and CO concurrently or no later than 1 calendar day of its submission to FDA.

H.2.4 FDA Audits

In the event of an FDA inspection which occurs as a result of this contract and for the product, or for any other FDA inspection that has the reasonable potential to impact the performance of this contract, the Contractor shall provide the USG with an exact copy (non-redacted) of the FDA Form 483 and the Establishment Inspection Report (EIR). The Contractor shall provide the COR and CO with copies of the plan for addressing areas of non-conformance to FDA regulations for GLP, GMP, or GCP guidelines as identified in the audit report, status updates during the plans execution and a copy of all final responses to the FDA. The Contractor shall also provide redacted copies of any FDA audits received from subcontractors that occur as a result of this contract or for this product. The Contractor shall make arrangements for BARDA representative(s) to be present during the final debrief by the regulatory inspector.

- (1) Contractor shall notify CO and COR within 10 business days of a scheduled FDA audit or within 24 hours of an ad hoc site visit/audit if the FDA does not provide advanced notice.
- (2) Contractor shall provide copies of any FDA audit report received from subcontractors that occur as a result of this contract or for this product within 5 business days of receiving correspondence from the FDA or third party.
- (3) Within 10 business days of audit report, Contractor shall provide CO and COR with a plan for addressing areas of nonconformance, if any are identified.

H.3 Key Personnel

Pursuant to HHSAR 352.237-75 (Dec 2015), Key Personnel, any key personnel specified in this contract are considered to be essential to work performance. At least thirty (30) calendar days prior to the Contractor voluntarily diverting any of the specified individuals to other programs or contracts the Contractor shall notify the Contracting Officer and shall submit a justification for the diversion or replacement and a request to replace the individual. The request must identify the proposed replacement and provide an explanation of how the

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replacement's skills, experience, and credentials meet or exceed the requirements of the contract (including, when applicable, Human Subjects Testing requirements). If the employee of the Contractor is terminated for cause or separates from the Contractor voluntarily with less than thirty (30) calendar-day notice, the Contractor shall provide the maximum notice practicable under the circumstances. The Contractor shall not divert, replace, or announce any such change to key personnel without the written consent of the Contracting Officer. The contract will be modified to add or delete key personnel as necessary to reflect the agreement of the parties. The following individuals are determined to be key personnel:

[***]	[***]	[***]
[***]	[***]	[***][***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]

H.3.1 Personnel Qualifications

The Contractor shall provide curriculum vitae (CV) for each individual identified as key personnel. The CV shall clearly describe the individual's knowledge, work experiences, registrations, and certifications, and applicable experience. The CV shall include a summary describing the individual's involvement in similar work.

H.4 Substitution of Key Personnel

- The Contractor agrees to assign to the contract those persons whose resumes/CVs were submitted with the proposal who are necessary to fill the requirements of the contract. No substitutions shall be made except in accordance with this clause.
- All requests for substitution must provide a detailed explanation of the circumstance necessitating the proposed substitution, a complete resume for the proposed substitute and any other information requested by the contracting officer to approve or disapprove the proposed substitution. All proposed substitutes must have qualifications that are equal to or higher than the qualifications of the person to be replaced. The contracting officer or authorized representative will evaluate such requests and promptly notify the contractor of his approval or disapproval thereof.
- The contractor further agrees to include the substance of this clause in any subcontract, which may be awarded under this contract.

H.5 Contracting Officer's Authorization (COA) for Subcontracting

The Contractor shall submit a Contracting Officer's Authorization (COA) approval request, to the Contracting Officer, for all subcontractors, consultants and equipment purchases proposed during the course of this contract. COAs for subcontractors and consultant agreements shall be submitted when the potential subcontract is expected to exceed \$150,000; for equipment purchases, when the unit price per item is expected to exceed \$25,000. Sufficient time shall be provided for the Government to fully assess the transaction proposed. The supporting documents shall include, but not be limited to:

- Competition activities, as well as technical and cost/price evaluation activities performed, in the selection of the subcontractor(s);
- The subcontractor's qualifications/capabilities statement as they pertain to the activities included in the proposed subcontract;
- The subcontractor's willingness to perform under the Contractor (i.e. commitment letters/preliminary agreements), with a list of specific duties included in the proposed subcontract;
- A complete subcontractor cost proposal or quote, in similar format as the Contractor's cost proposal.

H.6 No Personal Services or Inherently Governmental Function

Pursuant to FAR 37.1, no personal services shall be performed under this contract. All work requirements shall flow only from the COR to the Contractor's Project Manager. No Contractor employee will be directly supervised by the Government. All employee assignments, and daily work direction, shall be given by the applicable Contractor supervisor. If the Contractor believes any Government action or communication has been given that would create a personal services relationship between the Government and any Contractor employee, the Contractor shall promptly notify the Contracting Officer of this communication or action.

Pursuant to FAR 7.5, the Contractor shall not perform any inherently governmental actions under this contract. No Contractor employee shall hold him or herself out to be a Government employee, agent, or representative. No Contractor employee shall state orally or in writing at any time that he or she is acting on behalf of the Government. In all communications with third parties in connection with this contract, Contractor employees shall identify themselves as Contractor employees and specify the name of the company for which they work. In all communications with other Government Contractors in connection with this contract, the Contractor employee shall state that they have no authority to in any way change this contract and that if the other Contractor believes this communication to be a direction to change their contract, they shall notify the Contracting Officer for that contract and not carry out the direction until a clarification has been issued by the Contracting Officer.

The Contractor shall ensure that all of its employees working on this contract are informed of the substance of this article. Nothing in this article shall limit the Government's rights in any way under the other provisions of this contract, including those related to the Government's right to inspect and accept the services to be performed under this contract. The substance of this article shall be included in all subcontracts at any tier.

H.7 Acknowledgement of Federal Funding – Publication and Publicity

The Contractor shall acknowledge the support of the Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority whenever publicizing the work under this contract in any media by including an acknowledgment substantially as follows:

"This project has been funded in whole or in part with Federal funds from the Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority, under Contract No. 75A50120C00034."

Press Releases:

The Contractor shall clearly state, when issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money: (1) the percentage of the total costs of the program or project which will be financed with Federal money; (2) the dollar amount of Federal funds for the project or program; and (3) the percentage and dollar amount of the total costs of the project or program that will be financed by nongovernmental sources.

H.8 352.270-4b, Protection of Human Subjects (Dec 2015)

(a) The Contractor agrees that the rights and welfare of human subjects involved in research under this contract shall be protected in accordance with 45 CFR part 46 and with the Contractor's current Federal-wide Assurance (FWA) on file with the Office for Human Research Protections (OHRP), Department of Health and Human Services. The Contractor further agrees to provide certification at least annually that the Institutional Review Board has reviewed and approved the procedures, which involve human subjects in accordance with 45 CFR part 46 and the Assurance of Compliance.

(b) The Contractor shall bear full responsibility for the performance of all work and services involving the use of human subjects under this contract and shall ensure that work is conducted in a proper manner and as safely as is feasible. The parties hereto agree that the Contractor retains the right to control and direct the performance of all work under this contract. Nothing in this contract shall create an agency or employee relationship between the Government and the Contractor, or any subcontractor, agent or employee of the Contractor, or any other person, organization, institution, or group of any kind whatsoever. The Contractor agrees that it has entered into this contract and will discharge its obligations, duties, and undertakings and the work pursuant thereto, whether requiring professional judgment or otherwise, as an independent Contractor without creating liability on the part of the Government for the acts of the Contractor or its employees.

(c) Contractors involving other agencies or institutions in activities considered to be engaged in research involving human subjects must ensure that such other agencies or institutions obtain their own FWA if they are routinely engaged in research involving human subjects or ensure that such agencies or institutions are covered by the Contractors' FWA via designation as agents of the institution or via individual investigator agreements (see OHRP website at: <http://www.hhs.gov/ohrp/policy/guidanceonalternativetofwa.pdf>).

(d) If at any time during the performance of this contract the Contractor is not in compliance with any of the requirements and or standards stated in paragraphs (a) and (b) above, the Contracting Officer may immediately suspend, in whole or in part, work and further payments under this contract until the Contractor corrects the noncompliance. The Contracting Officer may communicate the notice of suspension by telephone with confirmation in writing. If the Contractor fails to complete corrective action within the period of time designated in the Contracting Officer's written notice of suspension, the Contracting Officer may, after consultation with OHRP, terminate this contract in whole or in part.

(End of clause)

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H.9 HHSAR 352.270-5a, Notice to Offerors of Requirement for Compliance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals (Dec 2015)

The Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (PHS Policy) establishes a number of requirements for research activities involving animals. Before awarding a contract to an offeror, the organization shall file, with the Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH), a written Animal Welfare Assurance (Assurance) which commits the organization to comply with the provisions of the PHS Policy, the Animal Welfare Act, and the Guide for the Care and Use of Laboratory Animals (National Academy Press, Washington, DC). In accordance with the PHS Policy, offerors must establish an Institutional Animal Care and Use Committee (IACUC), qualified through the experience and expertise of its members, to oversee the institution's animal program, facilities, and procedures. Offerors must provide verification of IACUC approval prior to receiving an award involving live vertebrate animals. No award involving the use of animals shall be made unless OLAW approves the Assurance and verification of IACUC approval for the proposed animal activities has been provided to the Contracting Officer. Prior to award, the Contracting Officer will notify Contractor(s) selected for projects involving live vertebrate animals of the Assurance and verification of IACUC approval requirement. The Contracting Officer will request that OLAW negotiate an acceptable Assurance with those Contractor(s) and request verification of IACUC approval. For further information, contact OLAW at NIH, 6705 Rockledge Drive, RKL1, Suite 360, MSC 7982 Bethesda, Maryland 20892-7982 (E-mail: olaw@od.nih.gov; Phone: 301-496-7163).

(End of provision)

H.10 HHSAR 352.270-5b, Care of Life Vertebrate Animals (Dec 2015)

(a) Before undertaking performance of any contract involving animal-related activities where the species is regulated by the United States Department of Agriculture (USDA), the Contractor shall register with the Secretary of Agriculture of the United States in accordance with 7 U.S.C. 2136 and 9 CFR 2.25 through 2.28. The Contractor shall furnish evidence of the registration to the Contracting Officer.

(b) The Contractor shall acquire vertebrate animals used in research from a dealer licensed by the Secretary of Agriculture under 7 U.S.C. 2133 and 9 CFR 2.1 2.11, or from a source that is exempt from licensing under those sections.

(c) The Contractor agrees that the care, use, and intended use of any live vertebrate animals in the performance of this contract shall conform with the Public Health Service (PHS) Policy on Humane Care of Use of Laboratory Animals (PHS Policy), the current Animal Welfare Assurance (Assurance), the Guide for the Care and Use of Laboratory Animals (National Academy Press, Washington, DC) and the pertinent laws and regulations of the United States Department of Agriculture (see 7 U.S.C. 2131 et seq. and 9 CFR subchapter A, Parts 1-4). In case of conflict between standards, the more stringent standard shall govern.

(d) If at any time during performance of this contract, the Contracting Officer determines, in consultation with the Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH), that the Contractor is not in compliance with any of the requirements and standards stated in paragraphs (a) through (c) above, the Contracting Officer may immediately suspend, in whole or in part, work and further payments under this contract until the Contractor corrects the noncompliance. Notice of the suspension may be communicated by telephone and confirmed in writing. If the Contractor fails to complete corrective action within the period of time designated in the Contracting Officer's written notice of suspension, the Contracting Officer may, in consultation with OLAW, NIH, terminate this contract in whole or in part, and the Contractor's name may be removed from the list of those contractors with Animal Welfare Assurances.

Note: The Contractor may request registration of its facility and a current listing of licensed dealers from the Regional Office of the Animal and Plant Health Inspection Service (APHIS), USDA, for the region in which its research facility is located. The location of the appropriate APHIS Regional Office, as well as information concerning this program may be obtained by contacting the Animal Care Staff, USDA/APHIS, 4700 River Road, Riverdale, Maryland 20737 (Email: ace@aphis.usda.gov; Web site: <http://www.aphis.usda.gov/wps/portal/aphis/ourfocus/animalwelfare>)

(End of clause)

H.11 Animal Welfare

All research involving live, vertebrate animals shall be conducted in accordance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy). The PHS Policy can be accessed at: <http://grants1.nih.gov/grants/olaw/references/phspol.htm>

H.12 Dissemination of False or Deliberately Misleading Information

The Contractor shall not use contract funds to disseminate information that is deliberately false or misleading.

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H.13 Electronic Information and Technology Accessibility Notice

- a. Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998 and the Architectural and Transportation Barriers Compliance Board Electronic and Information (EIT) Accessibility Standards (36 CFR part 1194), require that when Federal agencies develop, procure, maintain, or use electronic and information technology, Federal employees with disabilities have access to and use of information and data that is comparable to the access and use by Federal employees who are not individuals with disabilities, unless an undue burden would be imposed on the agency. Section 508 also requires that individuals with disabilities, who are members of the public seeking information or services from a Federal agency, have access to and use of information and data that is comparable to that provided to the public who are not individuals with disabilities, unless an undue burden would be imposed on the agency.
- b. Accordingly, any Offeror responding to this solicitation must comply with established HHS EIT accessibility standards. Information about Section 508 is available at <http://www.hhs.gov/web/508>. The complete text of the Section 508 Final Provisions can be accessed at <http://www.access-board.gov/sec508/standards.htm>.
- c. The Section 508 accessibility standards applicable to this solicitation are stated in the clause at 352.239-74, Electronic and Information Technology Accessibility.

In order to facilitate the Government's determination whether proposed EIT supplies meet applicable Section 508 accessibility standards, Offerors must submit an HHS Section 508 Product Assessment Template, in accordance with its completion instructions. The purpose of the template is to assist HHS acquisition and program officials in determining whether proposed EIT supplies conform to applicable Section 508 accessibility standards. The template allows Offerors or developers to self-evaluate their supplies and document--in detail--whether they conform to a specific Section 508 accessibility standard, and any underway remediation efforts addressing conformance issues. Instructions for preparing the HHS Section 508 Evaluation Template are available under Section 508 policy on the HHS Web site <http://hhs.gov/web/508>.

In order to facilitate the Government's determination whether proposed EIT services meet applicable Section 508 accessibility standards, Offerors must provide enough information to assist the Government in determining that the EIT services conform to Section 508 accessibility standards, including any underway remediation efforts addressing conformance issues.

- d. Respondents to this solicitation must identify any exception to Section 508 requirements. If a Offeror claims its supplies or services meet applicable Section 508 accessibility standards, and it is later determined by the Government, i.e., after award of a contract or order, that supplies or services delivered do not conform to the described accessibility standards, remediation of the supplies or services to the level of conformance specified in the contract will be the responsibility of the Contractor at its expense.
(End of provision)

H.14 Confidentiality of Information

- a. Confidential information, as used in this article, means information or data of a personal nature about an individual, or proprietary information or data submitted by or pertaining to an institution or organization.
- b. The Contracting Officer and the Contractor may, by mutual consent, identify elsewhere in this contract specific information and/or categories of information which the Government will furnish to the Contractor or that the Contractor is expected to generate which is confidential. Similarly, the Contracting Officer and the Contractor may, by mutual consent, identify such confidential information from time to time during the performance of the contract. Failure to agree will be settled pursuant to the "Disputes" clause.
- c. If it is established elsewhere in this contract that information to be utilized under this contract, or a portion thereof, is subject to the Privacy Act, the Contractor will follow the rules and procedures of disclosure set forth in the Privacy Act of 1974, 5 U.S.C. 552a, and implementing regulations and policies, with respect to systems of records determined to be subject to the Privacy Act.
- d. Confidential information, as defined in paragraph (a) of this article, shall not be disclosed without the prior written consent of the individual, institution, or organization.
- e. Whenever the Contractor is uncertain with regard to the proper handling of material under the contract, or if the material in question is subject to the Privacy Act or is confidential information subject to the provisions of this article, the Contractor shall obtain a written determination from the Contracting Officer prior to any release, disclosure, dissemination, or publication.
- f. Contracting Officer Determinations will reflect the result of internal coordination with appropriate program and legal officials.
- g. The provisions of paragraph (d) of this article shall not apply to conflicting or overlapping provisions in other Federal, State or local laws.

H.15 Institutional Responsibility Regarding Investigator Conflicts of Interest

The Institution (includes any Contractor, public or private, excluding a Federal agency) shall comply with the requirements of 45 CFR Part 94, Responsible Prospective Contractors, which promotes objectivity in research by establishing standards to ensure that Investigators (defined as the project director or principal Investigator and any other person, regardless of title or position,

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who is responsible for the design, conduct, or reporting of research funded under BARDA contracts, or proposed for such funding, which may include, for example, collaborators or consultants) will not be biased by any Investigator financial conflicts of interest. 45 CFR Part 94 is available at the following Web site: <http://www.ecfr.gov/cgi-bin/textidx?c=ecfr&SID=0af84ca649a74846f102aaf664da1623&rgn=div5&view=text&node=45:1.0.1.1.51&idno=45>

As required by 45 CFR Part 94, the Institution shall, at a minimum:

- a. Maintain an up-to-date, written, enforceable policy on financial conflicts of interest that complies with 45 CFR Part 94, inform each Investigator of the policy, the Investigator's reporting responsibilities regarding disclosure of significant financial interests, and the applicable regulation, and make such policy available via a publicly accessible Web site, or if none currently exist, available to any requestor within five business days of a request. A significant financial interest means a financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:
 1. With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. Included are payments and equity interests;
 2. With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest; or
 3. Intellectual property rights and interests, upon receipt of income related to such rights and interest.

Significant financial interests do not include the following:

1. Income from seminars, lectures, or teaching, and service on advisory or review panels for G agencies, Institutions of higher education, academic teaching hospitals, medical centers, or research institutes with an Institution of higher learning; and
 2. Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles.
- b. Require each Investigator to complete training regarding the Institution's financial conflicts of interest policy prior to engaging in research related to any BARDA funded contract and at least every four years. The Institution must take reasonable steps [see Part 94.4(c)] to ensure that investigators working as collaborators, consultants or subcontractors comply with the regulations.
- c. Designate an official(s) to solicit and review disclosures of significant financial interests from each Investigator who is planning to participate in, or is participating in, the BARDA funded research.
- d. Require that each Investigator who is planning to participate in the BARDA funded research disclose to the Institution's designated official(s) the Investigator's significant financial interest (and those of the Investigator's spouse and dependent children) no later than the date of submission of the Institution's proposal for BARDA funded research. Require that each Investigator who is participating in the BARDA funded research to submit an updated disclosure of significant financial interests at least annually, in accordance with the specific time period prescribed by the Institution during the period of the award as well as within thirty days of discovering or acquiring a new significant financial interest.
- e. Provide guidelines consistent with the regulations for the designated official(s) to determine whether an Investigator's significant financial interest is related to BARDA funded research and, if so related, whether the significant financial interest is a financial conflict of interest. An Investigator's significant financial interest is related to BARDA funded research when the Institution, through its designated official(s), reasonably determines that the significant financial interest: Could be affected by the BARDA funded research; or is in an entity whose financial interest could be affected by the research. A financial conflict of interest exists when the Institution, through its designated official(s), reasonably determines that the significant financial interest could directly and significantly affect the design, conduct, or reporting of the BARDA funded research.
- f. Take such actions as necessary to manage financial conflicts of interest, including any financial conflicts of a subcontractor Investigator. Management of an identified financial conflict of interest requires development and implementation of a management plan and, if necessary, a retrospective review and mitigation report pursuant to Part 94.5(a).
- g. Provide initial and ongoing FCOI reports to the Contracting Officer pursuant to Part 94.5(b).

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- h. Maintain records relating to all Investigator disclosures of financial interests and the Institution's review of, and response to, such disclosures, and all actions under the Institution's policy or retrospective review, if applicable, for at least 3 years from the date of final payment or, where applicable, for the other time periods specified in 48 CFR Part 4, subpart 4.7, Contract Records Retention.
- i. Establish adequate enforcement mechanisms and provide for employee sanctions or other administrative actions to ensure Investigator compliance as appropriate.
- j. Complete the certification in Section K - Representations, Certifications, and Other Statements of Contractors titled "Certification of Institutional Policy on Financial Conflicts of Interest".

If the failure of an Institution to comply with an Institution's financial conflicts of interest policy or a financial conflict of interest management plan appears to have biased the design, conduct, or reporting of the BARDA funded research, the Institution must promptly notify the Contracting Officer of the corrective action taken or to be taken. The Contracting Officer will consider the situation and, as necessary, take appropriate action or refer the matter to the Institution for further action, which may include directions to the Institution on how to maintain appropriate objectivity in the BARDA funded research project.

The Contracting Officer and/or HHS may inquire at any time before, during, or after award into any Investigator disclosure of financial interests, and the Institution's review of, and response to, such disclosure, regardless of whether the disclosure resulted in the Institution's determination of a financial conflict of interests. The Contracting Officer may require submission of the records or review them on site. On the basis of this review of records or other information that may be available, the Contracting Officer may decide that a particular financial conflict of interest will bias the objectivity of the BARDA funded research to such an extent that further corrective action is needed or that the Institution has not managed the financial conflict of interest in accordance with Part 94.6(b). The issuance of a Stop Work Order by the Contracting Officer may be necessary until the matter is resolved.

If the Contracting Officer determines that BARDA funded clinical research, whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment, has been designed, conducted, or reported by an Investigator with a financial conflict of interest that was not managed or reported by the Institution, the Institution shall require the Investigator involved to disclose the financial conflict of interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

H.16 Reporting Matters Involving Fraud, Waste and Abuse

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in BARDA funded programs is encouraged to report such matters to the HHS Inspector General's Office in writing or on the Inspector General's Hotline. The toll free number is 1-800-HHS-TIPS (1-800-447-8477). All telephone calls will be handled confidentially. The e-mail address is Htips@os.dhhs.gov and the mailing address is:

Office of Inspector General
Department of Health and Human Services
TIPS HOTLINE
P.O. Box 23489
Washington, D.C. 20026

H.17 Prohibition on Contractor Involvement with Terrorist Activities

The Contractor acknowledges that U.S. Executive Orders and Laws, including but not limited to E.O. 13224 and Pub. L. 107-56, prohibit transactions with, and the provision of resources and support to, individuals and organizations associated with terrorism. It is the legal responsibility of the Contractor to ensure compliance with these Executive Orders and Laws. This clause must be included in all subcontracts issued under this contract.

H.18 FAR 52.227-14, Rights in Data – General (May 2014), Alternate II (December 2007)

As prescribed in FAR 27.409(b)(3), the following paragraph is inserted into (g)(3) of the basic clause:

(g)(3) Notwithstanding paragraph (g)(1) of this clause, the contract may identify and specify the delivery of limited rights data, or the Contracting Officer may require by written request the delivery of limited rights data that has been withheld or would otherwise be entitled to be withheld. If delivery of that data is required, the Contractor shall affix the following "Limited Rights Notice" to the data and the Government will treat the data, subject to the provisions of paragraphs (e) and (f) of this clause, in accordance with the notice:

Limited Rights Notice (Dec 2007)

(a) These data are submitted with limited rights under Government Contract No. 75A50120C00034 and subcontracts. These data may be reproduced and used by the Government with the express limitation that they will not, without written permission of the Contractor, be used for purposes of manufacture nor disclosed outside the Government; except that the Government may disclose

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these data outside the Government for the following purposes, if any; provided that the Government makes such disclosure subject to prohibition against further use and disclosure:

(i) Use (except for manufacture) by support service.

(b) This notice shall be marked on any reproduction of these data, in whole or in part.

(End of notice)

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PART II – CONTRACT CLAUSES

I. CONTRACT CLAUSES

I.1 52.252-2 Clauses Incorporated by Reference (Feb 1998)

This contract incorporates one or more clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this address: <http://acquisition.gov/far/>

The following FAR clauses, pertinent to Section I, are hereby incorporated by reference:

FAR Clause	Title	Date
52.202-1	Definitions	Nov 2013
52.203-3	Gratuities	Apr 1984
52.203-5	Covenant Against Contingent Fees	May 2014
52.203-6	Restrictions on Subcontractor Sales to the Government	Sep 2006
52.203-7	Anti-Kickback Procedures	May 2014
52.203-8	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity	May 2014
52.203-10	Price or Fee Adjustment for Illegal or Improper Activity	May 2014
52.203-12	Limitation on Payments to Influence Certain Federal Transactions	Oct 2010
52.203-13	Contractor Code of Business Ethics and Conduct	Oct 2015
52.203-14	Display of Hotline Poster(s)	Oct 2015
52.203-17	Contractor Employee Whistleblower Rights and Requirement To Inform Employees of Whistleblower Rights	Apr 2014
52.203-19	Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements	Jan 2017
52.204-1	Administrative Matters Provisions and Clauses	Dec 1989
52.204-4	Printed or Copied Double-Sided on Postconsumer Fiber Content Paper	May 2011
52.204-7	System for Award Management	Oct 2018
52.204-10	Reporting Executive Compensation and First-Tier Subcontract Awards	Oct 2018
52.204-13	System for Award Management Maintenance	Oct 2018
52.204-16	Commercial and Government Entity Code Reporting	Jul 2016
52.204-17	Ownership of Control or Offeror	Jul 2016
52.204-18	Commercial and Government Entity Code Maintenance	Jul 2016
52.204-19	Incorporation by Reference of Representations and Certifications	Dec 2014
52.204-23	Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities	Jul 2018
52.209-5	Certification Regarding Responsibility Matters	Oct 2015
52.209-6	Protecting the Government's Interests When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment	Oct 2015
52.209-9	Updates of Publicly Available Information Regarding Responsibility Matters	Oct 2018
52.209-10	Prohibition on Contracting with Inverted Domestic Corporations	Nov 2015
52.210-1	Market Research	Apr 2011
52.215-2	Audit and Records – Negotiation	Oct 2010
52.215-8	Order of Precedence - Uniform Contract Format	Oct 1997
52.215-10	Price Reduction for Defective Cost or Pricing Data	Aug 2011
52.215-11	Price Reduction for Defective Certified Cost or Pricing Data—Modifications.	Aug 2011
52.215-12	Subcontractor Certified Cost or Pricing Data	Oct 2010

Contract No. 75A50120C00034 Development of an mRNA Vaccine for SARS-CoV-2

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52.215-13	Subcontractor Certified Cost or Pricing Data—Modifications	Oct 2010
52.215-14	Integrity of Unit Prices (Over SAT)	Oct 2010
52.215-15	Pension Adjustments and Asset Reversions	Oct 2010
52.215-18	Reversion or Adjustment of Plans for Postretirement Benefits (PRB) other than Pensions	Jul 2005
52.215-19	Notification of Ownership Changes	Oct 1997
52.215-20	Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data)	Oct 2010
52.215-21	Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data -Modifications	Oct 2010
52.215-22	Limitations on Pass-Through Charges—Identification of Subcontract Effort	Oct 2009
52.215-23	Limitations on Pass-Through Charges	Oct 2009
52.216-7	Allowable Cost and Payment	Aug 2018
52.216-8	Fixed Fee	Jun 2011
52.217-8	Option to Extend Services <i>[within thirty (30) calendar days from contract expiration.]</i>	Nov 1999
52.219-8	Utilization of Small Business Concerns	Oct 2018
52.219-28	Post-Award Small Business Program Representation	July 2013
52.222-1	Notice to the Government of Labor Disputes	Feb 1997
52.222-2	Payment for Overtime Premiums <i>[\$0.00]</i>	July 1990
52.222-3	Convict Labor	Jun2003
52.222-21	Prohibition of Segregated Facilities	Apr 2015
52.222-24	Pre-award On-Site Equal Opportunity Compliance Evaluation	Feb 1999
52.222-26	Equal Opportunity	Sept 2016
52.222-35	Equal Opportunity for Veterans (\$150,000 or more)	Oct 2015
52.222-36	Equal Opportunity for Workers with Disabilities	Jul 2014
52.222-37	Employment Reports on Veterans	Feb 2016
52.222-38	Compliance with Veterans' Employment Reporting Requirements	Feb 2016
52.222-40	Notification of Employee Rights Under the National Labor Relations Act	Dec 2010
52.222-50	Combating Trafficking in Persons	Jan 2019
52.222-54	Employment Eligibility Verification	Oct 2015
52.223-6	Drug-Free Workplace	May 2001
52.223-18	Encouraging Contractor Policy to Ban Text Messaging While Driving	Aug 2011
52.224-1	Privacy Act Notification	April 1984
52.224-2	Privacy Act	April 1984
52.224-3	Privacy Training	Jan 2017
52.225-13	Restrictions on Certain Foreign Purchases	Jun 2008
52.225-25	Prohibition on Contracting with Entities Engaging in Certain Activities or Transactions Relating to Iran—Representation and Certifications	Aug 2018
52.227-1	Authorization and Consent	Dec 2007
52.227-2	Notice and Assistance Regarding Patent and Copyright Infringement	Dec 2007
52.227-11	Patent Rights-Ownership by the Contractor	May 2014
52.227-14	Rights in Data – General	May 2014
52.227-14	Rights in Data – General, Alternate II (Dec 2007)	May 2014
52.228-7	Insurance – Liability to Third Persons	Mar 1996
52.232-9	Limitation on Withholding of Payments	Apr 1984

Contract No. 75A50120C00034 Development of an mRNA Vaccine for SARS-CoV-2

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52.232-17	Interest	May 2014
52.232-20	Limitation of Cost	Apr 1984
52.232-23	Assignment of Claims	May 2014
52.232-25	Prompt Payment Alt I	Jan 2017
52.232-33	Payment by Electronic Funds Transfer--System for Award Management	Oct 2018
52.232-39	Unenforceability of Unauthorized Obligations	Jun 2013
52.232-40	Providing Accelerated Payments to Small Business Subcontractors	Dec 2013
52.233-1	Disputes	May 2014
52.233-3	Protest After Award, Alternate I (Jun 1985)	Aug 1996
52.233-4	Applicable Law for Breach of Contract Claim	Oct 2004
52.242-1	Notice of Intent to Disallow Costs	Apr 1984
52.242-3	Penalties for Unallowable Costs	May 2014
52.242-4	Certification of Final Indirect Costs	Jan 1997
52.242-13	Bankruptcy	Jul 1995
52.243-2	Changes--Cost-Reimbursement, Alternate I (Apr 1984)	Apr 1984
52.243-2	Changes--Cost-Reimbursement, Alternate V (Apr 1984)	Aug 1987
52.243-6	Change Order Accounting	Apr 1984
52.243-7	Notification of Changes	Jan 2017
52.244-2	Subcontracts, Alternate I (Jun 2007)	Oct 2010
52.244-5	Competition in Subcontracting	Dec 1996
52.244-6	Subcontracts for Commercial Items	Jan 2019
52.245-1	Government Property	Jan 2017
52.245-9	Use and Charges	Apr 2012
52.246-25	Limitation of Liability--Services	Feb 1997
52.249-6	Termination (Cost-Reimbursement)	May 2004
52.249-14	Excusable Delays	Apr 1984
52.253-1	Computer Generated Forms	Jan 1991

I.2 Department of Health and Human Services Acquisition Regulation (HHSAR) Clauses

Full text of HHSAR clauses may be accessed electronically at this address: <http://www.hhs.gov/grants/contracts/contract-policies-regulations/hhsar>

HHSAR Clause	Title	Date
352.203-70	Anti-Lobbying	Dec 2015
352.208-70	Printing and Duplication	Dec 2015
352.222-70	Contractor Cooperation in Equal Employment Opportunity Investigations	Dec 2015
352.223-70	Safety and Health	Dec 2015
352.224-71	Confidential Information	Dec 2016
352.227-70	Publications and Publicity	Dec 2015
352.231-70	Salary Rate Limitation	Dec 2015
352.233-71	Litigation and Claims	Dec 2015
352.237-75	Key Personnel	Dec 2015
352.239-74	Electronic and Information Technology Accessibility	Dec 2015
352.270-9	Non-discrimination for Conscience	Dec 2015

I.3 Additional Contract Clauses

I.3.1 Additional Federal Acquisition Regulation (FAR) Clauses in Full Text

52.217-9 Option to Extend the Term of the Contract (Mar 2000)

(a) The Government may extend the term of this contract by written notice to the Contractor within thirty (30) calendar days; provided that the Government gives the Contractor a preliminary written notice of its intent to extend at least thirty (30) days before the contract expires. The preliminary notice does not commit the Government to an extension.

(b) If the Government exercises this option, the extended contract shall be considered to include this option clause.

(c) The total duration of this contract, including the exercise of any options under this clause, shall not exceed five (5) years and six (6) months.

(End of Clause)

52.203-18 Prohibition on Contracting with Entities that Require Certain Internal Confidentiality Agreements or Statements--Representation (Jan 2017)

a) Definition. As used in this provision—

"Internal confidentiality agreement or statement", "subcontract", and "subcontractor", are defined in the clause at 52.203-19, Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements.

b) In accordance with section 743 of Division E, Title VII, of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113-235) and its successor provisions in subsequent appropriations acts (and as extended in continuing resolutions), Government agencies are not permitted to use funds appropriated (or otherwise made available) for contracts with an entity that requires employees or subcontractors of such entity seeking to report waste, fraud, or abuse to sign internal confidentiality agreements or statements prohibiting or otherwise restricting such employees or subcontractors from lawfully reporting such waste, fraud, or abuse to a designated investigative or law enforcement representative of a Federal department or agency authorized to receive such information.

c) The prohibition in paragraph (b) of this provision does not contravene requirements applicable to Standard Form 312, (Classified Information Nondisclosure Agreement), Form 4414 (Sensitive Compartmented Information Nondisclosure Agreement), or any other form issued by a Federal department or agency governing the nondisclosure of classified information.

d) Representation. By submission of its offer, the Offeror represents that it will not require its employees or subcontractors to sign or comply with internal confidentiality agreements or statements prohibiting or otherwise restricting such employees or subcontractors from lawfully reporting waste, fraud, or abuse related to the performance of a Government contract to a designated investigative or law enforcement representative of a Federal department or agency authorized to receive such information (e.g., agency Office of the Inspector General).

(End of provision)

52.222-35 Equal Opportunity Veterans (Oct 2015)

a) Definitions. As used in this clause—

"Active duty wartime or campaign badge veteran," "Armed Forces service medal veteran," "disabled veteran," "protected veteran," "qualified disabled veteran," and "recently separated veteran" have the meanings given at FAR 22.1301.

b) Equal opportunity clause. The Contractor shall abide by the requirements of the equal opportunity clause at 41 CFR 60-300.5(a), as of March 24, 2014. This clause prohibits discrimination against qualified protected veterans, and requires affirmative action by the Contractor to employ and advance in employment qualified protected veterans.

c) Subcontracts. The Contractor shall insert the terms of this clause in subcontracts of \$150,000 or more unless exempted by rules, regulations, or orders of the Secretary of Labor. The Contractor shall act as specified by the Director, Office of Federal Contract Compliance Programs, to enforce the terms, including action for noncompliance. Such necessary changes in language may be made as shall be appropriate to identify properly the parties and their undertakings.

(End of Clause)

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52.222-36 Equal Opportunity for Workers with Disabilities (Jul 2014)

- a) Equal opportunity clause. The Contractor shall abide by the requirements of the equal opportunity clause at 41 CFR 60.741.5(a), as of March 24, 2014. This clause prohibits discrimination against qualified individuals on the basis of disability, and requires affirmative action by the Contractor to employ and advance in employment qualified individuals with disabilities.
- b) Subcontracts. The Contractor shall include the terms of this clause in every subcontract or purchase order in excess of \$15,000 unless exempted by rules, regulations, or orders of the Secretary, so that such provisions will be binding upon each subcontractor or vendor. The Contractor shall act as specified by the Director, Office of Federal Contract Compliance Programs of the U.S. Department of Labor, to enforce the terms, including action for noncompliance. Such necessary changes in language may be made as shall be appropriate to identify properly the parties and their undertakings.

(End of Clause)

PART III – LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

J. LIST OF ATTACHMENTS

- Attachment 2: INVOICING INSTRUCTIONS FOR COST REIMBURSEMENT CONTRACTS
- Attachment 3: SAMPLE INVOICE/PAYMENT REQUEST AND CONTRACT FINANCIAL REPORT
- Attachment 4: FINANCIAL REPORT OF INDIVIDUAL PROJECT/CONTRACT
- Attachment 5: INSTRUCTION FOR COMPLETING FINANCIAL REPORT OF INDIVIDUAL PROJECT/CONTRACT
- Attachment 6: INCLUSION ENROLLMENT REPORT
- Attachment 7: RESEARCH PATIENT CARE COSTS
- Attachment 8: CONTRACTING SITE – CONTRACT NUMBER – INVENTORY SHEET
- Attachment 9: DISCLOSURE OF LOBBYING ACTIVITIES
- Attachment 10: DATA ITEM DESCRIPTION
- Attachment 11: SEVEN PRINCIPLES OF EARNED VALUE MANAGEMENT LITE

Contract No. 75A50120C00034 Development of an mRNA Vaccine for SARS-CoV-2

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AMENDMENT OF SOLICITATION/MODIFICATION OF		1. CONTRACT ID CODE		PAGE OF PAGES 1 1	
2. AMENDMENT/MODIFICATION NO. P00002		3. EFFECTIVE DATE See Block 16C		4. REQUISITION/PURCHASE REQ. NO.	
6. ISSUED BY ASPR-BARDA 200 Independence Ave., S.W. Room 640-G Washington DC 20201		CODE ASPR-BARDA		7. ADMINISTERED BY (If other than Item 6) US DEPT OF HEALTH & HUMAN SERVICES ASST SEC OF PREPAREDNESS & RESPONSE ACQ MANAGEMENT, CONTRACTS, & GRANTS O'NEILL HOUSE OFFICE BUILDING Washington DC 20515	
8. NAME AND ADDRESS OF CONTRACTOR (No., street, county, State and ZIP Code) MODERNATX, INC 1492235 Attn: HAMILTON BENNETT MODERNATX, INC. 200 TECHNOLOGY 200 TECHNOLOGY SQ CAMBRIDGE MA 021393578		(X)		9A. AMENDMENT OF SOLICITATION NO.	
CODE 1492235		FACILITY CODE		9B. DATED (SEE ITEM 11)	
		X		9A. MODIFICATION OF CONTRACT/ORDER NO. 75A50120C00034	
				9B. DATED (SEE ITEM 13) 04/03/2020	

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers ☐ is extended, ☐ is not extended.

Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or electronic communication which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by letter or electronic communication, provided each letter or electronic communication makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

See Schedule

12. ACCOUNTING AND APPROPRIATION DATA (If required)

13. THIS ITEM ONLY APPLIES TO MODIFICATION OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

CHECK ONE	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.
	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation data, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).
	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:
X	D. OTHER (Specify type of modification and authority) FAR 43.103(a)

E. IMPORTANT: Contractor is not X is required to sign this document and return _____ 1 copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)

[***]

[***]

The purpose of this modification is to add the revised Statement of Work (SOW) dated June 3, 2020 to Option CLIN 0003. The CLIN value remains unchanged at \$53,000,000. All other contract terms and conditions remain unchanged.

Except as provided herein, all terms and conditions of the document referenced in Item 9 A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (Type or print) [***]		16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print) WENDELL CONYERS	
15B. CONTRACTOR/OFFEROR [***] (Signature of person authorized to sign)	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA (Signature of Contracting Officer)	16C. DATE SIGNED 06/16/2020

Previous edition unusable

ACTIVE/104412070.3

STANDARD FORM 30 (REV. 11/2016)

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Continuation Page

 messenger therapeutics	Contract Number: 75A50120C00034
Development of an mRNA Vaccine for SARS-CoV-2	
Option 1 Statement of Work	
Dated June 3, 2020	
[***]	[***]
[***]	[***]

CONFIDENTIAL

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moderna

200 Tech Square • Cambridge, MA 02139 phone
617-714-6500 • fax 617-583-1998

[***]
[***]
[***]
[***]

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT HAVE BEEN OMITTED AND REPLACED WITH "[***]". SUCH IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS (I) NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF DISCLOSED.

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT		1. CONTRACT ID CODE	PAGE OF PAGES
2. AMENDMENT/MODIFICATION NO. P00001		3. EFFECTIVE DATE See Block 16C	4. REQUISITION/PURCHASE REQ. NO. OS259279
5. PROJECT NO. (If applicable)		6. ISSUED BY ASPR-BARDA 200 Independence Ave., S.W. Room 640-G Washington DC 20201	
7. ADMINISTERED BY (If other than Item 6) US DEPT OF HEALTH & HUMAN SERVICES ASST SEC OF PREPAREDNESS & RESPONSE ACQ MANAGEMENT, CONTRACTS, & GRANTS O'NEILL HOUSE OFFICE BUILDING Washington DC 20515		CODE ASPR-BARDA02	
8. NAME AND ADDRESS OF CONTRACTOR (No., street, county, State and ZIP Code) MODERNATX, INC 1492235 Attn: [***] MODERNATX, INC. 200 TECHNOLOGY 200 TECHNOLOGY SQ CAMBRIDGE MA 021393578		(x) 9A. AMENDMENT OF SOLICITATION NO.	
CODE 1492235		9B. DATED (SEE ITEM 11)	
FACILITY CODE		x 10A. MODIFICATION OF CONTRACT/ORDER NO. 75A50120C00034	
		10B. DATED (SEE ITEM 13) 04/03/2020	
11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS			
☐ The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers ☐ is extended, ☐ is not extended.			
Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or electronic communication which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by letter or electronic communication, provided each letter or electronic communication makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.			
12. ACCOUNTING AND APPROPRIATION DATA (If required) 2020.199c001.25103 Net Increase: \$53,000,000.00			
13. THIS ITEM ONLY APPLIES TO MODIFICATION OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.			
CHECK ONE	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.		
	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation data, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).		
	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:		
X	D. OTHER (Specify type of modification and authority) FAR 43.103 (a)		
E. IMPORTANT: Contractor ☐ is not ☒ is required to sign this document and return _____ 1 _____ copies to the issuing office.			
14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)			
Tax ID Number: 27-0226313 DUNS Number: 069723520 The purpose of this modification is to exercise the Government's right to exercise an Option 1 CLIN 0003 - Domestic Manufacturing Scale-Out domestic manufacturing in accordance with the contract's clause FAR 52.217-9, Option to Extend the Term of the Contract. 1. The Government hereby exercises Option 1 CLIN 0003 as priced in Section B.3.2 of the Contract at a Total Price of \$53,000,000. 2. Funding and Contract Total Summary: The total funded amount on the contract is hereby increased by \$53,000,000 from \$430,298,520 to \$483,298,520 and that the total contract amount is hereby increased by \$53,000,000 from \$430,298,520 to \$483,298,520. 3. Reference SOW Attached for Option 1 CLIN 0003 Continued ... Except as provided herein, all terms and conditions of the document referenced in Item 9 A or 10A, as heretofore changed, remains unchanged and in full force and effect.			
15A. NAME AND TITLE OF SIGNER (Type or print) Stephane Bancel, Chief Executive Officer		16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print) WENDELL CONYERS	

15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
/s/ Stephane Bancel (Signature of person authorized to sign)		/s/ Wendell Conyers (Signature of Contracting Officer)	05/24/2020

NAME OF THE OFFEROR OR CONTRACTOR

MODERNATX, INC 1492235					
ITEM NO.	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
(A)	(B)	(C)	(D)	(E)	(F)
	Appr. Yr.: 2020 CAN: 199C001 Object Class: 25103				
	Change Item 3 to read as follows (amount shown is the obligated amount):				
3	Option 1 Kit Build-Out				53,000,000.00
	Obligated Amount: \$53,000,000.00				

	Contract Number: 75A50120C00034
Development of an mRNA Vaccine for SARS-CoV-2 Request to Award Option 1 Revised 8 May 2020	
Prime Contract	Moderna Therapeutics, Inc. 200 Technology Square Cambridge, MA02139-3578
Point of Contact	[***]

CONFIDENTIAL

200 Tech Square • Cambridge, MA 02139
phone 617-714-6500 • fax 617-583-1998

1- Objective:

This document outlines the current plans to enable a second node of domestic mRNA-1273 supply at Lonza's New Hampshire facility [***].

2- Approach & Estimated cost
[***]

Statement of Work Nr. 2

This Statement of Work ("SOW") is effective as of [May 8, 2020] (the "Effective Date") by and between ModernaTX, Inc., with an address at 200 Technology Square, Cambridge, MA 02139 USA ("Moderna") on the one part; and [***]

[***]

[**]

[**]

IN WITNESS WHEREOF, each Party hereto has caused this Statement of Work to be executed on its behalf by its duly authorized representative.

MODERNATX, INC

[**]

By: _____
(Signature)

By: _____
(Signature)

Print Name:
Title:

Print Name: _____
Title: _____

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT HAVE BEEN OMITTED AND REPLACED WITH "[***]". SUCH IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS (I) NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF DISCLOSED

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT		1. CONTRACT ID CODE		PAGE OF PAGES 1 1									
2. AMENDMENT/MODIFICATION NO. P00002		3. EFFECTIVE DATE See Block 16C		4. REQUISITION/PURCHASE REQ. NO.									
6. ISSUED BY ASPR-BARDA 200 Independence Ave., S.W. Room 640-G Washington DC 20201		CODE ASPR-BARDA		5. PROJECT NO. (If applicable) ASPR-BARDA02									
8. NAME AND ADDRESS OF CONTRACTOR (No., street, county, State and ZIP Code) MODERNATX, INC 1492235 Attn: [***] MODERNATX, INC. 200 TECHNOLOGY 200 TECHNOLOGY SQ CAMBRIDGE MA 021393578		(x)		9A. AMENDMENT OF SOLICITATION NO.									
CODE 1492235		FACILITY CODE		9B. DATED (SEE ITEM 11)									
		(x)		10A. MODIFICATION OF CONTRACT/ORDER NO. 75A50120C00034									
				10B. DATED (SEE ITEM 13) 04/03/2020									
15. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS													
☐ The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers ☐ is extended, ☐ is not extended.													
Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or electronic communication which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by letter or electronic communication, provided each letter or electronic communication makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.													
16. ACCOUNTING AND APPROPRIATION DATA (If required) See Schedule													
17. THIS ITEM ONLY APPLIES TO MODIFICATION OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.													
<table border="1"> <tr> <td>CHECK ONE</td> <td>A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.</td> </tr> <tr> <td></td> <td>B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation data, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).</td> </tr> <tr> <td></td> <td>C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:</td> </tr> <tr> <td>X</td> <td>D. OTHER (Specify type of modification and authority) FAR 43.103 (a)</td> </tr> </table>						CHECK ONE	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.		B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation data, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).		C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:	X	D. OTHER (Specify type of modification and authority) FAR 43.103 (a)
CHECK ONE	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.												
	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation data, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).												
	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:												
X	D. OTHER (Specify type of modification and authority) FAR 43.103 (a)												
E. IMPORTANT: Contractor ☐ is not ☒ is required to sign this document and return <u>1</u> copies to the issuing office.													
18. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)													
Tax ID Number: 27-0226313 DUNS Number: 069723520 The purpose of this modification is to add the revised Statement of Work (SOW) dated June 3, 2020 to the Option CLIN 0003. The CLIN value remains unchanged at \$53,000,000. All other contract terms and conditions remain unchanged.													
Except as provided herein, all terms and conditions of the document referenced in Item 9 A or 10A, as heretofore changed, remains unchanged and in full force and effect.													
15A. NAME AND TITLE OF SIGNER (Type or print) Stephane Bancel, Chief Executive Officer		16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print) WENDELL CONYERS											
15B. CONTRACTOR/OFFEROR /s/ Stephane Bancel (Signature of person authorized to sign)		15C. DATE SIGNED 6/4/2020		16B. UNITED STATES OF AMERICA /s/ Wendell Conyers (Signature of Contracting Officer)									
				16C. DATE SIGNED 6/16/2020									

Continuation Page

 moderna [™] messenger therapeutics	Contract Number: 75A50120C00034
Development of an mRNA Vaccine for SARS-CoV-2 Option 1 Statement of Work Dated June 3, 2020	
Prime Contract	Moderna Therapeutics, Inc. 200 Technology Square Cambridge, MA02139-3578
Point of Contact	[***]

CONFIDENTIAL



200 Tech Square • Cambridge, MA 02139
phone 617-714-6500 • fax 617-583-1998

1-Objective:

This document outlines the current plans to enable a second node of domestic mRNA-1273 supply at Lonza's New Hampshire facility [***]

2-Approach & Estimated cost:

[***]

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT HAVE BEEN OMITTED AND REPLACED WITH "[***]". SUCH IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS (I) NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF DISCLOSED

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT		1. CONTRACT ID CODE		PAGE OF PAGES 1 39	
2. AMENDMENT/MODIFICATION NO. P00003		3. EFFECTIVE DATE See Block 16C		4. REQUISITION/PURCHASE REQ. NO. OS262588	
5. PROJECT NO. (If applicable)		6. ISSUED BY ASPR-BARDA		7. ADMINISTERED BY (If other than Item 6) US DEPT OF HEALTH & HUMAN SERVICES ASST SEC OF PREPAREDNESS & RESPONSE ACQ MANAGEMENT, CONTRACTS, & GRANTS O'NEILL HOUSE OFFICE BUILDING Washington DC 20515	
CODE		CODE		CODE ASPR-BARDA02	
8. NAME AND ADDRESS OF CONTRACTOR (No., street, county, State and ZIP Code) MODERNATX, INC 1492235 Attn: [***] MODERNATX, INC. 200 TECHNOLOGY 200 TECHNOLOGY SQ CAMBRIDGE MA 021393578		(x)		9A. AMENDMENT OF SOLICITATION NO.	
CODE 1492235		FACILITY CODE		9B. DATED (SEE ITEM 11)	
		(x)		10A. MODIFICATION OF CONTRACT/ORDER NO. 75A50120C00034	
				10B. DATED (SEE ITEM 13) 04/03/2020	
19. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS					

☐ The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers ☐ is extended, ☐ is not extended.

Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or electronic communication which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by letter or electronic communication, provided each letter or electronic communication makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

20. ACCOUNTING AND APPROPRIATION DATA (If required)
See Schedule Net Increase: \$471,596,459.00

21. THIS ITEM ONLY APPLIES TO MODIFICATION OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

☒	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.
	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation data, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).
	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:
	D. OTHER (Specify type of modification and authority) FAR 43.103(a)

E. IMPORTANT: Contractor is not is required to sign this document and return 1 copies to the issuing office.
☐ ☒

22. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)

Tax ID Number: 27-0226313

DUNS Number: 069723520

The purpose of this modification is to support the additional scope of the Clinical Development Plan including direct increases to the clinical subcontractors on the P201 (Work Breakdown Structure 1.4.2.1) and P301 (Work Breakdown Structure 1.4.3.1) clinical studies, and forecasted overruns across the remaining WBS elements. This modification with Moderna to develop a mRNA vaccine for SARS-CoV-2 is part of the USG effort to accelerate the development, manufacturing, and distribution of COVID-19 vaccines, therapeutics, and diagnostics (medical countermeasures) in the midst of a global novel coronavirus pandemic.

As a result of the additional scope, the following was updated in this modification.

Continued ...

Except as provided herein, all terms and conditions of the document referenced in Item 9 A or 10A, as heretofore changed, remains unchanged and in full force and effect .

15A. NAME AND TITLE OF SIGNER *(Type or print)*

Stephane Bancel, Chief Executive Officer

16A. NAME AND TITLE OF CONTRACTING OFFICER *(Type or print)*

WENDELL CONYERS

15B. CONTRACTOR/OFFEROR

/s/ Stephane Bancel

(Signature of person authorized to sign)

15C. DATE SIGNED

7-25-20

16B. UNITED STATES OF AMERICA

(Signature of Contracting Officer)

16C. DATE SIGNED

CONTINUATION SHEET

REFERENCE NO. OF DOCUMENT BEING CONTINUED
75A50120C00034/P00003PAGE OF
2 39NAME OF OFFEROR OR CONTRACTOR
MODERNATX, INC 1492235

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	- Increase in total contract value from \$483,298,520 to \$954,894,979; - Section B.4.14 Enrollment Chart - Section C.2 Statement of Work - Section C.2.1 Development Approach - Section F.1.6. Organizational Chart - Section F.1.7. Contractor Provided Facilities, Infrastructure and Other Resources - Section F.2 Deliverables - Section F.3 Contract WBS Milestones/Deliverables and Technical Deliverables - Section H.3 Key Personnel - Section H.9 Security - Section H.20 Organizational Conflicts of Interest - Section H.21 Disclosure of Information - Section H.22 Publication and Publicity - Section H.23 Vetting Period of Performance: [***] Change Item 2 to read as follows (amount shown is the obligated amount):				
2	Base CLIN 0002 - Development of mRNA vaccine to BLA				471,596,459.00
	[***]				
	[***]				
	[***]				
	Funded: \$471,596,459.00				

CONTINUATION PAGE

1. Modification Purpose

The purpose of this modification is to support the additional scope of the Clinical Development Plan including direct increases to the clinical subcontractors on the P201 (Work Breakdown Structure 1.4.2.1) and P301 (Work Breakdown Structure 1.4.3.1) clinical studies, and forecasted overruns across the remaining WBS elements. This modification with Moderna to develop a mRNA vaccine for SARS-CoV-2 is part of the USG effort to accelerate the development, manufacturing, and distribution of COVID-19 vaccines, therapeutics, and diagnostics (medical countermeasures) in the midst of a global novel coronavirus pandemic.

As a result of the additional scope, the following was updated in this modification.

- Increase in total contract value from \$483,298,520 to \$954,894,979;
- Section B.4.14 Enrollment Chart
- Section C.2 Statement of Work
- Section C.2.1 Development Approach
- Section F.1.6. Organizational Chart
- Section F.1.7. Contractor Provided Facilities, Infrastructure and Other Resources
- Section F.2 Deliverables
- Section F.3 Contract WBS Milestones/Deliverables and Technical Deliverables
- Section H.3 Key Personnel
- Section H.9 Security
- Section H.20 Organizational Conflicts of Interest
- Section H.21 Disclosure of Information
- Section H.22 Publication and Publicity
- Section H.23 Vetting

2. Modification to Contract

This modification adds \$471,596,459 to CLIN 0002 and increases the total contract value from \$483,298,520 to \$954,894,979. [***]

CLIN 0003 POP extends to [***] at no additional cost.

Period	CLIN	Awarded 4/16/2020	Additional Scope	Total Contract
Pre Award	CLIN 0001	[***]	[***]	[***]
Base	CLIN 0002	[***]	[***]	[***]
Option 1	CLIN 0003	[***]	[***]	[***]
Total		\$483,298,520	\$471,596,459	\$954,894,979

The period of performance changes
[***]

B.4.14 Enrollment Chart

	Unit Price	Unit Qty	Total
***	***	***	***
***	***	***	***
***	***	***	***
***	***	***	***
		***	***

***	***	***
***	***	***
***	***	***
***	***	***
***	***	***
***	***	***
***	***	***

C.2 Statement of Work (Revised 7-14-2020) Updates to WBS 1.4.2.1 and 1.4.3.1 Only

Independently, and not as an agent of the United States Government, the contractor shall furnish all necessary services, qualified professional, technical, and administrative personnel, material, equipment and facilities, not otherwise provided by the Government under the terms of this contract, as needed to perform the tasks set forth below.

mRNA-1273 Vaccine Development (WBS 1.0)

The Contractor, ModernaTX, Inc. ("Moderna") shall execute the preclinical, clinical, and chemistry, manufacturing and controls (CMC) activities required to license a vaccine against the SARS-CoV-2 virus (hereafter referred to as "mRNA-1273"). Building upon early clinical development already underway, this proposal will support the late stage development, including the demonstration of clinical efficacy and generation of a dataset supportive of licensure. Moderna will additionally evaluate the platform manufacturing capabilities relative to the needs for supply in response to a pandemic.

Program Management (WBS 1.1)

mRNA-1273 Program Management (WBS 1.1.1)

Moderna's mRNA-1273 program team is composed of a multidisciplinary, highly matrixed, group of functional leads with experience in, and responsibility for, integrating plans and operationalizing strategies across Research, Toxicology, CMC, Regulatory Affairs, Clinical Development and Quality. Collectively, the team has advanced ten programs to first-in-human studies within five years. The group will be led by a program lead (PL) who will oversee and coordinate the activities necessary to meet program objectives. The PL will be the point of accountability for the development of mRNA-1273. [***] A program management office (PMO) will be responsible for managing the cost and schedule constraints of the contract via an integrated master schedule and corresponding budget, identifying and managing program risk, and ensuring contract compliance. With the input from the mRNA-1273 project team, the PMO will be responsible for coordinating the drafting of and management to an integrated development plan. Upon execution of the contract, weekly meetings with BARDA will be held to monitor program performance and monthly and annual reports will be delivered to BARDA for the record.

Nonclinical Toxicology (WBS 1.2)

Development and Reproductive Toxicology of mRNA-1273 (WBS 1.2.2.1)

To assess the risk of administering the vaccine to pregnant women, a complete GLP rat developmental and reproductive toxicology (DART) study is planned. Female Sprague Dawley rats will be dosed at the highest anticipated clinical dose level and include a control arm of phosphate-buffered saline (PBS). As is typical for DART evaluations for vaccines, the animals will be immunized three times prior to mating and two times during gestation. Each group will have two cohorts (one group will undergo Cesarean section with examination of the uteri and embryos; the other group will have natural delivery and will be terminated at weaning).

Nonclinical (WBS 1.3)

For the purposes of this proposal it is assumed that the VRC continues to support nonclinical activities to develop murine and non-human primate efficacy studies, and animal models to assess the potential of vaccine-enhanced disease. The scope of work below will execute additional robustness experiments in these developed models.

Assess Disease Enhancement (WBS 1.3.3.1)

[***]

We plan to perform studies in mouse and NHPs to assess the theoretical risk of vaccine induced disease enhancement triggered by CoV infection following vaccination with imRNA-1273.

[***]

Establish a Surrogate of Protection (WBS 1.3.3.2)

The primary endpoint for accelerated approval of a SARS-CoV-2 vaccine would be a neutralization assay. This endpoint must be supported with a body of pre-clinical work that demonstrates a correlation between neutralizing titers and efficacy and that quantifies a protective serologic threshold titer using the same neutralization assay. Murine and NHP efficacy models are being developed in parallel to the Phase

1

clinical study. Building on data from these preliminary models and studies, Moderna will conduct NHP efficacy and murine passive transfer studies to confirm and refine the surrogate of protection.

Clinical (WBS 1.4)

[***]

Phase 2 Safety and Immunogenicity Study (WBS 1.4.2.1) - Updated

[***]

Phase 3 Pivotal Study:(WBS 1.4.3.1) - Updated

Phase 3 Pivotal Study (WBS 1.4.3.1). The Phase 3 mRNA-1273-P301 study will confirm the trends observed during the Phase 1 and 2 trials, evaluating safety and efficacy in a larger number of subjects aged 18 and above. Approximately 30,000 subjects will be enrolled according to 1:1 randomization (active: placebo). Primary objectives will be 1) to demonstrate the efficacy of mRNA-1273 to prevent COVID-19

and 2) to evaluate the safety and reactogenicity of 2 injections of the mRNA-1273 vaccine given 28 days apart. [***]

Lot to Lot Consistency (WBS 1.4.3.2)

[***]

Pediatrics (WBS 1.4.3.3)

[***]

Regulatory (WBS 1.5)

IND Preparation and Filing (WBS 1.5.1.1)

Moderna's Regulatory Affairs group, in close collaboration with BARDA, will work to draft a comprehensive regulatory master plan to guide the preclinical, CMC and clinical development of mRNA-1273 within the first 90 days of the contract. An original investigational new drug application (IND) will

be filed with the United States Food and Drug Administration (FDA) to support the clinical development of the Moderna product from Phase 2 onwards.

IND Maintenance (WBS 1.5.1.2)

The Moderna-owned IND will be maintained to support the desired clinical development plan. As needed, meetings will be conducted to receive feedback and gain concurrence on the specifics of the development activities with the FDA.

BLA Submission (WBS 1.5.2.1)

Moderna will submit a Biologics License Application (BLA) and seek approval for the mRNA-1273 vaccine. CMC (WBS 1.6)

CTM Manufacture for Phase 2 (WBS 1.6.3.2)

[***]

Process Development for Late Stage Clinical Supply (WBS 1.6.3.3)

mRNA Process Development

Technical Development will confirm and optimize the process parameters for mRNA manufacture. [***]

BLA Readiness (WBS 1.6.3.8)

In support of the Biologics License Application (BLA) due to the nature of the proposed timeline, it is likely that Moderna will need to complete some of process validation activities, primarily process characterization, after the completion of process performance qualification and before BLA filing. Moderna intends to rapidly develop a robust process for clinical manufacturing and PPQ, and then fully describe the acceptable design space for the process prior to BLA filing. Other activities to support this BLA filing, such as completing raw material qualification activities; if not included in the BLA submission, will require a supplement to the initial BLA. In the initial BLA filing Moderna will describe its control strategy to cover the gap between initial BLA filing and the BLA supplement.

Process Development for Full Commercial Scale (WBS 1.6.4.1)

The following section outlines the process development activities [***]. The goal of this work is to demonstrate the capability to produce mRNA- 1273 at a scale that can support clinical demand.

[***]

[***]

Stability Studies (WBS 1.6.5.4)

Throughout the program, many studies will be undertaken [***]. This includes studies using development bench scale material, engineering lot material, and GMP material. This body of data will be used to apply interim and long-term shelf life to the drug product and process intermediates.

C.2.1. Development Approach

[***]

F.3 Contract WBS Milestones/Deliverables and Technical Deliverables

Work Breakdown Structure (WBS), Go/No Go Program Stage Gates Gantt Chart, Integrated Master Schedule (IMS)

Work Breakdown Structure and Option Periods

[***]

F.3. Deliverables

The primary deliverable of this proposal is a licensed mRNA-1273 vaccine. In addition, the team, in partnership with BARDA, will also design a plan to enhance Moderna's ability to rapidly respond to a Coronavirus pandemic by leveraging our mRNA platform. Interim deliverables are presented below.

WBS	Title	Deliverable	Timing
1	mRNA-1273 Vaccine Development		
1.1	Program Management		
1.1.1	Program and Alliance Management	- Management Plans; Routine Reporting Deliverables	***
1.2	Nonclinical Toxicology		
1.2.2	Safety		
1.2.2.1	Development and Reproductive Toxicology	- Final Study Report	***
1.3	Nonclinical		
1.3.1	Model Development (reserved)		
1.3.1.2	NHP Efficacy Study	- Final Study Report	***
1.3.1.3	Mouse Efficacy Study	- Final Study Report	***
1.4	Clinical		
1.4.2	Phase 2		
1.4.2.1	Phase 2 Safety and Immunogenicity Study	- Clinical Study Protocol - Final Clinical Study Report	*** ***
1.4.3	Phase 3		
1.4.3.1	Phase 3 Efficacy or Safety and Immunogenicity	- Clinical Study Protocol - Final Clinical Study Report	*** ***
1.4.3.2	Phase 3 Lot-to-Lot	- Clinical Study Protocol - Final Clinical Study Report	*** ***
1.4.3.3	Phase 3 Adolescents	- Clinical Study Protocol	***
		- Final Clinical Study Report	***
	Regulatory		
1.5.1	IND		
1.5.1.1	IND Filing	- NA	
1.5.1.2	IND Maintenance	- Record of FDA Communications	***
1.5.2	BLA		***
1.5.2.1	BLA Submission	- NA	
1.6	CMC		
1.6.3	Pilot Scale Manufacturing		
1.6.3.2	CTM Manufacture for P201	- CoA for Clinical Lots	***
1.6.3.4	CTM Manufacture for P301	- CoA for Clinical Lots	***
1.6.3.6	CTM Manufacture for P302/P303	- CoA for Clinical Lots	***

H.3 Key Personnel

[illegible]

F.1.6.Organizational Chart

The organizational chart depicts the project team reporting structure of the key personnel for the scope of work for this proposal. [***]

[***]

ARTICLE F.2. DELIVERABLES SCHEDULE

ARTICLE F.2. DELIVERABLES

Successful performance of the final contract shall be deemed to occur upon performance of the work set forth in the Statement of Work attached to this contract as Attachment 1 (SECTION J-List of Attachments), and upon delivery and acceptance, as required by the Statement of Work, by the Contracting Officer, or the duly authorized representative pursuant to SECTION E-Inspection and Acceptance, of the following items listed below under heading 1 "Summary of Contract Deliverables" in accordance with the stated delivery schedule.

The items specified below under heading 1 "Summary of Contract Deliverables", as described in the Statement of Work which is Attachment 1 to this contract will be required to be delivered by the date(s) specified below and in accordance with any specifications stated in SECTION D- PACKAGING, MARKING AND SHIPPING, of this contract. All reports identified below relate solely to the development activity funded under this contract:

1. Summary of Contract Deliverables

Unless otherwise stated, each deliverable in the table below shall be provided as one (1) electronic copy to the contracting officer representative (COR), contract specialist (CS), and contracting officer (CO) as set forth in SECTION D.

In addition to or in replacement of electronic copies, the CO may direct the Contractor to submit the below deliverables via BARDA Digital Resources Portal in machine-readable format.

CDRL#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
01	Meetings		
01.6	Daily check in with project staff for COVID-19 Contract	Upon request of the Government, the Contractor shall participate in a daily check-in update with the project staff (via teleconference or email). The updates will address key cost, schedule and technical updates. Daily updates may be shared with senior Government leaders during the COVID-19 response and should be provided on a non-confidential basis, unless the update includes confidential information in which case	• No agenda will be required for the meeting • No meeting minutes are required • Contractor will provide bulleted email updates following any call or in lieu of a call by 2PM for that day

CDRL#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		Contractor shall provide the update in both confidential and non-confidential formats. Daily check-ins may occur on weekdays, excluding federal holidays. Upon request of the Government, check-ins may also occur on weekends and on federal holidays, provided at least 24 hours' notice.	
02	Technical Reporting		
02.8	Product Development Source Material and Manufacturing Reports and Projections	The Contractor shall submit a detailed spreadsheet regarding critical project materials that are sourced from a location other than the United States, sources, and manufacturing sites, including but not limited to: physical locations of sources of raw and processed material by type of material; location and nature of work performed at manufacturing sites; and location and nature of non-clinical and clinical study sites. The Contractor will provide manufacturing reports and manufacturing dose tracking projections/actuals utilizing the "COVID-19 Dose Tracking Templates", on any contract/agreement that is manufacturing product for the USG	- Contractor will submit Product Development Source Material Report - Within month of contract award - Within 30 days of substantive changes are made to sources and/or materials - Or on the 6th month contract anniversary. - Contractor will update the Dose Tracking Template weekly, during manufacturing campaigns and COVID response, with the first deliverable submission within 15 days of award/modification. Updates to be provided weekly. - The Government will provide written comments to the Product Development Source Material and Manufacturing Report within 15 business days after the submission - If corrective action is recommended, Contractor must address all concerns raised by BARDA in writing
02.9	Contractor Locations	The contractor shall submit detailed data regarding locations where work will be performed	Contractor will submit Work Locations Report:

CDRL#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		under this contract, including addresses, points of contact, and work performed per location, to include sub-contractors.	• Within 5 business days of contract award • Within 30 business days after a substantive location or capabilities change • Within 2 business days of a substantive change if the work performed supports medical countermeasure development that addresses a threat that has been declared a Public Health Emergency by the HHS Secretary or a Public Health Emergency of International Concern (PHEIC) by the WHO
09	Advanced R&D Products		

CDRL#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
09.5	Contractor Publication Timeline and USG Right to Publish Data	The Contractor and Government are committed to transparent and timely publication of clinical trial data to ensure rapid distribution of information during the COVID-19 Pandemic. Within 30 days of the primary analysis, results from clinical studies funded in whole or in part under this contract and consistent with Good Publications Practices. Sponsor must publish the primary endpoint analysis. Within 90 days of the of study end date [last subject last visit] for studies funded in part or whole under this contract and consistent with Good Publication Practices sponsor shall publish clinical trial data. If the contractor does not elect to publish data, Contractor shall provide CO and COR with clinical trial data to support the government publication of data as deemed appropriate by the government, without the contractor involvement.	- Contractor shall notify CO and within 30 of primary analysis results and study end date [last subject last visit] if they plan not to publish data. - Within 10 calendar days of a request for clinical data from the CO, the Contractor shall provide CO with requested data, information and materials in the form(s) requested by the government, to support the government publication of the clinical trial data funded in part or whole under this contract
09.6	Additional Clinical Trial Deliverables	Contractor shall provide read-only access to clinical trials management system [***] Contractor shall provide for review for all study operational	Contractor shall provide upon request of the CO or COR.

H.19 Security

BARDA Security Requirements:

All COVID-19 contracts are required to address security requirements. In the event that Moderna does not have another contract in place with the USG within 45 days of execution of this contract modification that incorporates the security requirement, Moderna will submit a cost estimate for implementing security requirements for this contract. Moderna will be entitled to an equitable upward adjustment in the value of this contract to cover all additional costs associated with additional security requirements imposed by the Government.

H.20 Organizational Conflicts of Interest

Performance under this contract may create an actual or potential organizational conflict of interest such as are contemplated by FAR Part 9.505-General Rules. The Contractor shall not engage in any other contractual or other activities which could create an organizational conflict of interest (OCI). This provision shall apply to the prime Contractor and all sub-Contractors. This provision shall have effect throughout the period of performance of this contract, any extensions thereto by change order or supplemental agreement, and for two (2) years thereafter. The Government may pursue such remedies as may be permitted by law or this contract, upon determination that an OCI has occurred.

The work performed under this contract may create a significant potential for certain conflicts of interest, as set forth in FAR Parts 9.505-1, 9.505-2, 9.505-3, and 9.505-4. It is the intention of the parties hereto to prevent both the potential for bias in connection with the Contractor's performance of this contract, as well as the creation of any unfair competitive advantage as a result of knowledge gained through access to any non- public data or third party proprietary information.

The Contractor shall notify the Contracting Officer immediately whenever it becomes aware that such access or participation may result in any actual or potential OCI. Furthermore, the Contractor shall promptly submit a plan to the Contracting Officer to either avoid or mitigate any such OCI. The Contracting Officer will have sole discretion in accepting the Contractor's mitigation plan. In the event the Contracting Officer unilaterally determines that any such OCI cannot be satisfactorily avoided or mitigated, other remedies may be taken to prohibit the Contractor from participating in contract requirements related to OCI.

Whenever performance of this contract provides access to another Contractor's proprietary information, the Contractor shall:

(1) enter into a written agreement with the other entities involved, as appropriate, in order to protect such proprietary information from unauthorized use or disclosure for as long as it remains proprietary; and refrain from using such proprietary information other than as agreed to, for example to provide assistance during technical evaluation of other Contractors' offers or products under this contract. An executed copy of all proprietary information agreements by individual personnel or on a corporate basis shall be furnished to the CO within fifteen (15) calendar days of execution

H.21 Disclosure of Information

Performance under this contract may require the Contractor to access non-public data and information proprietary to a Government agency, another Government Contractor or of such nature that its dissemination or use other than as specified in the work statement would be adverse to the interests of the Government or others. Neither the Contractor, nor Contractor personnel, shall divulge nor release data nor information developed or obtained under performance of this contract, except authorized by Government personnel or upon written approval of the CO. The Contractor shall not use, disclose, or reproduce proprietary data that bears a restrictive legend, other than as specified in this contract, or any information at all regarding this agency.

Consistent with HHS Directive 1139, the Contractor shall comply with HHS requirements for protection of non-public information. Unauthorized disclosure of nonpublic information is prohibited by the HHS's rules. Unauthorized disclosure may result in termination of the contract, replacement of a Contractor employee, or other appropriate redress. Neither the Contractor nor the Contractor's employees shall disclose or cause to be disseminated, any information concerning the operations of the activity, which could result in, or increase the likelihood of, the possibility of a breach of the activity's security or interrupt the continuity of its operations.

No information related to data obtained under this contract shall be released or publicized without the prior written consent of the COR, whose approval shall not be unreasonably withheld, conditioned, or delayed, provided that no such consent is required to comply with any law, rule, regulation, court ruling or similar order; for submission to any government entity' for submission to any securities exchange on which the Contractor's (or its parent corporation's) securities may be listed for trading; or to third parties relating to securing, seeking, establishing or maintaining regulatory or other legal approvals or compliance, financing and capital raising activities, or mergers, acquisitions, or other business transactions.

H. 22 PUBLICATION AND PUBLICITY

The contractor shall not release any reports, manuscripts, press releases, or abstracts about the work being performed under this contract without written notice in advance to the Government, for additional information see HHSAR 352.227-70. Publications and Publicity (Dec2015).

(a) Unless otherwise specified in this contract, the contractor may publish the results of its work under this contract. The contractor shall promptly send a copy of each submission to the COR for security review prior to submission. The contractor shall also inform the COR when the abstract article or other publication is published, and furnish a copy of it as finally published.

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT HAVE BEEN OMITTED AND REPLACED WITH "[***]". SUCH IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS (I) NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF DISCLOSED

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT		1. CONTRACT ID CODE	PAGE OF PAGES 1 4	
2. AMENDMENT/MODIFICATION NO. P00004		3. EFFECTIVE DATE See Block 16C	4. REQUISITION/PURCHASE REQ. NO.	
6. ISSUED BY ASPR-BARDA 200 Independence Ave., S.W. Room 640-G Washington DC 20201		CODE ASPR-BARDA	5. PROJECT NO. (If applicable) ASPR-BARDA02	
8. NAME AND ADDRESS OF CONTRACTOR (No., street, county, State and ZIP Code) MODERNATX, INC 1492235 Attn: [***] MODERNATX, INC. 200 TECHNOLOGY 200 TECHNOLOGY SQ CAMBRIDGE MA 021393578		7. ADMINISTERED BY (If other than Item 6) US DEPT OF HEALTH & HUMAN SERVICES ASST SEC OF PREPAREDNESS & RESPONSE ACQ MANAGEMENT, CONTRACTS, & GRANTS O'NEILL HOUSE OFFICE BUILDING Washington DC 20515		
CODE 1492235		FACILITY CODE		
9A. AMENDMENT OF SOLICITATION NO.		(x)		
9B. DATED (SEE ITEM 11)				
10A. MODIFICATION OF CONTRACT/ORDER NO. 75A50120C00034		x		
10B. DATED (SEE ITEM 13) 04/03/2020				

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers ☐ is extended, ☐ is not extended.

Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or electronic communication which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by letter or electronic communication, provided each letter or electronic communication makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required)

See Schedule

13. THIS ITEM ONLY APPLIES TO MODIFICATION OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

CHECK ONE	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.
	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation data, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).
	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:
X	D. OTHER (Specify type of modification and authority) FAR 43.103 (a)

E. IMPORTANT: Contractor is not is required to sign this document and return 1 copies to the issuing office.

☐ ☒

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)

Tax ID Number: 27-0226313

DUNS Number: 069723520

The purpose of this modification is to add the Defense Priorities and Allocations System (DPAS) priority rating language to the contract. The modification changes the contract from unrated to a DO-H5 rating at no additional cost.

Section B.4.14 DPAS PRIORITY RATING has been added to the contract. Reference the Continuation Page for detail.

All other contract terms and conditions remain unchanged.

Continued...

Except as provided herein, all terms and conditions of the document referenced in Item 9 A or 10A, as heretofore changed, remains unchanged and in full force and effect .

15A. NAME AND TITLE OF SIGNER <i>(Type or print)</i>		16A. NAME AND TITLE OF CONTRACTING OFFICER <i>(Type or print)</i>	
Stephane Bancel, Chief Executive Officer		WENDELL CONYERS	
15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
/s/ Stephane Bancel <i>(Signature of person authorized to sign)</i>	8/31/2020	/s/ Wendell Conyers <i>(Signature of Contracting Officer)</i>	8/31/2020

CONTINUATION PAGE**B.4 Advanced Understandings****B.4.14 DPAS PRIORITY RATING**

This is a **DO rated order** for the purpose of emergency preparedness and the Contractor shall follow all the provisions of the Defense Priorities and Allocations System regulation (15 CFR Part 700). If the contractor needs to utilize industrial resources to fulfill this rated order for capacity and industrial expansion, it is authorized pursuant to 15 CFR §700.16(b) to place the same priority rating and program identification symbol on its orders for industrial resources with its suppliers.

DPAS PRIORITY RATING LANGUAGE:

The purpose of this no cost bilateral modification is to provide notice that this is a priority **DO-H5 rated** Contract #75A50120C00034. The Contractor and its subcontractors at all tiers are required to follow all of the provisions of the *Defense Priorities and Allocations System regulation (15 C.F.R. part 700)* as this contract is certified for national defense and emergency preparedness use. The authority for this rating is attached (Attachment A). The priority rating issued pursuant to the authorization is subject to the restrictions in the authorization.

The Parties agree that this change from an unrated contract to a DO-H5 priority rated is a no-cost change. Upon execution of this modification, the Contractor and its subcontractors must give the appropriate preferential treatment to the contract as of the date of the modification. The Contractor shall accept, perform, and prioritize this contract.

The Parties agree that this modification to rate this contract does not significantly alter the production or delivery schedule already in existence under this contract.

This contract shall take precedence over any and all other contracts and orders that do not have a priority rating and shall take precedence over orders or contracts that have the same level of priority rating but were received later in time.

This priority rating allows the Contractor to priority rate orders to its subcontractors and suppliers for purpose of fulfilling the priority-rated order expediently.

This priority rating automatically expires at the end of the contract's period of performance. The parties agree that the U.S. Government (USG) may withdraw or extend this authorization at any time prior to the expiration of the contract's period of performance at no cost to the USG.

If the Contractor and/or its subcontractors are unable to comply fully with the terms of this rated order Clause, the Contractor must immediately notify the Assistant Secretary for Preparedness and Response (ASPR) in writing and explain the extent to which compliance is possible and provide reasons why full compliance is not possible.

The contractor understands that use of this DO-rating can only be used for the procurement of raw materials, consumables, equipment, etc. necessary for the work covered under the scope of this contract.

The Contractor agrees that the Government's right to exercise priorities and allocations authority with respect to this contract to include the use of directives constitutes a no-cost change to this contract. The written signature on a manually placed order, or the digital signature or name on an electronically placed order, of an individual authorized to sign rated orders for the person placing the order is

provided. The signature, manual or digital, certifies that the rated contract is authorized under this regulation and that the requirements of this regulation are being followed. This language shall be added to the contract or task order by modification, if previously awarded.

This is a rated order certified for national defense use and you are required to follow all provisions of the Defense Priorities and Allocations System regulations (15 CFR part 700). This rated order is placed for the purpose of emergency preparedness.

The Parties agree that this modification includes the following documents:

Attachment Number	Title	Date
A	Authorization to issue Defense Priorities and Allocations System Rating for Operation Warp Speed Contract – ModernaTx. Inc.	August 30, 2020

AMENDMENT/MODIFICATION OF CONTRACT		1. CONTRACT ID CODE		PAGE OF PAGES	
		1		11	
2. AMENDMENT/MODIFICATION NO. P00005		3. EFFECTIVE DATE See Block 16C		4. REQUISITION/PURCHASE REQ. NO.	
6. ISSUED BY ASPR-BARDA		CODE ASPR-BARDA		5. PROJECT NO. (If applicable) ASPR-BARDA02	
ASPR-BARDA 200 Independence Ave., S.W. Room 640-G Washington DC 20201		7. ADMINISTERED BY (If other than Item 6) US DEPT OF HEALTH & HUMAN SERVICES ASST SEC OF PREPAREDNESS & RESPONSE ACQ MANAGEMENT, CONTRACTS, & GRANTS O'NEILL HOUSE OFFICE BUILDING Washington DC 20515			
8. NAME AND ADDRESS OF CONTRACTOR (No., street, county, State and ZIP Code) MODERNATX, INC 1492235 Attn: [***] MODERNATX, INC. 200 TECHNOLOGY 200 TECHNOLOGY SQ CAMBRIDGE MA 021393578		(x) 9A. AMENDMENT OF SOLICITATION NO. 9B. DATED (SEE ITEM 11) x 10A. MODIFICATION OF CONTRACT/ORDER NO. 75A50120C00034 10B. DATED (SEE ITEM 13) 04/03/2020			
CODE 1492235		FACILITY CODE			
23. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS					
☐ The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers ☐ is extended, ☐ is not extended.					
Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or electronic communication which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by letter or electronic communication, provided each letter or electronic communication makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.					
24. ACCOUNTING AND APPROPRIATION DATA (If required) See Schedule					
25. THIS ITEM ONLY APPLIES TO MODIFICATION OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.					
CHECK ONE	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.				
	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation data, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).				
	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:				
X	D. OTHER (Specify type of modification and authority) FAR 43.103(a)				
E. IMPORTANT: Contractor is not ☐ is required to sign this document and return <u>1</u> copies to the issuing office. ☒					
26. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible)					
Tax ID Number: 27-0226313 DUNS Number: 069723520 The purpose of this modification is to revise the Statement of Work (SOW) to reflect recent feedback from the FDA and OWS on the clinical development plan, and to reallocate the resulting funding to the ongoing mRNA-1273-P301 clinical study. As a result of the additional scope, the following was updated in this modification. - Section B.4.14 Enrollment Chart - Section C.2 Statement of Work - This modification reallocates up to \$48,137,292 within CLIN 0002					

Except as provided herein, all terms and conditions of the document referenced in Item 9 A or 10A, as heretofore changed, remains unchanged and in full force and effect .

15A. NAME AND TITLE OF SIGNER <i>(Type or print)</i>		16A. NAME AND TITLE OF CONTRACTING OFFICER <i>(Type or print)</i>	
Stephane Bancel, Chief Executive Officer		WENDELL CONYERS	
15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
/s/ Stephane Bancel <i>(Signature of person authorized to sign)</i>	9/15/2020	/s/ Wendell Conyers <i>(Signature of Contracting Officer)</i>	Sept. 5, 2020

CONTINUATION SHEET	REFERENCE NO. OF DOCUMENT BEING CONTINUED	PAGE	OF
	75A50120C00034/P00005	2	11

75A50120C00034/P00005

2

11

NAME OF OFFEROR OR CONTRACTOR	MODERNATX, INC 1492235
-------------------------------	------------------------

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	All other contract terms and conditions remain unchanged.				
	Period of Performance: [***]				

Contract #75A50120C00034
Modification P00005

CONTINUATION PAGE

B.4.14 Enrollment Chart
[**]

C. Statement of Work – Dated 9-14-2020

Independently, and not as an agent of the United States Government, the contractor shall furnish all necessary services, qualified professional, technical, and administrative personnel, material, equipment and facilities, not otherwise provided by the Government under the terms of this contract, as needed to perform the tasks set forth below.

mRNA-1273 Vaccine Development (WBS 1.0)

The Contractor, Moderna, Inc. ("Moderna") shall execute the preclinical, clinical, and chemistry, manufacturing and controls (CMC) activities required to license a vaccine against the SARS-CoV-2 virus (hereafter referred to as "mRNA-1273"). Building upon early clinical development already underway, this proposal will support the late stage development, including the demonstration of clinical efficacy and generation of a dataset supportive of licensure. Moderna will additionally evaluate the platform manufacturing capabilities relative to the needs for supply in response to a pandemic.

Program Management (WBS 1.1)

mRNA-1273 Program Management (WBS 1.1.1)

Moderna's mRNA-1273 program team is composed of a multidisciplinary, highly matrixed, group of functional leads with experience in, and responsibility for, integrating plans and operationalizing strategies across Research, Toxicology, CMC, Regulatory Affairs, Clinical Development and Quality. Collectively, the team has advanced ten programs to first-in-human studies within five years. The group will be led by a program lead (PL) who will oversee and coordinate the activities necessary to meet program objectives. The PL will be the point of accountability for the development of mRNA-1273. [***]. A program management office (PMO) will be responsible for managing the cost and schedule constraints of the contract via an integrated master schedule and corresponding budget, identifying and managing program risk, and ensuring contract compliance. With the input from the mRNA-1273 project team, the PMO will be responsible for coordinating the drafting of and management to an integrated development plan. Upon execution of the contract, weekly meetings with BARDA will be held to monitor program performance and monthly and annual reports will be will delivered to BARDA for the record.

Nonclinical Toxicology (WBS 1.2)

Development and Reproductive Toxicology of mRNA-1273 (WBS 1.2.2.1)

To assess the risk of administering the vaccine to pregnant women, a complete GLP rat developmental and reproductive toxicology (DART) study is planned. Female Sprague Dawley rats will be dosed at the highest anticipated clinical dose level and include a control arm of phosphate-buffered saline (PBS). As is typical for DART evaluations for vaccines, the animals will be immunized three times prior to mating and two times during gestation. Each group will have two cohorts (one group will undergo Cesarean section with examination of the uteri and embryos; the other group will have natural delivery and will be terminated at weaning).

Contract #75A50120C00034
Modification P00005

Nonclinical (WBS 1.3)

For the purposes of this proposal it is assumed that the VRC continues to support nonclinical activities to develop murine and non-human primate efficacy studies, and animal models to assess the potential of vaccine-enhanced disease. The scope of work below will execute additional robustness experiments in these developed models.

Assess Disease Enhancement (WBS 1.3.3.1)

***]

We plan to perform studies in mouse and NHPs to assess the theoretical risk of vaccine induced disease enhancement triggered by CoV infection following vaccination with imRNA-1273. [***]

***]

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Modification P00005

[Establish a Surrogate of Protection \(WBS 1.3.3.2\)](#)

The primary endpoint for accelerated approval of a SARS-CoV-2 vaccine would be a neutralization assay. This endpoint must be supported with a body of pre-clinical work that demonstrates a correlation between neutralizing titers and efficacy and that quantifies a protective serologic threshold titer using the same neutralization assay. Murine and NHP efficacy models are being developed in parallel to the Phase 1 clinical study. Building on data from these preliminary models and studies, Moderna will conduct NHP efficacy and murine passive transfer studies to confirm and refine the surrogate of protection.

Clinical (WBS 1.4)

[***]

Contract #75A50120C00034
Modification P00005

[**]

Phase 3 Pivotal Study (WBS 1.4.3.1)

Phase 3 Pivotal Study (WBS 1.4.3.1). The Phase 3 mRNA-1273-P301 study will confirm the trends observed during the Phase 1 and 2 trials, evaluating safety and efficacy in a larger number of subjects aged 18 and above. Approximately 30,000 subjects will be enrolled according to 1:1 randomization (active: placebo). Primary objectives will be 1) to demonstrate the efficacy of mRNA-1273 to prevent COVID-19 and 2) to evaluate the safety and reactogenicity of 2 injections of the mRNA-1273 vaccine given 28 days apart. [**]

[**]

Contract #75A50120C00034
Modification P00005

Lot to Lot Consistency (WBS 1.4.3.2)

Based on FDA feedback received on 27 Aug this study is no longer required for licensure.

Pediatrics (WBS 1.4.3.3)

[**]

Regulatory (WBS 1.5)

IND Preparation and Filing (WBS 1.5.1.1)

Moderna's Regulatory Affairs group, in close collaboration with BARDA, will work to draft a comprehensive regulatory master plan to guide the preclinical, CMC and clinical development of mRNA-1273 within the first 90 days of the contract. An original investigational new drug application (IND) will be filed with the United States Food and Drug Administration (FDA) to support the clinical development of the Moderna product from Phase 2 onwards.

IND Maintenance (WBS 1.5.1.2)

The Moderna-owned IND will be maintained to support the desired clinical development plan. As needed, meetings will be conducted to receive feedback and gain concurrence on the specifics of the development activities with the FDA.

BLA Submission (WBS 1.5.2.1)

Moderna will submit a Biologics License Application (BLA) and seek approval for the mRNA-1273 vaccine.

CMC (WBS 1.6)

CTM Manufacture for Phase 2 (WBS 1.6.3.2)

[**]

Process Development for Late Stage Clinical Supply (WBS 1.6.3.3)

mRNA Process Development

Technical Development will confirm and optimize the process parameters for mRNA manufacture. [**]\

***]

BLA Readiness (WBS 1.6.3.8)

In support of the Biologics License Application (BLA) due to the nature of the proposed timeline, it is likely that Moderna will need to complete some of process validation activities, primarily process characterization, after the completion of process performance qualification and before BLA filing. Moderna intends to rapidly develop a robust process for clinical manufacturing and PPQ, and then fully describe the acceptable design space for the process prior to BLA filing. Other activities to support this BLA filing, such as completing raw material qualification activities; if not included in the BLA submission, will require a supplement to the initial BLA. In the initial BLA filing Moderna will describe its control strategy to cover the gap between initial BLA filing and the BLA supplement.

Process Development for Full Commercial Scale (WBS 1.6.4.1)

The following section outlines the process development activities [***]. The goal of this work is to demonstrate the capability to produce mRNA-1273 at a scale that can support clinical demand.

Contract #75A50120C00034
Modification P00005

[***]

Stability Studies (WBS 1.6.5.4)

Throughout the program, many studies will be undertaken [***]. This includes studies using development bench scale material, engineering lot material, and GMP material. This body of data will be used to apply interim and long-term shelf life to the drug product and process intermediates.

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT HAVE BEEN OMITTED AND REPLACED WITH "[***]". SUCH IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS (I) NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF DISCLOSED.

Lonza

CONFIDENTIAL

GLOBAL LONG TERM AGREEMENT

This Global Long Term Agreement is made as of September 4, 2020, and effective as of May 1, 2020 (the "**Effective Date**") among **Lonza Ss Ltd.**, having an address at Münchensteinerstrasse 38, 4002 Basel, Switzerland] ("**LONZA SALES**"), Lonza Ltd., having an address at Münchensteinerstrasse 38, 4002 Basel, Switzerland ("**LONZA LTD**", and together with LONZA SALES, "**LONZA**"), and **ModernaTX, Inc.**, with an address at 200 Technology Square, Cambridge, MA 02139 USA ("**MODERNA**" or "**CLIENT**") (each, a "**Party**" and, collectively, the "**Parties**").

RECITALS

- A. MODERNA possesses extensive intellectual property, proprietary technology and expertise with respect to the research, development, manufacture and formulation of messenger RNA (mRNA) therapeutics and vaccines;
- B. LONZA possesses world class manufacturing and process expertise in biologics manufacturing consistent with cGMP (as defined below);
- C. MODERNA and LONZA entered into that certain Strategic Collaboration Agreement, dated as of April 30, 2020, pursuant to which the Parties entered into a multi-year global long term strategic collaboration (the "**SCA**");
- D. The SCA contemplates that the Parties will enter into this Agreement, pursuant to which MODERNA will engage LONZA to perform process development work and to manufacture and supply the Products at the LONZA facilities for clinical and commercial supply;
- E. The Parties (or their respective Affiliates) desire to enter into individual Statements of Work for various workstreams, as further defined below.

NOW, THEREFORE, in consideration of the foregoing and the mutual promises and covenants hereinafter set forth, LONZA and MODERNA, intending to be legally bound, hereby agree as follows:

AGREEMENT

1. DEFINITIONS

When used in this Agreement, capitalized terms will have the meanings as defined below and throughout the Agreement. Unless the context indicates otherwise, the singular will include the plural and the plural will include the singular.

- a. "**Additional Products**" means any products owned or controlled by MODERNA or its Affiliates (other than the Covid Products) that are mutually agreed by the Parties and identified in the relevant Statement of Work.
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- a. **"Affiliate"** means, with respect to either Party, any other corporation, partnership or business entity that directly, or indirectly through one or more intermediaries, controls, is controlled by or is under common control with such Party. For purposes of this definition, the term "control" and, with correlative meanings, the terms "controlled by" and "under common control with" means direct or indirect ownership of at least fifty percent (50%) of the securities or other ownership interests representing the equity voting stock or general partnership or membership interest of such entity or the power to direct or cause the direction of the management or policies of such entity, whether through the ownership of voting securities, by contract, by corporate governance, resolution, regulation or otherwise.
- b. **"Agreement"** means this Global Long Term Agreement, together with all Exhibits, Schedules and Appendices attached hereto, and all Statements of Work issued in connection therewith, in each case as amended or restated from time to time by the Parties.
- c. **"Applicable Laws"** means all relevant international, federal, provincial, state and local laws, statutes, rules, regulations, directives, ordinances, codes and guidelines promulgated by any relevant Governmental Authority, whether currently in existence or hereafter promulgated, that are applicable to a Party's activities hereunder, including the Services performed under the relevant Statement of Work (including cGMP, if applicable to such Services) together with amendments thereto.
- d. **"BARDA"** has the meaning set forth in Section 2.6.2.
- e. **"BARDA Contract"** has the meaning set forth in Section 2.6.2.
- f. **"Batch"** means a specific quantity of Product that is intended to have uniform character and quality, within specified limits, and is produced according to a single manufacturing order during the same cycle of manufacture.
- g. **"Batch Record"** means the production record pertaining to a Batch.
- h. **"Business Continuity Plans"** has the meaning set forth in Section 17.2.
- i. **"Business Day"** means any day other than a Saturday or Sunday on which banking institutions in New York, NY and Visp, Switzerland are open for business.
- j. **"Calendar Quarter"** means the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31; provided, however, that (a) the first Calendar Quarter of this Agreement shall commence on the Effective Date and end at the end of the Calendar Quarter in which the Effective Date occurs and (b) the last Calendar Quarter of this Agreement shall commence at the commencement of such Calendar Quarter and end on the expiration of the Term.
- k. **"Calendar Year"** means each twelve (12) month period beginning on January 1st; provided, however, that (a) the first Calendar Year of this Agreement shall commence on the Effective Date and end on December 31 of the same year and (b) the last Calendar Year of this Agreement shall commence on January 1 of the Calendar Year in which this Agreement expires and end on the expiration of the Term.
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- a. **"Certificate of Analysis"** means a document signed by an authorized representative of LONZA, certifying that a particular Batch of Product was Manufactured in accordance with the Quality Agreement, Applicable Law and the Specifications.
 - b. **"Certificate of Testing"** means a document signed by an authorized representative of LONZA, certifying that certain tests identified by MODERNA or mutually agreed upon in writing by the Parties and conducted by LONZA on a Batch of Product meets all Specifications.
 - c. **"cGMP" or "GMP"** means the then-current good manufacturing practices, standards, guidelines and regulations promulgated and published by the FDA, EMA and such other jurisdiction agreed upon by the Parties in writing, relating to the testing, manufacturing, processing, packaging, holding or distribution of drug substances and finished drugs including any standards, guidelines and regulations as promulgated by, as applicable: (a) the FDA under and in accordance with the U.S. Federal Food, Drug and Cosmetic Act and Title 21, Parts 210 and 211 of the U.S. Code of Federal Regulations, (b) the EMA and the EU Commission under European Directive 2003/94/EC, and/or (c) the ICH Harmonised Tripartite Good Manufacturing Practice Guide For Active Pharmaceutical Ingredients (ICH Q7), as such standards, guidelines and regulations may be amended from time to time.
 - d. **"cGMP Batch"** means any Batch which is required under the relevant Statement of Work to be Manufactured in accordance with cGMP.
 - e. **"Change Order"** has the meaning set forth in Section 2.2.
 - f. **"CMC"** means chemistry, manufacturing and control.
 - g. **"Commencement Date"** means the date set forth in the relevant Statement of Work for the commencement of Services, including the Manufacture of the Product.
 - h. **"Confidential Information"** has the meaning set forth in Section 10.1.
 - i. **"Controlled"** means, with respect to any Know-How, patent or other intellectual property right, the possession (whether by ownership, license or sublicense, other than by a license, sublicense or other right granted (but not assignment) pursuant to this Agreement) by a Party (or its Affiliate) of the ability to assign or grant to the other Party the licenses, sublicenses or rights to access and use such Know- How, patent or other intellectual property right as provided for in this Agreement, without violating the terms of any agreement or other arrangement with any Third Party in existence as of the time such Party would be required hereunder to grant such license, sublicense, or rights of access and use.
 - j. **"Covid Products"** means (a) MODERNA's proprietary mRNA constructs and lipid nanoparticles for a potential vaccine against SARS-CoV-2, including mRNA-1273 (including any improved or modified version thereof, **"mRNA-1273"**), and (b) any other mRNA Constructs or lipid nanoparticles (i) for the treatment or prevention of infection by SARS-CoV-2 and (ii) identified as "Covid Products" in the relevant Statement of Work.
 - k. **"DMF"** means any drug master file filed with the FDA, and equivalent filing in other countries or jurisdictions.
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- a. **“EMA”** means the Regulatory Authority known as the European Medicines Agency and any successor agency thereto.
 - b. **“Engineering Batch”** means any Batch Manufactured under the relevant Statement of Work that is intended to demonstrate the transfer of the Process to the Facility.
 - c. **“Environmental, Health and Safety Laws”** or **“EHS Laws”** means all applicable environmental and similar Applicable Laws, including those relating to (a) safety (including occupational health and safety); protection of human health and the environment; (b) the introduction of any chemical substances into the stream of commerce; and (c) the generation, use, storage, handling, treatment, transportation or disposal of waste.
 - d. **“EUA”** means an Emergency Use Authorization, which is an authorization issued by the FDA allowing use of an unapproved medical product or unapproved use of an approved medical product during a declared emergency as determined by the Secretary of the Department of Health and Human Services pursuant to Section 564(b)(1) of the FD&C Act, or a comparable accelerated, conditional or temporary Regulatory Approval.
 - e. **“Equipment”** means the MODERNA Equipment or LONZA Equipment, as the context requires.
 - f. **“Exclusivity Term”** means, [***].
 - g. **“Executive Officers”** means, with respect to MODERNA, its Chief Executive Officer, and, with respect to LONZA, its Chief Executive Officer.
 - h. **“Existing SOWs”** means any Statements of Work entered into by the Parties prior to the execution of this Agreement, including (a) Statement of Work Nr. 1, effective as of April 20, 2020, attached hereto as Appendix A-1, (b) Statement of Work Nr. 2, effective as of May 13, 2020, attached hereto as Appendix A-2, and (c) Statement of Work Nr. 3, effective as of May 13, 2020, attached hereto as Appendix A-3.
 - i. **“Facility”** means any of LONZA’s facilities located in [***], or such additional facilities that the Parties may mutually agree upon, as
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identified in the relevant Statement of Work. In all cases, the Facility(ies) to be utilized for performing Services or Manufacturing Product under this Agreement related to a specific Statement of Work shall be designated in such Statement of Work.

- a. **“FD&C Act”** means the United States Food, Drug and Cosmetic Act (21 U.S.C. § 301 et seq.), as amended from time to time, together with any rules, regulations and requirements promulgated thereunder (including all additions, supplements, extensions, and modifications thereto).
 - b. **“FDA”** means the U.S. Food and Drug Administration, and any successor agency thereof.
 - c. **“Flow-Down Provisions”** has the meaning set forth in Section 2.6.
 - d. **“Force Majeure Event”** has the meaning set forth in Section 18.2.
 - e. **“Governmental Authority”** means any applicable government authority, court, tribunal, agency, department, legislative body, commission, authority, or other instrumentality of any national, supra-national, state, county, city, or other political subdivision.
 - f. **“Indemnitee”** has the meaning set forth in Section 16.3.1.
 - g. **“Indemnitor”** has the meaning set forth in Section 16.3.1.
 - h. **“JMT”** has the meaning set forth in Section 3.2.1.
 - i. **“JSC”** has the meaning set forth in Section 3.1.1.
 - j. **“Know-How”** means all non-public technical, scientific, and other know-how and information, trade secrets, knowledge, technology, means, methods, processes, practices, formulae, instructions, skills, techniques, procedures, experiences, ideas, designs, drawings, assembly procedures, software, computer programs, apparatuses, specifications, data, results and materials, including: biological, chemical, vaccine-related, pharmacological, toxicological, pharmaceutical, physical and analytical, pre-clinical, clinical, safety, manufacturing and quality control data and information, including study designs and protocols, assays, and biological methodology, in all cases, whether or not copyrightable or patentable, in written, electronic or any other form now known or hereafter developed.
 - k. **“Lien”** means any legal charge, debenture, mortgage, deed of trust, security interest, pledge, lien, assignment, or other encumbrance of any kind whether imposed by contract, Applicable Law or otherwise, whether fixed or floating, or conferring priority of payment.
 - l. **“Lipid Nanoparticle”** means any delivery technology for mRNA or other nucleic acids using solid particles at room temperature, of 50-1,000 nm size, consisting of solid lipids or a mixture of a solid lipid and a liquid lipid.
 - m. **“LONZA”** except where otherwise mentioned in the relevant SOW means [***] and Lonza Ltd [***].
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- a. **“LONZA Equipment”** means all equipment and machinery for which LONZA or its Affiliates shall hold title and that is used by LONZA or its Affiliates to (or otherwise necessary for), directly or indirectly, Manufacture Product or perform any Services.
- b. **“LONZA Improvement”** means all Technology conceived, discovered, invented, developed, created, made or reduced to practice in connection with this Agreement that is [***].
- c. **“LONZA Operating Documents”** means the standard operating procedures, standard manufacturing procedures, raw material specifications, protocols, validation documentation, and supporting documentation used by LONZA, such as environmental monitoring, for operation and maintenance of the Facility and LONZA Equipment used in the process of producing the Product, and any other LONZA documents containing information required to be provided to a Regulatory Authority in connection with obtaining Regulatory Approval of a Product, excluding any of the foregoing that are unique to the Manufacture of Product.
- d. **“LONZA Parties”** has the meaning set forth in Section 16.2.
- e. **“LONZA Personnel”** has the meaning set forth in Section 7.12.
- f. **“LONZA Process Equipment”** all LONZA Equipment that is process equipment and is designated by the Parties as “LONZA Process Equipment” in the relevant Statement of Work or other written agreement by the Parties, or in the list of equipment maintained by the JMT as set forth in Section 3.2.2(f). For clarity, Lonza Process Equipment excludes process equipment that is customized or proprietary to Moderna.
- g. **“LONZA Technology”** means all Technology of LONZA (a) existing prior to the effective date of this Agreement; or (b) developed or obtained by or on behalf of LONZA independent of this Agreement and without the use or reference to any confidential information of MODERNA (including the MODERNA Manufacturing Know-How, Products (or components thereof) or any manufacturing equipment for the Products (or components thereof)).
- h. **“Losses”** has the meaning set forth in Section 16.1.
- i. **“Manufacture”** and **“Manufacturing”** means any steps, processes and activities necessary to produce Product, including the production, manufacture, synthesis, processing, packaging, labeling, quality control testing, release, storage, shipping or supply of Product or any intermediate or component thereof. To the extent set forth in the relevant Statement of Work, “Manufacturing” could include process development, process qualification and validation, scale-up, analytic development, product characterization, stability testing, filling, finishing, quality assurance and quality control and supply. **“Manufacturing”** refers to Manufacturing of Product for pre-clinical, clinical and commercial purposes. **“Manufacture”** and **“Manufactured”** will have corresponding meanings.
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- a. **"Materials"** means all raw materials, components (including packaging materials), and other potential materials, supplies, consumables or similar items reasonably necessary for, or otherwise used in, the Manufacture of Product.
- b. **"Member"** has the meaning set forth in Section 3.1.1.
- c. **"MODERNA Equipment"** means all equipment or machinery designated by the Parties as "MODERNA Equipment" in the relevant Statement of Work or other written agreement by the Parties, or in the list of equipment maintained by the JMT as set forth in Section 3.2.2(f).
- d. **"MODERNA Improvement"** means all Technology conceived, discovered, invented, developed, created, made or reduced to practice in connection with this Agreement [***].
- e. **"MODERNA Manufacturing Know-How"** means Know-How Controlled by MODERNA or its Affiliates, which is maintained in confidence by MODERNA or its Affiliates, relating to the manufacturing of a given Product, including documentation constituting material support, performance advice, shop practice, specifications as to materials to be used, control methods, standard operating procedures, protocols, descriptions of the manufacturing process and related know-how, development reports, analytical methods, equipment size/name/customizations/components, validation reports, cleaning methods and batch records and any other information, in each case, that is (a) necessary or reasonably useful to manufacture such Product in accordance with the applicable Specifications or (b) disclosed to LONZA or its Affiliates by or on behalf of MODERNA or its Affiliates in connection with this Agreement, including any Statement of Work.
- f. **"MODERNA Materials"** has the meaning set forth in Section 7.1.
- g. **"MODERNA Personnel"** has the meaning set forth in Section 7.11.1.
- h. **"MODERNA Technology"** means all Technology Controlled by MODERNA or its Affiliates (a) existing prior to the effective date of this Agreement; or (b) developed or obtained by or on behalf of MODERNA or its Affiliates independent of this Agreement and without the use or reference to any confidential information of LONZA. For clarity, the MODERNA Technology includes (i) the Product and any Product-intermediates, components or derivatives of Product, (ii) starting materials and any intermediates, components or derivatives of starting materials, (iii) Specifications, (iv) Test Methods and (v) Process.
- i. **"mRNA-1273"** has the meaning set forth in the definition of "Covid Products".
- j. **"mRNA Construct"** means a messenger RNA construct (modified or unmodified) for the expression of a polypeptide, including the sequence of such construct (which may include a cap, 5' UTR, the associated open reading frame, 3' UTR and a poly A tail), the chemistry of natural and non-natural nucleic acids, and the other chemical elements contained in such construct.
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- a. **"mRNA Product"** means a pharmaceutical or vaccine product that includes, incorporates or contains as an active ingredient one (1) or more mRNA Constructs (whether alone or in combination with one or more other active ingredients).
 - b. **"OFAC"** has the meaning set forth in Section 17.4.2.
 - c. **"Person"** means any natural person, corporation, unincorporated organization, partnership, association, sole proprietorship, joint stock company, joint venture, limited liability company, trust or government, or Governmental Authority, or any other similar entity.
 - d. **"Process"** means any and all processes and activities (or any step in any process or activity) specified by MODERNA that is to be used by LONZA to Manufacture the Product.
 - e. **"Product"** has the meaning set forth in the relevant Statement of Work. Product includes the Covid Products and any Additional Products.
 - f. **"Project Documentation"** means the compilation of documentation generated or to be generated by LONZA in preparation of and during the performance of the relevant Statement of Work, including, without limitation, executed Batch Records, component records, test records and test record forms, Certificates of Analysis, Certificate of Testing, release documentation, study protocols, study summary reports, deviation reports, laboratory investigations, environment excursions, formulation records, and other related documents, which show that the Product was Manufactured in accordance with the Quality Agreement, Applicable Law and the Specifications, or that Services were otherwise performed in accordance with the requirements of this Agreement.
 - g. **"Quality Agreement"** means the document established by MODERNA and LONZA in conjunction with this Agreement to establish the quality requirements applicable to Manufacture in accordance with applicable guidelines issued by the Regulatory Authorities that control authorization and licensing for manufacture and sale of pharmaceutical or medicinal products.
 - h. **"Regulatory Approval"** means the approval by any Regulatory Authority to market and sell the Products in the respective markets, including any pricing approval. For clarity, Regulatory Approvals include EUAs and other accelerated, conditional or temporary authorizations or approvals.
 - i. **"Regulatory Authority"** means the Service and Product relevant international, federal, provincial, state or local governmental or regulatory bodies, agencies, departments, bureaus, courts or other entities responsible for (a) the regulation (including pricing) of any aspect of pharmaceutical or medicinal products intended for human use, including the FDA, EMA, United States Drug Enforcement Agency or any other international, federal, state or local regulatory bodies, agencies, departments, bureaus, courts or other entities responsible for the regulation of drugs, (b) granting approvals for the performance of Services under this Agreement or for issuing regulations pertaining to the manufacturing or use of products, or (c) health, safety or environmental matters generally.
 - j. **"Sanctions"** has the meaning set forth in Section 17.4.3.
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- a. **"SARS-CoV-2"** means the novel coronavirus known as SARS-CoV-2, including any subtypes or strains thereof.
- b. **"Services"** means the activities to be performed by LONZA hereunder that are agreed to by the Parties and set forth in the relevant Statement of Work. The Statement of Work shall indicate whether the applicable Services are cGMP services or non-cGMP services.
- c. **"SOP"** means a standard operating procedure.
- d. **"Specifications"** means, for a given Product, the list of tests, references to any analytical procedures and acceptance criteria which are numerical limits, ranges or other criteria for tests described in order to establish a set of criteria to which final Product should conform to be considered acceptable for its intended use that are provided by MODERNA in a Statement of Work or otherwise approved by MODERNA in writing, as well as dispensing and labeling information, as such specifications are amended or supplemented from time to time by MODERNA in writing.
- e. **"Statement of Work" or "SOW"** means any written plan to perform Services that has been agreed to by the Parties and executed by an authorized representative of each Party. Each Statement of Work will be in the form of the template attached hereto as [Appendix B](#) ("**SOW Template**"), and will include, at a minimum, a reference to this Agreement, a description of the nature and scope of the Services to be performed, a timetable for the performance of the Services, the fees to be charged for such Services, and any other relevant items set forth in the SOW Template. An initial Statement of Work is attached hereto as [Appendix A](#). Each Existing SOW shall be deemed a Statement of Work under this Agreement and is hereby governed by, subject to, and incorporated into this Agreement. Each subsequent Statement of Work shall be governed by, subject to, and incorporated into this Agreement, although the terms in the relevant Statement of Work will apply only to Services described in that Statement of Work.
- f. **"Taxes"** means any form of tax or taxation, levy, duty, charge, social security charge, contribution or withholding of whatever nature (including any related fine, penalty, surcharge or interest) imposed by, or payable to, a Tax Authority, and has the additional meaning set forth in Section 9.4.
- g. **"Technology"** means all patents, patent applications, inventions, trade secrets, copyrights, know-how, methods, processes, techniques, improvements, data, technical documentation, manuals, regulatory submissions, specifications, SOPs, instructions, and other intellectual property of any kind (whether or not protected or protectable under patent, trademark, copyright or similar laws).
- h. **"Technology Transfer"** means the transfer of Know-How, documentation, specifications, SOPs, analytical methods and process validation documents related to MODERNA's Process or Product by MODERNA to LONZA for the development of the Project Documentation for the Manufacture of the Product specifically for MODERNA or its Affiliates.
- i. **"Test Methods"** means any assays or other test methods identified by MODERNA in the relevant Statement of Work, or as amended or modified in any Change Order.
- j. **"Third Party"** means any party other than LONZA, MODERNA or their respective Affiliates.
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- a. **“United States”** or **“U.S.”** means the United States of America, including its territories and possessions.
- b. **“U.S. Government Supply Agreement”** means an agreement between Moderna and the United States Department of Defense or other U.S. government agency pursuant to which the U.S. government procures supplies of mRNA-1273 from Moderna, as may be amended or supplemented.
- c. **“Waste”** means all waste material generated from or in connection with any Services.

1. STATEMENTS OF WORK - PROCESS AND PRODUCT DEVELOPMENT; PROCESS OR PRODUCT MANUFACTURE; FLOW-DOWN PROVISIONS; QUALITY AGREEMENT

a. **Statement of Work.** Prior to performing any Process or Product development, Technology Transfer, or Product Manufacture, the Parties will collaborate to prepare a Statement of Work describing the activities to be performed by the Parties (or to be subcontracted by LONZA to one or more Third Parties in accordance with Section 2.5). In the event of a conflict between the terms and conditions of this Agreement and any Statement of Work, the terms and conditions of this Agreement shall control.

b. **Modification of Statement of Work.** Should MODERNA want to change a Statement of Work or to include additional Services to be provided by LONZA, including any changes to the Specifications, Process or Test Methods for the Products, MODERNA may propose to LONZA (including via the JSC or JMT) an amendment to such Statement of Work with the desired changes or additional Services (each a **“Change Order”**). LONZA will provide MODERNA with a Change Order containing a description of the required modifications to the relevant Statement of Work, and any proposed changes to the pricing or other fees as well as impact on timelines as a result of such modifications, and will use diligent efforts to do so within [***] of receiving such notice from MODERNA. LONZA may also propose a Change Order to MODERNA, and MODERNA will use diligent efforts to answer to such proposal within [***] of receiving such proposal. If the proposed Change Order is not acceptable to the receiving Party, the Parties will promptly negotiate in good faith a Change Order that is mutually acceptable. LONZA shall continue to work under this Agreement (including under the existing Statement of Work) during any such negotiations. LONZA shall use commercially reasonable efforts to accommodate any of MODERNA’s requested changes, provided if a change is required by any Regulatory Authority on or after the Commencement Date for a Product, such change shall be included in a Change Order. The modified Statement of Work shall be binding on the Parties only if it is signed by both Parties. Thereafter such modified version of the Statement of Work will be deemed to have replaced the prior version of the Statement of Work. Notwithstanding the foregoing, if a modified version of the Statement of Work is not agreed to by both Parties, the existing Statement of Work shall remain in effect, unless terminated by MODERNA in accordance with this Agreement or the existing Statement of Work.

c. **Performance by LONZA.** Subject to the provision by MODERNA of the MODERNA Materials pursuant to Section 7.1, LONZA (directly or through one or more Third Parties in accordance with Section 2.5) will use diligent efforts to perform, subject to the terms of the relevant Statement of Work, the work described in such Statement of Work in a professional manner in accordance with prevailing industry standards, the terms of this Agreement, the terms of the relevant Statement of Work (including the estimated timelines set forth therein), and all Applicable Laws. LONZA will promptly notify

MODERNA of any material potential or actual delays that arise or are anticipated during the performance of the Statement of Work, and will diligently work to mitigate any such delays.

a. Affiliates. Each Party shall have the right to extend the rights, licenses, immunities and obligations granted or imposed under this Agreement to one or more of its Affiliates. All applicable terms and provisions of this Agreement shall apply to any such Affiliate to which this Agreement has been extended to the same extent as such terms and provisions apply to the applicable Party. Each Party shall however remain primarily liable for any acts or omissions, including financial liabilities, of its Affiliates. In addition, an Affiliate of a Party may execute a Statement of Work pursuant to this Agreement and submit or pay invoices (as applicable) under such Statement of Work. In such circumstances, all references in this Agreement to a Party shall be deemed to be to the applicable Affiliate of such Party with respect to (i) the relevant Statement of Work or (ii) the relevant portions of the relevant Statement of Work under which the Affiliate will be performing specified Services or obligations. The Affiliate shall be entitled to enforce this Agreement with respect to such Statement of Work, or as applicable the relevant portions of such Statement of Work, in its own name as an intended third party beneficiary and the Affiliate shall be liable to the other Party for any obligations and liabilities undertaken pursuant to such Statement of Work and subject to the terms and conditions of this Agreement. Without limiting the foregoing, all Statements of Work will be executed by the appropriate legal entities of the Parties, including as may be required to comply with any specific requirements of governments, governmental agencies or other Third Parties that are funding, purchasing or distributing the Covid Products.

b. Subcontracting. With MODERNA’s prior written consent, LONZA may subcontract the performance of specific obligations of LONZA under this Agreement or a Statement of Work to an Affiliate or to a qualified Third Party contractor; provided that (a) the relevant Statement of Work identifies the subcontractor and the specific Services to be performed by the subcontractor or MODERNA separately approves such Third Party contractor in writing, and (b) the subcontractor performs such Services or obligations under the relevant Statement of Work in a manner consistent with the terms and conditions of this Agreement and such Statement of Work. Except as otherwise agreed upon in a Statement of Work, LONZA will be solely responsible for the performance of any permitted subcontractor, and for Losses arising out of such performance as if such performance had been provided by LONZA itself under this Agreement or the relevant Statement of Work. LONZA will cause any such permitted subcontractor to be bound by, and to comply with, the terms of this Agreement or the relevant Statement of Work, including all confidentiality, intellectual property, recordkeeping, audit and inspection, quality assurance, regulatory and other obligations and requirements of LONZA set forth in this Agreement or the relevant Statement of Work. For clarity and notwithstanding anything to the contrary in this Section 2.5, [***].

c. Flow-Down Provisions.

i. The Parties acknowledge and agree that the Manufacturing of certain Products or the performance of certain Services may be subject to restrictions or requirements based upon funding or grants received by or on behalf of MODERNA or its Affiliates from governments, governmental agencies or other funding sources [***]. The Statements of Work will include appropriate mandatory flow-down provisions (the “**Flow-Down Provisions**”) that are required to be incorporated as a result of any funding, grants or other funding sources for the Products or Services strictly for the purpose of ensuring MODERNA’s performance of its obligations under such Flow-Down Provisions as incorporated in its prime contract.

ii. Without limiting the generality of the foregoing, the Parties acknowledge and agree that certain Services may include work under one or more prime contracts between the Biomedical Advanced Research and Development Authority (“**BARDA**”) and MODERNA (or its Affiliate), including the contract dated April 16, 2020 (NO. HHSO75A50120C00034) as may be amended, supplemented or replaced (each, a “**BARDA Contract**”). Additionally, the Parties acknowledge and agree that Services regarding the Manufacture of mRNA-1273 in the United States will be subject to the terms required under the U.S. Government Supply Agreement.

iii. If a Statement of Work includes Flow-Down Provisions, LONZA hereby covenants that LONZA and its Affiliates will comply with the Flow-Down Provisions set forth in such Statement of Work. If the relevant Statement of Work indicates that the Services are being performed in connection with a BARDA Contract, the Flow-Down Provisions included in Attachment C hereto shall apply with respect to such Services. [***].

a. **Quality Agreement.** Promptly following the Effective Date, the Parties shall negotiate in good faith and enter into a Quality Agreement on terms to be mutually agreed by the Parties. If reasonably determined necessary by LONZA, the parties shall enter into separate Quality Agreements for different Facilities. LONZA shall Manufacture and supply the Product in accordance with the Quality Agreement as reasonably updated by the Parties from time to time, notably to take into consideration any marketing authorization(s) for Product. In the event of a conflict between any of the provisions of this Agreement and the Quality Agreement with respect to quality-related activities, including compliance with cGMP, the provisions of the Quality Agreement shall govern. In the event of a conflict between any of the provisions of this Agreement and the Quality Agreement with respect to any commercial matters, including allocation of risk, liability and financial responsibility, the provisions of this Agreement shall govern.

1. GOVERNANCE

a. **Joint Steering Committee.**

i. Immediately following the Effective Date, the Parties shall establish a joint steering committee ("**JSC**") to oversee, review, approve and coordinate the activities of the Parties under this Agreement, including each Statement of Work. Each Party shall appoint three (3) members to the JSC (each a "**Member**"). Each Party may change one or more of its Members by written notice to the other Party.

ii. The JSC shall be responsible for:
[***]

iii. The JSC shall meet [***]

i. [***]

a. **Joint Manufacturing Team.**

i. Within [***] of the Effective Date, the JSC shall establish a joint manufacturing team (the “**JMT**”) to oversee the Services under each Statement of Work. The JMT shall be composed of a mutually agreed number of members, with an equal number appointed by each of MODERNA and LONZA. The JMT shall include individuals with expertise and responsibilities appropriate (in terms of their seniority, availability, function in their respective organizations, training and experience) for the tasks then being undertaken. Each Party shall designate one of its representatives as its primary contact for JMT matters (such Party’s “**Team Co-Leader**”). A Party may replace any or all of its representatives (and designated Team Co-Leader) at any time by informing the other Team Co-Leader in advance, in writing (which may be by email).

ii. The JMT shall be responsible for:

[***]

i. The JMT shall meet [***].

ii. The Parties acknowledge and agree that the JMT is intended to act as a body solely overseeing and deciding upon items within the scope of work defined and agreed upon in writing by the Parties in the relevant SOWs, as well as a discussion forum, and not a decision-making body for any items outside of the agreed upon scope of work. Other than with respect to questions regarding the JMT's authority to review and approve modifications to Statements of Work within parameters prescribed by the JSC, the JMT's responsibilities are not subject to the oversight of, or escalation to, the JSC in the event of any dispute or disagreement between the Parties.

a. **Limitations of Authority.** Each Party will retain the rights, powers and discretion granted to it under this Agreement and no such rights, powers, or discretion will be delegated to or vested in the JSC or JMT, unless such delegation or vesting of rights is expressly provided for in this Agreement or the Parties expressly so agree in writing. Except as provided in Section 3.1.2 and Section 3.2.2(f), the JSC and the JMT will not have the power to (a) amend, modify or waive compliance with this Agreement, including any Statement of Work, (b) alter, increase or expand the Parties' rights or obligations under this Agreement, including any Statement of Work, beyond those explicitly set forth in this Agreement, including any Statement of Work, (c) determine that a Party has fulfilled any obligations under this Agreement or that a Party has breached any obligation under this Agreement, including any Statement of Work, or (d) make a decision that is expressly stated to require the mutual agreement of the Parties or for which MODERNA or LONZA have final decision making authority.

1. TECHNOLOGY TRANSFER

a. Based on the information provided by MODERNA and including process definition or changes mutually agreed by the Parties pursuant to the relevant Statement of Work, LONZA will prepare the Project Documentation for the applicable Process in accordance with the schedule set forth in the relevant Statement of Work and the Specifications, the LONZA Operating Documents and any written instructions provided by MODERNA (provided that LONZA shall be required to comply with such written instructions only if such instructions comply with cGMP requirements, data integrity specifications or commitments made by MODERNA to the applicable Regulatory Authorities). MODERNA will inform LONZA of any specific requirements MODERNA may have relating to the Project Documentation, including, without limitation, any information or procedures MODERNA wishes to have incorporated therein. The applicable Project Documentation, as set forth in the relevant Statement of Work, shall be completed and delivered by LONZA at completion of a Batch.

b. LONZA will not use or incorporate any non-commercially available materials, Technology, LONZA Technology or LONZA Improvements in connection with the performance of any Services or the

Process, unless such non-commercially available materials, Technology, LONZA Technology or LONZA Improvements are specifically agreed to by the Parties and identified in the relevant Statement of Work, including the applicable terms and conditions of the use or incorporation of such non-commercially available materials, Technology, LONZA Technology or LONZA Improvements. [***].

- c. As set forth in the relevant Statement of Work, MODERNA will cooperate with LONZA to assist LONZA to develop the Project Documentation and Process, including, without limitation, by providing LONZA with additional information and procedures as may be required to create the Project Documentation, Process, and/or any of the following: (a) manufacturing process information, SOPs, development reports, (b) quality control assays and related method validation reports, (c) raw material specifications (including vendor, grade and sampling/testing requirements), (d) Product and sample packing and shipping instructions, and (e) Product-specific cleaning and decontamination information.
 - d. LONZA will deliver a draft version of the applicable portions of the Project Documentation to MODERNA for its review and approval in accordance with the timeline set forth in the relevant Statement of Work. MODERNA will notify LONZA in writing of any objections it has to the draft Project Documentation, and upon such notification, representatives of LONZA and MODERNA will meet promptly in good faith to resolve such objections. LONZA will incorporate all reasonable comments from MODERNA in the Project Documentation. Upon MODERNA's written acceptance of the draft Project Documentation, such draft will be deemed approved by MODERNA. Any failure by MODERNA to accept in writing any agreed-upon Project Documentation within [***] of receipt will be promptly be escalated to the JSC.
 - e. The Process, Project Documentation, Specifications, and any improvements or modifications thereto developed during the Term, but excluding any LONZA Operating Documents, LONZA Technology, LONZA Improvements or LONZA Confidential Information included in any of the foregoing, will be deemed MODERNA Confidential Information and subject to the provisions set forth in Article 10.
 - f. For clarity, LONZA will use the LONZA Operating Documents in the Process or the Project Documentation, but LONZA represents and warrants that LONZA Operating Documents are not necessary for MODERNA or a Third Party contract manufacturer to Manufacture Product as it is assumed that MODERNA or a Third Party contract manufacturer would have its own operating documents and SOPs. LONZA shall make LONZA Operating Documents available to support MODERNA or its Third Party contract manufacturer [***].
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1. MODERNA EQUIPMENT.

a. Relevant Terms. Each Statement of Work shall include the terms and conditions applicable to the MODERNA Equipment to be used by LONZA to perform the Services set forth in such Statement of Work.

2. [INTENTIONALLY LEFT BLANK]

3. MANUFACTURE OF PRODUCT

a. MODERNA Materials. Within the time period agreed to in the relevant Statement of Work, MODERNA will ensure that LONZA is provided with the materials listed in such Statement of Work required to be supplied by MODERNA for the production of the Product, and any handling instructions, protocols, SOPs and other documentation necessary to maintain the properties of such materials for the performance of the Services (collectively, the “MODERNA Materials”). The MODERNA Materials are the Confidential Information of MODERNA and shall be used by LONZA solely for purposes of this Agreement and the relevant Statement of Work. MODERNA will promptly inform LONZA of any delays in providing MODERNA Materials that would prevent LONZA from performing the Services or in accordance with the timeline set forth in the relevant Statement of Work, and, in the event of any such delay, LONZA will use commercially reasonable efforts to accommodate any requests by MODERNA to adjust the timeline for the Services to compensate for such delay. LONZA shall ensure that the MODERNA Materials is secure and safe from loss, damage or misuse.

b. LONZA Materials. Except for the MODERNA Materials and as otherwise agreed in the relevant Statement of Work, LONZA shall supply, at its sole cost and expense and accordance with the relevant approved specifications, all materials in adequate quantities to be used by LONZA for the Manufacture of the Product and the performance of Services (“LONZA Supplied Materials”). The Parties agree that LONZA is responsible for the procurement of LONZA Supplied Materials, including with respect to transporting, testing, inspecting and storing the LONZA Supplied Materials; maintaining systems for management of LONZA Supplied Materials; and maintaining adequate supplies of LONZA Supplied Materials based on binding forecasts. LONZA shall not be responsible for raw material shortages or supplier delays outside of its control to the extent it diligently complied with its duties to procure and maintain adequate LONZA supplies Supplied Materials.

c. Commencement Date. Each Statement of Work governing the Manufacture of Product will include a Commencement Date agreed upon by the Parties. Subject to the terms of the relevant Statement of Work, LONZA will commence Manufacture of the Product on or before the Commencement Date.

d. Manufacture by LONZA. During the time period specified in the relevant Statement of Work, LONZA will Manufacture, package, ship, handle quality assurance and quality control for the Product exclusively at the applicable Facility, all as set forth in such Statement of Work, and will deliver to MODERNA the Product requested by MODERNA in such Statement of Work in accordance with the estimated timelines set forth in such Statement of Work, all in accordance with the terms set forth in Section 7.6 below. LONZA shall, at its own cost and expense, ensure that at all times the applicable Facility is in a qualified and validated state appropriate for inclusion as a Manufacturing site for the Products, as

required by the applicable Regulatory Authorities, Applicable Laws and the Specifications for the Products. Any costs or expenses related to bringing a Facility or any LONZA Equipment needed to Manufacture Products or to perform the Services into compliance with any applicable regulatory requirements of a Regulatory Authority at any time shall be borne exclusively by LONZA subject however to changes required solely based on the Products as well as change of Applicable Laws or cGMP requirements. Notwithstanding the foregoing, a Statement of Work may include terms and conditions relating to delays of the Commencement Date for a Product or other delays, including discounts, cancellation rights and other terms and conditions relating to any such delay.

- a. **Maintenance and Operation.** LONZA agrees to operate and maintain the Facilities and all LONZA Equipment used, directly or indirectly, to Manufacture Products, or, if applicable, to perform the Services, in accordance with the applicable Specifications and all Applicable Laws, as well as for the MODERNA Equipment in accordance with mutually agreed upon standards which are to be discussed based on MODERNA's maintenance standards, and to maintain the Facility and LONZA Equipment in an acceptable state of repair and operating efficiency.
 - b. **Qualification and Validation.** LONZA shall be responsible for validating the LONZA Equipment used for supply of Product or, if applicable, performance of the Services (including conducting installation, operational and performance qualification), and the production, cleaning and, to the extent applicable, packaging processes, as well as all other appropriate steps performed at the Facilities. All activities and procedures must: (i) meet applicable regulatory requirements; and (ii) be found acceptable by Regulatory Authority inspectors, if applicable. If any Regulatory Authority finds LONZA's validation procedures to be unacceptable, then LONZA will take (or have taken) appropriate remedial measures, including repeating the validation as necessary, such that the validation procedures meet all applicable regulatory requirements and guidelines, including those necessary to receive all Regulatory Authority approvals. If any of LONZA's validation procedures fail to comply with cGMP or the Specifications, LONZA shall promptly remedy such failure in order to comply with all cGMP and Specifications. Furthermore, LONZA shall also be responsible for validating the MODERNA Equipment under the terms set forth above when agreed upon in the relevant Statement of Work.
 - c. **Cancellation of a Statement of Work.** Each Statement of Work shall provide the termination or cancellation fees for such Statement of Work, if any (the "Cancellation Fees").
 - d. **Payment of Cancellation Fee and Costs.** Each Statement of Work shall provide the payment terms for any applicable Cancellation Fees.
 - e. **Packaging and Shipping.** LONZA will package and label the Product for shipment in accordance with the relevant Statement of Work, the Quality Agreement and any instructions provided in writing (e.g. storage and transport conditions). In no event will LONZA or its Affiliates ship, or be instructed to ship, to the United States any Product Manufactured at any Facility outside of the United States.
 - f. **Records.** LONZA will maintain complete and accurate records relating to the Services, the Manufacture of each Batch of the Product or the development of any Process, including as required by Applicable Laws (including cGMP, as applicable). LONZA will retain possession of the Project
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Documentation, LONZA Operating Documents and all other records, and will promptly provide copies of the Project Documentation and all other records other than the LONZA Operating Documents to MODERNA upon MODERNA's request and at MODERNA's expense; provided, however, that LONZA shall provide electronic copies thereof at MODERNA's request at no cost to MODERNA. [***]. LONZA shall not transfer, deliver or otherwise provide any Project Documentation or other records to any Third Party without the prior written approval of MODERNA. LONZA Operating Documents will remain LONZA Confidential Information. [***]. LONZA shall also provide such other information and assistance as MODERNA may reasonably request in connection with the completion of and submission of applications for Regulatory Approvals for Products and the maintenance thereof. MODERNA has the right to use and reference any of the foregoing, or any DMF covering the foregoing, in connection with any request from any Regulatory Authorities or with a regulatory filing or Regulatory Approval for the Product, to authorize release and final acceptance of Product or as otherwise authorized by the Agreement, including any Statement of Work. LONZA will, on written request by MODERNA or its Affiliate or Sublicensee, provide to the requesting party and to any specified Regulatory Authority a letter, in the form reasonably required by the requesting party, acknowledging that the requesting party has the foregoing right of reference.

- a. **MODERNA Access.**
 - i. Pursuant to and as set forth further in the applicable Statement of Work, [***] MODERNA's employees, consultants and agents (including its independent contractors or designees) (collectively, "**MODERNA Personnel**") in each Facility may participate in the Manufacture of the Product only in such capacities as set forth in the relevant Statement of Work or as may be approved in writing in advance by LONZA, such approval not to be unreasonably withheld, conditioned or delayed; provided, however, that, upon [***] prior written notice to LONZA, MODERNA Personnel shall have the right to be present at the Facility to observe the Manufacture of Product or performance
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of Services and for quality or technical reference purposes. MODERNA Personnel working at the Facility are required to comply with LONZA's Operating Documents and any other applicable LONZA cGMP or safety policies. LONZA shall make available office space to the MODERNA Personnel on-site at the applicable Facility, and shall also provide any reasonable and customary related office resources and support services for such on-site MODERNA Personnel. For the avoidance of doubt, unless otherwise agreed to by LONZA, following completion of technology transfer and stabilization of Manufacturing activities, MODERNA Personnel may not physically participate in the production or Manufacture of any Product that may be used in or on humans.

- i. MODERNA Personnel working at the Facility will be and remain employees, consultants or agents of MODERNA, and MODERNA will be solely responsible for the payment of compensation for such MODERNA Personnel (including applicable Federal, state and local withholding, FICA and other payroll taxes, workers' compensation insurance, health insurance, and other similar statutory and fringe benefits). MODERNA covenants and agrees to maintain workers' compensation benefits and employers' liability insurance as required by Applicable Laws with respect to all MODERNA Personnel working at the Facility.
 - ii. MODERNA will pay for the actual cost of repairing or replacing to its previous status (to the extent that LONZA determines, in its reasonable judgment, that repairs cannot be adequately effected) any property of LONZA damaged or destroyed by MODERNA Personnel, provided MODERNA shall not be liable for repair or replacement costs resulting from ordinary wear and tear.
 - iii. MODERNA Personnel visiting or having access to the Facility will abide by LONZA standard policies, operating procedures and the security procedures established by LONZA and provided to such MODERNA Personnel prior to any visits or access to the Facility. MODERNA will be liable for any breaches of security by MODERNA Personnel. In addition, MODERNA will reimburse LONZA for the cost of any lost security cards issued to MODERNA Personnel, at the rate of [***] per security card. All MODERNA Personnel will agree to abide by LONZA policies and SOPs established by LONZA, and will sign an appropriate confidentiality agreement.
 - iv. MODERNA will indemnify and hold harmless LONZA from and against any and all losses, damages, liabilities, costs and expenses (including reasonable attorneys' fees and expenses) arising out of any injuries suffered by MODERNA Personnel while at the Facility or elsewhere, except to the extent caused by the negligence, gross negligence or willful misconduct on the part of any LONZA Party or resulting from a breach of this Agreement, including any Statement of Work, by LONZA.
 - a. **LONZA Access.** If provided for in a Statement of Work, LONZA employees and agents ("**LONZA Personnel**") visiting or having access to any MODERNA facility will abide by MODERNA standard policies, operating procedures and the security procedures established by MODERNA and provided to such LONZA Personnel prior to any visits or access to such facility. LONZA will be liable for any breaches of security by LONZA Personnel. In addition, LONZA will reimburse MODERNA for the cost of any lost security cards issued to LONZA Personnel, at the rate of [***] per security card. All LONZA Personnel will agree to abide by MODERNA policies and SOPs established by MODERNA, and will sign an appropriate confidentiality agreement.
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a. **Disclaimers.** The LONZA Parties will not engage in any Product improvement, modification or refinement, or Manufacturing or development of the Product, other than as expressly set forth in this Agreement and each relevant Statement of Work. Except as set forth in a relevant Statement of Work, each Party acknowledges and agrees that the LONZA Parties have not participated in the invention or testing of any Product, and have not evaluated its safety or suitability for use in humans or otherwise.

1. **REGULATORY MATTERS**

a. **Permits and Approvals.** LONZA will ensure that any and all permits, licenses, registrations, and approvals required by Applicable Law have been obtained in connection with each Facility and LONZA Equipment used in connection with the Manufacture by or on behalf of LONZA hereunder. LONZA will maintain each Facility and the LONZA Equipment in a state of repair and operating efficiency consistent with industry standard practices and all Applicable Law. LONZA will only use disposal services or sites that have appropriate environmental permits and are in compliance with Applicable Law.

b. **Regulatory Approvals.** MODERNA shall own all Regulatory Approvals, permits, authorizations and certificates necessary for the use of Products. All DMFs for the Products will be filed in MODERNA's (or its designee's) name and will be owned by MODERNA (or its designee). LONZA shall assist MODERNA in the preparation of such regulatory filings, Regulatory Approvals, permits, authorizations and certificates necessary for the use of Products or DMFs, including providing such information and data, including CMC information and data, as may reasonably be requested by MODERNA, as further detailed in the relevant Statement of Work or as agreed by the Parties in writing. The DMF for the Facility shall be owned by LONZA.

c. **Inspections.**

i. Subject to the terms of the Quality Agreement with respect to Services and Product and upon not less than [***] prior written notice, or shorter period of time as may be reasonable given the circumstances, LONZA will permit MODERNA or its representatives or designees to inspect and audit the parts of the Facility where LONZA performs the Services, including the parts of the Facility where the Manufacture of the Product is carried out, and to review documents, operations, procedures, and records as they pertain to the Manufacture of Product or performance of any Services, in order to assess LONZA's compliance with Applicable Law (including cGMP, as applicable), this Agreement or any relevant Statement of Work, and to perform risk and loss control assessments to support MODERNA's insurance and self-insurance programs, and to discuss any related issues with LONZA's management personnel. Such audit shall not last for more than [***] (unless otherwise agreed by the Parties). MODERNA Personnel engaged in such inspection will abide by the terms and conditions set forth in Sections 7.11 and Article 10. As part of MODERNA's audit of a Facility, MODERNA's audit may include audit of any of LONZA's suppliers' (including suppliers of Materials) qualification procedures, risk assessments, audit reports or supplier questionnaires, and associated corrective actions; provided that in the event LONZA is prohibited from providing such supplier audit, at MODERNA's request, LONZA will provide an audit summary of a supplier containing all information necessary for MODERNA's regulatory filings with respect to the Product or confirmation that such an audit

has been performed. LONZA's quality assurance department shall cooperate with MODERNA, as necessary or useful, in any such inspection conducted pursuant to this Section 8.3.

i. In addition to the foregoing, MODERNA and/or its representatives shall have the right to perform "For Cause" audits as often as required at any time upon not less than [***] advance notice, or shorter period of time as may be reasonable given the circumstances, and during regular business hours. If a For Cause audit confirms that LONZA did not comply with its obligations in compliance with cGMP, this Agreement or any relevant Statement of Work, the audit shall not be charged by LONZA; in all other cases LONZA's standard hourly rates apply (not to exceed [***]). Notwithstanding the foregoing, a For Cause audit shall also be at no cost for MODERNA if it is MODERNA's sole audit in such Calendar Year.

ii. In addition to those audit rights of MODERNA under this Section 8.3, LONZA shall permit audits to be conducted by or on behalf of a bona fide actual or prospective Third Party collaborator or customer of MODERNA; provided that MODERNA (a) pays a fee of [***] to LONZA for each such audit; and (b) has one or more MODERNA employees accompany the representatives of such Third Party during such audit.

iii. In the event MODERNA identifies any deficiency with respect to LONZA's operations or activities related to or affecting the Services, Product or the Manufacture of Product or performance of any Services during any such inspection, audit, or review, MODERNA shall have the right to notify LONZA of such deficiency, and, in such case, (a) the Parties will discuss in good faith suitable approaches for correcting such observations, and (b) LONZA shall, within [***] from the date of receipt of such notice, deliver to MODERNA a corrective action plan, addressing each such deficiency (including timelines therefor). Upon acceptance of the corrective action plan by MODERNA (which acceptance shall not be unreasonably withheld), LONZA shall fully implement such corrective action plan to the reasonable satisfaction of MODERNA. MODERNA shall have the right to review all relevant documentation in connection with such deficiency and corrective action.

iv. LONZA shall ensure that its Affiliates involved in the Manufacture of Product (or any component thereof including Material suppliers) permit and afford MODERNA the same rights as set forth above, and LONZA shall use diligent efforts to procure for MODERNA similar rights with respect to any subcontractors involved in the Manufacture of Product on behalf of LONZA.

v. For clarity, any such inspection (or failure to inspect) shall not relieve LONZA of its obligation to comply with Applicable Laws and the provisions this Agreement, the relevant Statement of Work and the Quality Agreement and does not constitute a waiver of any right otherwise available to MODERNA. In addition, for critical raw material suppliers for Product, LONZA shall be required to audit each and MODERNA shall have the right to review the audit reports and findings and LONZA's procedures for auditing such suppliers; provided that in the event LONZA is prohibited from providing such reports, findings or procedures, at MODERNA's request, LONZA will provide confirmation that an audit took place and a summary of findings.

i. For each Facility, in addition to the audit rights above, MODERNA shall have the right to audit the Facility when such Facility is ready for and prior to initiation of cGMP Manufacturing for MODERNA hereunder.

a. **Notification of Regulatory Authority Action.** Each Party shall promptly notify the other Party of any notice such Party receives regarding any threatened or pending action by any Regulatory Authority regarding the Manufacture of Product, including any Regulatory Authority non-approval or regulatory action. Upon receipt of any such information, the Parties shall consult in an effort to arrive at a mutually acceptable procedure for taking appropriate action; provided, however, that nothing contained herein shall be construed as restricting the right of either Party to make a timely report of such matter to any Regulatory Authority or take other action that it deems to be appropriate or required by Applicable Law.

b. **Complaints.** LONZA shall immediately notify MODERNA of any complaints received by LONZA concerning a Product supplied hereunder. LONZA shall investigate complaints as requested by MODERNA and shall take corrective action to avoid future occurrences.

c. **Regulatory Authority Inspections.** LONZA shall advise MODERNA immediately (but in no event less than [***] prior to a pre-notified or scheduled visit or inspection) of any Regulatory Authority visit or inspection that relates to Product or the Manufacture thereof at any Facility, or any written or oral inquiries by such Regulatory Authority concerning Product (including safety and efficacy claims) or the Manufacture thereof at any Facility. LONZA will permit representatives of any Regulatory Authority to inspect and audit the parts of each Facility where LONZA performs the Services, including the parts of the Facility where the Manufacture of the Product is carried out, and to inspect or audit the Project Documentation, Batch Records or other records to verify compliance with cGMP and other Applicable Laws and will promptly notify MODERNA of the scheduling of any such inspection relating to the Services, including Manufacture of Product. MODERNA shall be permitted to be on site and available for questions regarding the Product during any such inspection or audit. LONZA shall promptly (and in no event later than [***) notify MODERNA of the results of any such inspection, and furnish MODERNA summaries of all reports, documents and correspondence with respect to any Regulatory Authority inquiries, visits or inspections, as well as a copy of each report, document and correspondence issued by or provided to any Regulatory Authority in connection with such request, visit or inquiry to the extent such documents relate to or affect the Services, Product or Manufacture of the Product. LONZA and MODERNA shall consult with one another in an effort to arrive at a mutually acceptable response to the extent related to Product, provided that if the Parties fail to timely arrive at a mutually acceptable response, LONZA shall not be required to delay or risk prejudice to LONZA's compliance with its legal requirements. Without limiting the foregoing, LONZA shall furnish to MODERNA, (a) within [***] after receipt, any report or correspondence issued by the Regulatory Authority in connection with such visit, inspection or inquiry, including any FDA Form 483, Establishment Inspection Report, or warning letter, and (b) copies of any and all responses or explanations to any Regulatory Authority relating to items set forth above prior to the submission of such responses or explanations to any Regulatory Authority by LONZA. LONZA shall comply with all reasonable requests and comments by MODERNA with respect to all responses or explanations to, or contacts and communications, with any Regulatory Authority relating in any way to the Products or Services, and shall immediately inform MODERNA in the event any Regulatory

Authority takes any regulatory action against LONZA that could have an effect on LONZA’s performance of the Services or the Manufacture of the Product.

a. **Recall; Withdrawal.** As may be further set forth in the Quality Agreement, in the event that either Party determines an event, incident or circumstance has occurred which may result in the need for a “recall”, “market withdrawal” or “field alert” of Product, as such terms are defined in the United States Code of Federal Regulations 21 CFR § 7.3 and 21 CFR§ 314, or other Applicable Law or regulation of a country (a “**Recall**”), such Party shall advise and consult with the other Party regarding such event. MODERNA shall be responsible for implementing and administering any Recall, in its sole discretion [***]. LONZA shall provide reasonable assistance to MODERNA in conducting a recall or withdrawal, including providing MODERNA with all reasonably pertinent records and information. If the parties dispute whether such Recall was primarily due to LONZA providing defective Product, then either party may seek the determination of whether the Product was defective Product in accordance with the relevant Statement of Work.

b. **Waste.** In connection with the Manufacture of Product hereunder or the performance of the Services, LONZA shall be solely responsible, at its cost and expense, for maintaining safety procedures in connection with the Manufacture of Product (or the performance of the Services, as applicable) and for the generation, treatment, storage and/or disposal of Waste relating thereto, all of which shall comply with all Applicable Law, including all applicable environmental and occupational safety and health requirements in the jurisdiction of the Facility.

1. FINANCIAL TERMS

- a. **Pricing.** [***].
- b. **Payments.** MODERNA will make payments to LONZA in the amounts and on the dates set forth in the relevant Statement of Work upon receipt of an invoice from LONZA.
- c. **Invoices and Pricing.** LONZA will charge for the Services in accordance with the price schedule in the relevant Statement of Work. LONZA will invoice MODERNA according to the schedule set forth in the relevant Statement of Work. LONZA will deliver invoices electronically by email, which shall be considered to be an original invoice. Invoices shall be e-mailed to
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[***], and/or to such other e-mail address(es) as MODERNA may stipulate from time to time. LONZA will not deliver a paper invoice. Payment of each invoice is due within [***] after MODERNA's receipt of such invoice. Unless otherwise provided in the relevant Statement of Work, all pricing excludes taxes and costs relating to shipping, validation and regulatory filings. The price shall be invoiced to MODERNA in U.S. Dollars or such other currency as agreed upon in the relevant Statement of Work.

a. Taxes. All amounts mentioned in this Agreement are exclusive of indirect taxes which, where applicable, will be paid by MODERNA on receipt of a valid indirect tax invoice. If MODERNA is required by law to deduct or withhold any taxes from any amount payable under this agreement, the amount payable hereunder shall be increased so that after making all required deductions and/or withholdings, LONZA receives an amount equal to the amount it would have received had no such deductions or withholdings been made. Notwithstanding anything to the contrary herein, if there should be any withholding tax imposed by the applicable jurisdictions on LONZA with respect to any payments to be made by MODERNA to LONZA under or in connection with this Agreement, MODERNA is allowed to deduct such withholding taxes from the payments to LONZA and pay such withholding taxes to the appropriate tax authorities on behalf of LONZA. Regarding the discharged withholding tax, MODERNA will submit to LONZA the corresponding original tax certificates or original tax receipts stamped by the receiving local tax authority within [***] after such withholding obligation is discharged. Notwithstanding the foregoing, upon presentation by LONZA to MODERNA of the relevant tax documentation indicating a reduction in or exemption from withholding tax for LONZA in such taxing jurisdiction pursuant to the provisions of the relevant double taxation treaty, MODERNA shall withhold such tax at the reduced rate (or not withhold any tax if there is an exemption) applicable to such payment in such taxing jurisdiction. .

b. Interest. Any undisputed fee, charge or other payment due to LONZA by MODERNA under this Agreement that is not paid within [***] after it is due will accrue interest on a daily basis at a rate of [***] (or the maximum legal interest rate allowed by applicable law, if less) from and [***] after MODERNA receives a notice from LONZA that such fee, charge or other payment has not been paid.

c. Method of Payment. Except as otherwise set forth in Section 9.2 or the relevant Statement of Work, all payments to LONZA hereunder by MODERNA will be in United States currency or such other currency agreed upon by the Parties in the relevant Statement of Work and will be by check, wire transfer, money order, or other method of payment approved by LONZA. Bank information for wire transfers will be provided in the relevant Statement of Work.

d. Cost Improvements. Promptly after a Product has been launched, LONZA will in good faith continuously seek to improve and reduce direct material costs, direct operating labor costs and indirect expenses attributable to the manufacture of the Product throughout the term of this Agreement and, at the request of MODERNA, provide MODERNA with written evidence demonstrating the efforts and activities undertaken by LONZA in furtherance thereof. LONZA and MODERNA agree to periodically, but not less than [***], review the cost of materials, labor, expenses and other matters

that influence the price MODERNA pays for the Product and determine whether any price decreases may be appropriate. Upon the request of MODERNA, LONZA will provide to MODERNA reasonable evidence of any and all improvements as they are achieved and of the availability of any potential improvements hereunder. LONZA agrees to reflect and incorporate into this Agreement achieved price reductions realized by LONZA after the effective date of such price change. MODERNA and LONZA will set specific key performance indicators defining timing and percent reduction for the manufacture of the Product ("KPIs") once a Product has been launched. KPIs may include, but are not limited to, manufacturing operations (including inventory reductions, process improvement, and lead-times), sourcing, international operations and logistics, and business practices. Progress of these goals will be reviewed periodically, but in any case no less than [***]. All savings achieved through these cost improvements by LONZA will be [***].

1. CONFIDENTIAL INFORMATION

a. **Definition.** "Confidential Information" means all technical, scientific and other know-how and information, trade secrets, knowledge, technology, means, methods, processes, practices, formulas, instructions, skills, techniques, procedures, specifications, data, results and other material, pre-clinical and clinical trial results, manufacturing procedures, test procedures and purification and isolation techniques, and any tangible embodiments of any of the foregoing, and any scientific, manufacturing, marketing and business plans, any financial and personnel matters relating to a Party or its present or future products, sales, suppliers, customers, employees, investors or business, that has been disclosed by or on behalf of such Party or such Party's Affiliates to the other Party or the other Party's Affiliates either in connection with the discussions and negotiations pertaining to this Agreement or in the course of performing this Agreement. Without limiting the foregoing, (a) the terms of this Agreement as well as all information pertaining to the relationship between the Parties will be deemed "Confidential Information" of both Parties, and as such both Parties will be treated as the receiving Party, (b) the Products, all MODERNA Technology, MODERNA Manufacturing Know-How, MODERNA Improvements, MODERNA Equipment, MODERNA Materials, Project Documentation, Specifications, all Regulatory Approvals for the Products and all DMFs for the Products are Confidential Information of MODERNA, (c) all LONZA Technology, LONZA Operating Documents and LONZA Improvements are Confidential Information of LONZA, and, in each case, will be subject to the terms and conditions set forth in this Article 10 (except to the extent necessary for MODERNA to exercise its rights or obligations under this Agreement, including any relevant Statement of Work, including in connection with the licenses granted by LONZA to MODERNA in Section 11.2).

b. **Exclusions.** Notwithstanding the foregoing Section 10.1, any information disclosed by a Party to the other Party will not be deemed "Confidential Information" of the disclosing Party to the extent that such information:

- (a) at the time of disclosure is in the public domain;
- (b) becomes part of the public domain, by publication or otherwise, through no fault of the receiving Party or its Affiliates;

- a. at the time of disclosure is already in possession of the receiving Party or its Affiliates on a non-confidential basis, as established by contemporaneous written records;
- b. is lawfully provided to a Party, without restriction as to confidentiality or use, by a Third Party lawfully entitled to possession of such Confidential Information; or
- c. is independently developed by a Party without use of, reliance upon or reference to the other Party's Confidential Information, as established by contemporaneous written records.

a. Disclosure and Use Restriction. Except as expressly provided herein, the Parties agree that for the Term and the ten (10)-year period following any expiration or termination of the Agreement, each Party and its Affiliates will keep completely confidential and will not publish or otherwise disclose any Confidential Information of the other Party, its Affiliates or sublicensees, except in accordance with Section 10.4; provided, however, that the obligations under Section 10.5 with respect to MODERNA Manufacturing Know-How or any other trade secret information in the MODERNA Confidential Information or LONZA Confidential Information will survive in perpetuity. Neither Party will use Confidential Information of the other Party except as necessary to perform its obligations, or in the case of MODERNA to exercise its rights, under this Agreement.

b. Permitted Disclosures. Subject to Section 10.5, each receiving Party agrees to (i) institute and maintain security procedures to identify and account for all copies of Confidential Information of the disclosing Party and (ii) limit disclosure of the disclosing Party's Confidential Information to its Affiliates and each of its and their respective officers, directors, employees, agents, consultants and independent contractors having a need to know such Confidential Information for purposes of this Agreement, including, with respect to MODERNA, to subcontractors and other Third Parties as necessary or reasonably useful for the purpose of performing MODERNA's obligations or exercising its rights hereunder in filing or requesting Regulatory Approvals or communications with Regulatory Authorities as set forth in Section 7.10; provided that such Affiliates and each of its and their respective officers, directors, employees, agents, consultants and independent contractors are informed of the terms of this Agreement and are subject to obligations of confidentiality, non-disclosure and non-use similar to those set forth herein. Notwithstanding the foregoing, (a) such Confidential Information may be disclosed to (1) actual (sub)licensees, collaborators or partners, and its and their directors, officers, employees, agents or advisors (including accountants, attorneys, consultants, bankers, financial advisors and members of advisory boards), or (2) any bona fide potential or actual financing sources, investors, underwriters or acquisition partners (including attorneys, accountants, consultants, bankers or financial advisors of the foregoing), in each case ((1)-(2)) who reasonably require such information, who are informed of the confidential nature of such information and are bound by non-use and confidentiality obligations with respect to such information (which may include, solely with respect to attorneys and accountants, professional ethical obligations); and [***].

a. MODERNA Manufacturing Know-How. Notwithstanding anything herein to the contrary, the Parties recognize that maintaining the confidentiality and trade secret nature of the MODERNA Manufacturing Know-How requires an even higher level of vigilance than other Confidential Information. LONZA shall: (i) maintain MODERNA Manufacturing Know-How in confidence with the same degree of care with which LONZA holds its own like confidential manufacturing information, (ii) disclose the MODERNA Manufacturing Know-How only to those employees of LONZA or its Affiliates who have a need to know such MODERNA Manufacturing Know-How to conduct activities for the Products under this Agreement, including any relevant Statement of Work, and (iii) use the MODERNA Manufacturing Know- How only for Manufacturing and supplying the applicable Product under the relevant Statement of Work and for no other purpose. LONZA will apply appropriate firewall protections and safeguards for all MODERNA Manufacturing Know-How to prevent the MODERNA Manufacturing Know-How from being disclosed, transferred or used to or by any LONZA personnel that are not conducting activities relating to the Products under the relevant Statement of Work. LONZA will not disclose, transfer or use any MODERNA Manufacturing Know-How to any Third Party without the prior written consent of MODERNA, which consent will be at MODERNA's sole discretion. For clarity, Section 10.4 will not apply to any MODERNA Manufacturing Know-How.

b. Government-Required Disclosure. If a duly constituted Governmental Authority, court or Regulatory Authority orders that a Party hereto disclose information subject to an obligation of confidentiality under this Agreement, such Party shall comply with the order, but shall notify the other Party as soon as possible, so as to provide the other Party a reasonable opportunity to apply to a court of record for relief from the order or for confidential treatment thereof, and thereafter such Party shall disclose only the minimum information required to be disclosed in order to comply.

c. Publicity.

i. Neither Party will refer to, display or use the other's name, trademarks or trade names confusingly similar thereto, alone or in conjunction with any other words or names, in any manner or connection whatsoever, including any publication, article, or any form of advertising or publicity, except with the prior written consent of the other Party or as otherwise set forth in this Section 10.7.

ii. Neither Party may issue any press release or make any other public announcement or statement concerning this Agreement, the transactions contemplated hereby or the terms hereof, without the prior written approval of the other Party, except as may be required by Applicable Law. In the event either Party (the "**Issuing Party**") desires to issue a press release or other public statement disclosing information relating to this Agreement, the transactions contemplated hereby or the terms hereof, the Issuing Party will provide the other Party (the "**Reviewing Party**") with a copy of the proposed press release or public statement (the "**Release**") and seek the Reviewing Party's prior written consent; provided that no such consent shall be required for press releases or other public statements required by Applicable Law (but the Issuing Party shall still provide the Reviewing Party with a copy of the Release for comment in accordance with this Section 10.7). The Issuing Party will specify with each such Release, taking into account the urgency of the matter being disclosed, a reasonable period of time within which the Reviewing Party may provide any comments on such Release and if the Reviewing Party fails to provide any comments during the response period called for by the Issuing Party, the Reviewing Party will be deemed to have not consented to the issuance of such Release. If the Reviewing

Party provides any comments, the Parties will consult on such Release and work in good faith to prepare a mutually acceptable Release. Either Party may subsequently publicly disclose any information previously contained in any Release so consented to.

i. Notwithstanding Section 10.7.2 or anything herein to the contrary, MODERNA’s obligation to submit any press release or other public announcement or statement concerning this Agreement to LONZA for prior written approval will not apply to any press release or other public announcement or statement regarding the achievement of any milestone identified in a Statement of Work, including regarding Process or Product development, Technology Transfer, or Process or Product Manufacture.

a. **Securities Filings; Law.** Each Party acknowledges and agrees that the other Party may submit this Agreement to the United States Securities and Exchange Commission (the “SEC”) or any other securities exchange and if a Party does submit this Agreement to the SEC or any other securities exchange, such Party agrees to consult with the other Party with respect to the preparation and submission of, a confidential treatment request for this Agreement. If a Party is required by Applicable Law to make a disclosure of the terms of this Agreement in a filing with or other submission to the SEC or any other securities exchange or otherwise to comply with Applicable Law, and (i) such Party has provided copies of the disclosure to the other Party as far in advance of such filing or other disclosure as is reasonably practicable under the circumstances, (ii) such Party has promptly notified the other Party in writing of such requirement and any respective timing constraints, and (iii) such Party has given the other Party a reasonable amount of time under the circumstances from the date of notice by such Party of the required disclosure to comment upon, request confidential treatment or approve such disclosure, then such Party will have the right to make such public disclosure at the time and in the manner reasonably determined by its counsel to be required by Applicable Law. Notwithstanding anything to the contrary herein, it is hereby understood and agreed that if a Party is seeking to make a disclosure as set forth in this Section 10.8, and the other Party provides comments within the respective time periods or constraints specified herein or within the respective notice, the Party seeking to make such disclosure or its counsel, as the case may be, will in good faith consider incorporating such comments.

1. INTELLECTUAL PROPERTY

a. Ownership.

i. Except as expressly otherwise provided herein, neither Party will, as a result of this Agreement, acquire any right, title, or interest in any Technology of the other Party. Except as expressly otherwise provided herein, ownership of any Technology that is developed, conceived, invented, first reduced to practice or made in connection with the performance under this Agreement shall follow inventorship all as determined under Applicable Laws.

ii. Subject to LONZA’s right, title and interest in and to any and all LONZA Improvements, MODERNA shall own all right, title, and interest in and to any and all MODERNA Improvements. LONZA hereby assigns to MODERNA (or its designee), without additional compensation, all of LONZA’s right, title and interest in and to such MODERNA Improvements. LONZA shall promptly disclose to MODERNA in writing all MODERNA Improvements. LONZA shall execute, and shall require its

personnel as well as its Affiliates, or other contractors or agents and their personnel involved in the performance of this Agreement to execute, any documents reasonably required to confirm MODERNA's ownership of MODERNA Improvements, and any documents required to apply for, maintain and enforce any patent or other right in the MODERNA Improvements. Notwithstanding the foregoing, and subject to the license granted in Section 11.2.2, LONZA shall own all right, title and interest in and to any and all LONZA Improvements.

- a. **License Grants.**
 - i. During the Term, MODERNA hereby grants to LONZA a fully paid-up, non- exclusive license, without the right to grant sublicenses, under any and all MODERNA Technology, MODERNA Manufacturing Know-How, and MODERNA Improvements that are necessary for LONZA to perform its obligations under this Agreement for the sole and limited purpose of LONZA's performance of its obligations under this Agreement and the relevant Statements of Work, including, without limitation, the development of the Process (if and to the extent applicable in the relevant Statements of Work) and the Manufacture of Product for MODERNA as set forth in the relevant Statements of Work. Except as set forth in this Section 11.2.1, Lonza shall not by virtue of this Agreement acquire any right, license or title in or to any MODERNA Technology, MODERNA Manufacturing Know-How, MODERNA Improvements, Products or Process.
 - ii. LONZA hereby grants to MODERNA a non-exclusive, world-wide, fully paid-up, perpetual, transferable (subject to the assignment provisions) license, including the right to grant sublicenses, under the LONZA Technology and LONZA Improvements, to use, sell, offer to sell, import and export the Product Manufactured under this Agreement, including any Statement of Work. In the event and to the extent that the Services or the Process incorporates, uses or contains non-commercially available LONZA Technology or LONZA Improvements that are not specifically agreed to by MODERNA in the relevant Statement of Work and that would be necessary for MODERNA or a Third Party contract manufacturer to Manufacture Products or would otherwise require MODERNA to obtain a license to the non-commercially available LONZA Technology or LONZA Improvements , LONZA hereby grants to MODERNA and its Affiliates a non-exclusive, worldwide, fully paid-up, perpetual, irrevocable, transferable license (subject to the assignment provisions), including the right to grant sublicenses, under such non- commercially available LONZA Technology or LONZA Improvements that are incorporated, used or contained in the Services or Process to Manufacture (or have Manufactured) Products (but no other products). For clarity LONZA will use its operating documents and standard operating procedures ("LONZA Operating Documents") in performing the Services but LONZA Operating Documents are not necessary for MODERNA or a third party contract manufacturer to manufacture Product as it is assumed that MODERNA or a third party contract manufacturer would have its own operating documents and standard operating procedures. LONZA Operating Documents will not be provided in a technology transfer to MODERNA or a third party contract manufacturer for manufacturing Product.
 - b. **Further Assurances.** Each Party agrees to take all necessary and proper acts, and will cause its employees, Affiliates, contractors, and consultants to take such necessary and proper acts, to effectuate the ownership provisions set forth in this Article 11.
 - c. **Prosecution of Patents.**
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- i. LONZA will have the sole right and discretion to file, prosecute and maintain patent applications and patents claiming LONZA Technology or LONZA Improvements at LONZA’s expense.
- ii. MODERNA will have the sole right and discretion to file, prosecute and maintain patent applications and patents claiming MODERNA Technology or MODERNA Improvements at MODERNA’s expense. LONZA will cooperate with MODERNA to file, prosecute and maintain patent applications and patents claiming MODERNA Technology or MODERNA Improvements.

1. EXCLUSIVITY [***]

- a. LONZA. LONZA and its Affiliates will not, during the applicable Exclusivity Term, [***].
- b. MODERNA. MODERNA and its Affiliates agree that, during the applicable Exclusivity Term, [***]. For clarity, the foregoing exclusivity shall not preclude MODERNA or its Affiliates from: [***].

12.3 [***]

2. REPRESENTATIONS, WARRANTIES AND COVENANTS

a. By MODERNA. MODERNA hereby represents and warrants to LONZA as of the Effective Date that, to the best of its knowledge, ((a)) it has the requisite intellectual property related to the MODERNA Technology and MODERNA Manufacturing Know-How to enable the performance of LONZA’s obligations under this Agreement, and ((b)) the performance of the Services and the production by LONZA of the Product as contemplated in this Agreement will not infringe the intellectual property rights of any Third Party. Such representation and warranty will not apply to any LONZA Equipment to the extent that such LONZA Equipment is the sole basis for the infringement of the intellectual property rights of a Third Party.

b. By LONZA.

- i. LONZA hereby represents and warrants to MODERNA that, to the best of its knowledge, as of the Effective Date ((a)) it or its Affiliates have the requisite intellectual property rights in LONZA Equipment and Facility and the LONZA Technology to be able to perform its obligations under this Agreement, and ((b)) that LONZA’s or its Affiliates’ use of the LONZA Equipment, Facility and the LONZA Technology as contemplated in this Agreement and independent of any infringement caused solely by the use of such LONZA Equipment, Facility and the LONZA Technology in combination with the MODERNA Technology, MODERNA Manufacturing Know-How and Product, will not infringe the intellectual property rights of any Third Party.
- ii. LONZA further represents and warrants that it has not and will not to its knowledge use in any capacity in connection with this Agreement the services of any individual, corporation, partnership, or association which has been debarred, excluded, or disqualified by the FDA or any other applicable Regulatory Authority. In the event that LONZA receives notice of the debarment or

threatened debarment, exclusion or disqualification or threatened disqualification, of any individual, corporation, partnership or association providing services to LONZA, which relate to its activities under this Agreement, including any Statement of Work, LONZA shall notify MODERNA in writing as soon as practicable.

i. LONZA represents, warrants and covenants that, save for security interests expressly given in favor of MODERNA or its Affiliates, it will have good and marketable title, free and clear of any pledge, lien, restriction, claim, charge, security interest and/or other encumbrance, to all Product to be delivered under this Agreement (including any Statement of Work), and all Product supplied to MODERNA shall be free and clear of all pledges, liens, restrictions, claims, charges, security interests and/or other encumbrances at the time of delivery.

1. **DISCLAIMER; LIMITATION OF LIABILITY**

a. **DISCLAIMER.** EXCEPT FOR THE EXPRESS REPRESENTATIONS AND WARRANTIES SET FORTH IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATIONS OR GRANTS ANY WARRANTIES, EXPRESS OR IMPLIED, EITHER IN FACT OR BY OPERATION OF LAW, BY STATUTE OR OTHERWISE, WITH RESPECT TO THE PRODUCTS, MATERIALS, AND SERVICES PROVIDED UNDER THIS AGREEMENT, AND EACH PARTY SPECIFICALLY DISCLAIMS ANY OTHER WARRANTIES, WHETHER WRITTEN OR ORAL, OR EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF QUALITY, MERCHANTABILITY OR FITNESS FOR A PARTICULAR USE OR PURPOSE WITH RESPECT TO SUCH PRODUCTS, MATERIALS, OR SERVICES.

b. **Disclaimer of Consequential Damages.** EXCEPT [***], IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER OR ANY OF ITS AFFILIATES FOR ANY CONSEQUENTIAL, INCIDENTAL, INDIRECT, SPECIAL, PUNITIVE OR EXEMPLARY DAMAGES (INCLUDING, WITHOUT LIMITATION, LOST PROFITS, BUSINESS OR GOODWILL) SUFFERED OR INCURRED BY SUCH OTHER PARTY OR ITS AFFILIATES IN CONNECTION WITH THIS AGREEMENT, EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

c. **Limitation of Liability.** BOTH PARTIES HEREBY AGREE THAT TO THE FULLEST EXTENT PERMITTED BY LAW, EACH PARTY’S LIABILITY TO THE OTHER PARTY, FOR ANY AND ALL INJURIES, CLAIMS, LOSSES, EXPENSES, OR DAMAGES, WHATSOEVER, ARISING OUT OF OR IN ANY WAY RELATED TO THIS AGREEMENT FROM ANY CAUSE OR CAUSES, INCLUDING, BUT NOT LIMITED TO, NEGLIGENCE, ERRORS, OMISSIONS OR STRICT LIABILITY, SHALL NOT EXCEED [***]. TO THE EXTENT THAT THIS CLAUSE CONFLICTS WITH ANY OTHER CLAUSE, THIS CLAUSE SHALL TAKE PRECEDENCE OVER SUCH CONFLICTING CLAUSE. IF APPLICABLE LAW PREVENTS ENFORCEMENT OF THIS CLAUSE, THEN THIS CLAUSE SHALL BE DEEMED

MODIFIED TO PROVIDE THE MAXIMUM PROTECTION FOR LONZA AS IS ALLOWABLE UNDER APPLICABLE LAW.

1. TERM AND TERMINATION

a. **Term.** The term of this Agreement will commence on the Effective Date and will continue until the tenth (10th) anniversary of the Effective Date unless terminated prior to that time or extended by the Parties (the “**Initial Term**”). This Agreement will automatically renew for successive additional periods of two (2) years (collectively with the Initial Term, the “**Term**”) unless MODERNA provides written notice to LONZA at least [***] prior to the end of the then-current Term that it declines to extend the Term. The term of each SOW shall be set forth in such SOW.

b. **Termination for Material Breach.** Either Party may terminate this Agreement, by written notice to the other Party, for any material breach of this Agreement by the other Party, if such breach is not cured within [***] after the breaching Party receives written notice of such breach from the non-breaching Party; provided, however, that if such breach is not capable of being cured within such thirty-day period and the breaching Party has commenced and diligently continued actions to cure such breach within such thirty-day period, except in the case of a payment default, the cure period shall be extended to 90 days, so long as the breaching Party is making diligent efforts to do so. Such termination shall be effective upon expiration of such cure period; provided that in the event that the breaching Party disputes in good faith the non-breaching Party’s grounds for terminating this Agreement pursuant to this Section 15.2, then the Parties shall refer such dispute for resolution in accordance with Section 18.14, and the provisions therein shall apply. To the extent any material breach by a Party relates specifically to an SOW, the non-breaching Party may elect to have the termination rights set forth in this Section 15.2 apply to just such SOW, rather than to this Agreement generally.

c. **Termination Without Cause.** MODERNA may terminate any SOW by providing written notice of termination no less than [***] in advance of the date of termination. For the avoidance of doubt, in the event of termination of any SOW by MODERNA under this Section 15.3, MODERNA shall remain liable for all fees owed pursuant to such Statement of Work.

d. **Termination by Insolvency.** Either Party may terminate this Agreement upon notice to the other Party, upon (a) the dissolution, termination of existence, liquidation or business failure of the other Party; (b) the appointment of a custodian or receiver for the other Party who has not been terminated or dismissed within [***] of such appointment; (c) the institution by the other Party of any proceeding under national, federal or state bankruptcy, reorganization, receivership or other similar laws affecting the rights of creditors generally or the making by such Party of a composition or any assignment for the benefit of creditors under any national, federal or state bankruptcy, reorganization, receivership or other similar law affecting the rights of creditors generally, which proceeding is not dismissed within [***] of filing. All rights and licenses granted pursuant to this Agreement are, and shall otherwise be deemed to be, for purposes of Section 365(n) of Title 11 of the United States Code, licenses of rights of “intellectual property” as defined therein.

e. **Effects of Termination.**

i. **Accrued Rights.** Termination of this Agreement or any SOW for any reason will be without prejudice to any rights that will have accrued to the benefit of a Party prior to such termination. Such termination will not relieve a Party of obligations that are expressly indicated to survive the termination of this Agreement or such SOW. Without limitation of the foregoing, in the event of termination of this Agreement or an SOW, LONZA shall be compensated for any Cancellation Fees (if any) in accordance with the relevant Statements of Work. In the case of termination by LONZA for MODERNA's material breach in accordance with Section 15.2, all scheduled Services and Batches shall be deemed cancelled by MODERNA, and Cancellation Fees set forth in the relevant Statements of Work shall be calculated as of the date of written notice of termination.

ii. **Disposition of Remaining MODERNA Property and Confidential Information.** Upon termination or expiration of this Agreement, LONZA will, at MODERNA's option, return or destroy any MODERNA Confidential Information in the possession or control of LONZA. Likewise, MODERNA will, at LONZA's option, return or destroy any LONZA Confidential Information in the possession or control of MODERNA. Notwithstanding the foregoing provisions: (i) LONZA may retain and preserve, in a secure manner, at its sole cost and expense, samples and standards of each Product following termination or expiration of this Agreement as required by Applicable Law solely for use in determining LONZA's rights and obligations hereunder; (ii) MODERNA may retain and preserve, in a secure manner, any LONZA Confidential Information following termination or expiration of this Agreement (A) for use in determining MODERNA's rights and obligations hereunder, (B) as necessary, in connection with MODERNA's regulatory filings or Regulatory Approvals, or (C) as required by Applicable Law and (iii) each Party may retain a single copy of the other Party's Confidential Information for documentation purposes only and which shall remain subject to the obligations of nonuse and confidentiality set forth in this Agreement.

15.5.3 Survival. Sections 1, 4.2, 4.5, 4.6, 5.1, 7.8, 7.10, 7.13, 8.2, 8.4, 8.5, 8.6, 8.7, 9.4, 9.5, 9.6, 10, 11, 13, 14, 15, 16, 17.1 and 18 of this Agreement, together with any appendices referenced therein, will survive any expiration or termination of this Agreement.

1. INDEMNIFICATION; INSURANCE

a. **Indemnification of MODERNA.** LONZA will indemnify MODERNA, its Affiliates, and their respective directors, officers, employees and agents, and defend and hold each of them harmless, from and against any and all losses, damages, liabilities, costs and expenses (including reasonable attorneys' fees and expenses) in connection with any and all actual or alleged liability suits, investigations, claims or demands (collectively, "**Losses**") to the extent such Losses arise out of or result from any claim, lawsuit or other action or threat by a Third Party arising out of: [***].

b. **Indemnification of LONZA.** MODERNA will indemnify LONZA and its Affiliates, and their respective directors, officers, employees and agents (the "**LONZA Parties**"), and defend and hold each of them harmless, from and against any and all Losses to the extent such Losses arise out of or result from

any claim, lawsuit or other action or threat by a Third Party arising out of: [***].

a. Indemnification Procedure.

- i. An “**Indemnitor**” means the indemnifying Party. An “**Indemnitee**” means the indemnified Party, its Affiliates, and their respective directors, officers, employees and agents.
 - ii. An Indemnitee which intends to claim indemnification under Section 16.1 or Section 16.2 hereof shall promptly notify the Indemnitor in writing of any claim, lawsuit or other action in respect of which the Indemnitee, its Affiliates, or any of their respective directors, officers, employees and agents intend to claim such indemnification. The Indemnitee shall permit, and shall cause its Affiliates and their respective directors, officers, employees and agents to permit, the Indemnitor, at its discretion, to settle any such claim, lawsuit or other action and agrees to the complete control of such defense or settlement by the Indemnitor; provided, however, that in order for the Indemnitor to exercise such rights, such settlement shall not adversely affect the Indemnitee’s rights under this Agreement or impose any obligations on the Indemnitee in addition to those set forth herein. No such claim, lawsuit or other action shall be settled without the prior written consent of the Indemnitor and the Indemnitor shall not be responsible for any legal fees or other costs incurred other than as provided herein. The Indemnitee, its Affiliates and their respective directors, officers, employees and agents shall cooperate fully with the Indemnitor and its legal representatives in the investigation and defense of any claim, lawsuit or other action covered by this indemnification, all at the reasonable expense of the Indemnitor. The Indemnitee shall have the right, but not the obligation, to be represented by counsel of its own selection and expense.
- b. Insurance.** Each Party shall, during the term and for [***] after the expiration of the last Product delivered under this Agreement (including any Statement of Work), obtain and maintain, at its own cost and expense and from a qualified insurance company, comprehensive general liability insurance including, but not limited to, contractual liability coverage and standard product liability coverage in an amount commensurate with industry standards. These insurance requirements are not intended to limit a party’s indemnification obligations hereunder. Coverage types and limits shall be global for occurrences and claims made and shall include: (a) Commercial General Liability insurance, including contractual liability and products/completed operations coverage – limits of [***]; (b) Workers Compensation/Employers Liability – statutory with minimum Employers Liability limit of [***]; (c) Commercial Umbrella Liability - [***]; and (d) Network Security/Cyber Liability - [***]. Each Party will provide the other Party with at least [***] written notice prior to termination or amendment of such any applicable insurance policy.
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1. ADDITIONAL COVENANTS

a. **Non-Solicitation.** Each Party will agree not to solicit for employment (or for use as an independent contractor) employees of the other Party during the Term and for a period of [***] thereafter; provided that nothing herein will prevent the employment by a Party of individuals who initiate contact with such Party, and such Party will not be in violation of the non-solicitation restriction as a result of making a general solicitation for employees or independent contractors or employing individuals who respond to such solicitations. For the avoidance of doubt, the publication of an advertisement will not constitute solicitation or inducement.

b. **Business Continuity Plan.** LONZA acknowledges the importance to MODERNA of an uninterrupted supply of Products. Based on the information available at the Effective Date, LONZA has, and reasonably expects that despite the COVID-19 Pandemic it will continue to have the available capacity and staff designated "essential workers" under Applicable Laws to perform Services and Manufacture and supply Product under this Agreement. Further, LONZA has a formal business continuity plan detailing LONZA's plans, procedures and designated resources for timely response to and recovery from potential civil, natural, and physical plant disasters that could reasonably be expected to disrupt LONZA's performance of services, including Services under this Agreement, and additional plans covering potential disruption that might arise in connection with the COVID-19 Pandemic ("**Business Continuity Plans**"). During the Term, LONZA will promptly notify MODERNA in writing of any potential disruption to the performance of the Services or the Manufacturing and supply of the Products.

c. **Anti-Corruption and Trade Compliance.**

i. Each party to this Agreement warrants that none of its employees, agents, officers or other members of its management are officials, officers, agents, or representatives of any government or international public organization. Each party to this Agreement further agrees that it shall not make any payment, either directly or indirectly through agents or otherwise, of money, assets, or anything of value, including the compensation derived from this Agreement, to government or political party officials, officials of international public organizations, candidates for public office, or representatives of other businesses or persons acting on behalf of any of the foregoing where such payment would constitute a violation of any Applicable Laws, whether by LONZA, MODERNA, or any other party.

ii. Each Party to this Agreement shall comply with all applicable laws relating to the import, export, reexport, and transfer of items and technologies subject to the Scope of Work of this Agreement, including without limitation the U.S. Export Administration Regulations of the Bureau of Industry and Security of the U.S. Department of Commerce, the U.S. economic sanctions administered by the U.S. Department of the Treasury's Office of Foreign Assets Control ("**OFAC**"), the import and customs laws of the United States, and all trade laws of any other Governmental Authority of competent jurisdiction.

iii. None of the Parties to this Agreement, including their respective Affiliates, nor any Person or entity acting on behalf of any of the foregoing, (a) is currently the subject or the target of any Sanctions, (b) is located, organized or resident in a country, territory or geographical region that is

itself the subject of Sanctions (including, without limitation, Cuba, Iran, North Korea, Sudan, Syria, and the Crimea region of Ukraine) or whose government is the subject or target of Sanctions, (c) is named in any Sanctions-related list maintained by the U.S. Department of State, the U.S. Department of Commerce, or the U.S. Department of the Treasury, including but not limited to the Specially Designated Nationals and Blocked Persons List maintained by OFAC and the Denied Persons, Entity, and Unverified Lists maintained by the Bureau of Industry and Security, (d) is, otherwise, by public designation of the United Nations Security Council, the European Union, Her Majesty's Treasury, or other equivalent, applicable Governmental Authority, the subject or target of any Sanctions, (e) is a Person with which any United States person is prohibited from dealing or otherwise engaging in any transaction by any applicable law or regulation, (f) is owned or controlled by Persons described in clauses (a) through (e) or is otherwise the subject of Sanctions, or (g) conducts any business or engages in, or has conducted any business or engaged in, making or receiving any contribution of goods, services or money to or for the benefit of any Person, or in any country or territory that is the subject of Sanctions, other than in compliance with Sanctions laws and regulations. "Sanctions" means any economic or financial sanctions or trade embargoes imposed, administered or enforced from time to time by any United States Governmental Authority (including but not limited to OFAC), the United Nations Security Council, the European Union, Her Majesty's Treasury, or other Governmental Authority of competent jurisdiction.

- i. None of the materials (including Products) to be supplied under this Agreement originated, in whole or in part, in Cuba, Iran, North Korea, Sudan, Syria, or the Crimea region of Ukraine.
- ii. None of the Parties to this Agreement nor their respective officers, directors, employees, or agents are or have been the subject of any actual or threatened allegation, investigation, voluntary disclosure, investigation, prosecution or other enforcement action related to Sanctions, the U.S. Foreign Corrupt Practices Act of 1977, as amended, or any other sanctions, trade, or anti-corruption laws.
- iii. All Parties to this Agreement have developed and maintain in effect policies and procedures specifically designed to achieve compliance with the requirements of this Section 17.4, including compliance by their respective authorized agents and other Third Parties acting on their behalf. In construing the compliance obligations under U.S. law with regard to the scope of this Agreement, each Party shall regard itself as a United States person. The Parties to this Agreement shall undertake to cooperate in good faith, to the extent permitted by law and in accordance with applicable legal privilege in connection with any investigation, by a party to this Agreement or any Governmental Authority, relating to compliance with this Section 17.4.

I. MISCELLANEOUS

- a. **Independent Contractors.** Each of the Parties is an independent contractor and nothing herein contained shall be deemed to create or constitute the relationship of partners, joint venturers, co- partners, employer/employee, nor of principal and agent between the Parties. Neither Party shall at any time enter into, incur, or hold itself out as having authority to enter into or incur, on behalf of the other Party, any commitment, expense, or liability whatsoever.
 - b. **Force Majeure.** Neither Party shall be in breach of this Agreement if there is any failure of performance under this Agreement (except for payment of any amounts due under this Agreement)
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occasioned by any reason beyond the reasonable control that is not reasonably foreseeable or avoidance and without the fault or negligence of the Party affected thereby, including, without limitation, an act of God, fire, flood, act of government or state, war, civil commotion, insurrection, acts of terrorism, embargo, sabotage, prevention from or hindrance in obtaining energy or other utilities, labor disputes of whatever nature, or any other reason beyond the reasonable control that is not reasonably foreseeable or avoidable and without the fault or negligence of the Party affected thereby (a “**Force Majeure Event**”). Such excuse shall continue as long as the Force Majeure Event continues. Upon cessation of such Force Majeure Event, the affected Party shall promptly resume performance under this Agreement as soon as it is commercially reasonable for the Party to do so. Each Party agrees to give the other Party prompt written notice of the occurrence of any Force Majeure Event, the nature thereof, and the extent to which the affected Party will be unable to fully perform its obligations under this Agreement. Each Party further agrees to use diligent efforts to mitigate the effect of such Force Majeure Event as quickly as practicable (provided that in no event shall a Party be required to settle any labor dispute) and to give the other Party prompt written notice when it is again fully able to perform such obligations. If the failure to perform due to such Force Majeure Event continues for a period of [***] or more, then the unaffected Party may terminate this Agreement.

- a. [intentionally left blank]
- b. **Notices.** Any notice required or permitted to be given under this Agreement by any Party shall be in writing and shall be (a) delivered personally, (b) sent by registered mail, return receipt requested, postage prepaid, (c) sent by a nationally-recognized courier service guaranteeing next-day or second day delivery, charges prepaid, or (d) delivered by facsimile (with documented evidence of transmission), to the addresses or facsimile numbers of the other Party set forth below or at such other addresses as may from time to time be furnished by similar notice by any Party. The effective date of any notice under this Agreement shall be the date of receipt by the receiving Party.

If to LONZA:

LONZA SALES LTD.
Attn: Business Head Münchensteinerstrasse 38
4002 Basel, Switzerland

With a copy to:

Group General Counsel LONZA Sales Ltd.
Münchensteinerstrasse 38
4002 Basel, Switzerland

If to MODERNA:

ModernaTx, Inc.
Attn: General Counsel 200 Technology Square
Cambridge, MA 02139 USA

Either Party may change its address for notice by giving notice thereof in the manner set forth in this Section 18.4.

a. Entire Agreement; Amendments. This Agreement, including the Appendices attached hereto and referenced herein, constitutes the full understanding of the Parties and a complete and exclusive statement of the terms of their agreement with respect to the specific subject matter hereof and supersedes all prior agreements and understandings, oral and written, among the Parties with respect to the subject matter hereof, including, without limitation, the SCA. No terms, conditions, understandings or agreements purporting to amend, modify or vary the terms of this Agreement (including any Appendix hereto) shall be binding unless hereafter made in a written instrument referencing this Agreement and signed by each of the Parties.

b. Governing Law. The construction, validity and performance of the Agreement shall be governed by and construed in accordance with the internal laws of the State of New York, without giving effect to its conflicts of laws provisions. The United Nations Convention on Contracts for the International Sale of Goods and the 1974 Convention on the Limitation Period in the International Sale of Goods, as amended by that certain Protocol, done at Vienna on April 11, 1980 shall not apply to this Agreement. The Parties hereby submit to and consent to the exclusive jurisdiction of the federal and state courts sitting in the State of New York and waive any objection to the laying of venue in, and any claim of inconvenient forum with respect to, these courts.

c. Counterparts. This Agreement and any amendment hereto may be executed in any number of counterparts, each of which shall for all purposes be deemed an original and all of which shall constitute the same instrument. This Agreement shall be effective upon full execution by facsimile, PDF, electronic reproduction or original, and a facsimile, PDF or electronic signature shall be deemed to be and shall be as effective as an original signature.

d. Severability. If any part of this Agreement shall be found to be invalid or unenforceable under Applicable Law in any jurisdiction, such part shall be ineffective only to the extent of such invalidity or unenforceability in such jurisdiction, without in any way affecting the remaining parts of this Agreement in that jurisdiction or the validity or enforceability of the Agreement as a whole in any other jurisdiction. In addition, the part that is ineffective shall be reformed in a mutually agreeable manner so as to as nearly approximate the intent of the Parties as possible.

e. Titles and Subtitles. All headings, titles and subtitles used in this Agreement (including any Appendix hereto) are for convenience only and are not to be considered in construing or interpreting any term or provision of this Agreement (or any Appendix hereto).

f. Exhibits. All "RECITALS", "DEFINITIONS", exhibits and appendices referred to herein form an integral part of this Agreement and are incorporated into this Agreement by such reference.

- a. **Pronouns.** Where the context requires, (i) all pronouns used herein will be deemed to refer to the masculine, feminine or neuter gender as the context requires, and (ii) the singular context will include the plural and vice versa.
- b. **Assignment.** This Agreement shall be binding upon the successors and assigns of the Parties and the name of a Party appearing herein shall be deemed to include the names of its successors and assigns. Neither Party may assign its interest under this Agreement without the prior written consent of the other Party, such consent not to be unreasonably withheld, conditioned or delayed; provided, however, a Party shall be entitled without the prior written consent of the other Party to assign this Agreement to an Affiliate or to any company to which such Party may transfer all or substantially all of its assets or capital stock relating to the activities contemplated under this Agreement, whether through purchase, acquisition, merger, consolidation, reorganization or otherwise. Any permitted assignment of this Agreement by either Party will be conditioned upon such Party's permitted assignee agreeing in writing to comply with all the terms and conditions contained in this Agreement. Any purported assignment without a required consent shall be null and void. No assignment shall relieve any Party of responsibility for the performance of any obligation that accrued prior to the effective date of such assignment.
- c. **Waiver.** No waiver hereunder shall be effective unless signed by the Party granting the waiver. The failure of any Party at any time or times to require performance of any provision of this Agreement (including any Appendix hereto) will in no manner affect its rights at a later time to enforce the same. No waiver by any Party of any term, provision or condition contained in this Agreement (including any Appendix hereto), whether by conduct or otherwise, in any one or more instances, shall be deemed to be or construed as a further or continuing waiver of any such term, provision or condition or of any other term, provision or condition of this Agreement (including any Appendix hereto).
- d. **Dispute Resolution.**
- i. **Disputes; Dispute Escalation.** Except as expressly set forth otherwise in this Agreement, disputes of any nature arising under, relating to, or in connection with this Agreement will be exclusively resolved pursuant to this Section 18.14. If the Parties are unable to resolve a dispute, despite their good faith efforts, either Party may, by written notice to the other, have such dispute referred to the Executive Officers (or their designees, which designee is required to have decision-making authority on behalf of such Party), who will attempt to resolve such dispute by negotiation and consultation for a [***] period following receipt of such written notice. Notwithstanding the dispute resolution procedures set forth in this Section 18, in the event of an actual or threatened breach of this Agreement, the aggrieved Party may seek provisional equitable relief (including restraining orders, specific performance or other injunctive relief), without first submitting to any dispute resolution procedures hereunder.
- ii. **Full Arbitration.** In the event that no agreement is reached by the Executive Officers (or other designees) with respect to a dispute within [***] after its referral to them, either Party may at any time after such [***] period submit such dispute to be finally settled by arbitration administered in accordance with the procedural rules of the American Arbitration Association ("**AAA**") in effect at the time of submission, as modified by this Section 18.14. The arbitration
-

will be heard and determined by three (3) arbitrators who are retired judges or attorneys with at least ten (10) years of relevant experience in the pharmaceutical and biotechnology industry, each of whom will be impartial and independent. Each Party will appoint one arbitrator and the third arbitrator will be selected by the two Party-appointed arbitrators, or, failing agreement within [***] following appointment of the second arbitrator, by AAA. The arbitration shall be held in New York, New York. The arbitration proceedings shall be conducted, and the award shall be rendered, in the English language. Fees, costs and expenses of arbitration are to be divided by the Parties in the following manner: [***].

i. **Expedited Arbitration.** Notwithstanding Section 18.14.2 the Parties may agree to refer a dispute to expedited arbitration (an "**Expedited Dispute**") rather than resolve the same pursuant to Section 18.14.2. Any such Expedited Dispute shall be finally settled by arbitration under the Commercial Arbitration Rules (Expedited Rules) of the American Arbitration Association ("**AAA Expedited Rules**"). Arbitration will be conducted in New York, New York by one (1) arbitrator who shall be reasonably acceptable to the Parties and who shall be appointed in accordance with the AAA Expedited Rules. If the Parties are unable to select an arbitrator within [***] of the notice that initiated the arbitration, then the arbitrator shall be appointed in accordance with the AAA Expedited Rules. Any arbitrator chosen hereunder shall have educational training and industry experience sufficient to demonstrate a reasonable level of scientific, financial, medical and industry knowledge relevant to the particular dispute. [***].

ii. **Arbitration Award.** The arbitrator(s) shall issue their decision in writing, setting forth the basis for such decision. The arbitration award so given will be a final and binding determination of the dispute, will be fully enforceable in any court of competent jurisdiction. Except in a proceeding to enforce the results of the arbitration or as otherwise required by law, neither Party nor any arbitrator may disclose the existence, content or results of any arbitration hereunder without the prior written consent of both Parties (each such consent not to be unreasonably withheld, delayed or conditioned).

iii. **Tolling.** The Parties agree that all applicable statutes of limitation and time-based defenses (such as estoppel and laches) shall be tolled while the dispute resolution procedures set forth in this Section 18.14 are pending, and the Parties shall cooperate in taking all actions reasonably necessary to achieve such a result. In addition, during the pendency of any dispute under this Agreement initiated before the end of the cure period under Section 15.2, this Agreement shall remain in full force and effect, and the time periods for cure under Section 15.2 shall be tolled. Notwithstanding the dispute resolution procedures set forth in this Section 18.14, in the event of an actual or threatened breach of this Agreement, the aggrieved Party may seek provisional equitable relief (including restraining orders, specific performance or other injunctive relief), without first submitting to any dispute resolution procedures hereunder.

iv. **Confidentiality.** Any and all activities conducted under this Section 18.14, including any and all non-public proceedings and decisions under Section 18.14.2, will be deemed Confidential Information of each of the Parties, and will be subject to the terms of 10.

- a. **No Presumption Against Drafter.** For purposes of this Agreement, each Party hereby waives any rule of construction that requires that ambiguities in this Agreement (including any Appendix hereto) be construed against the drafter.
- b. **No Third Party Beneficiaries.** The representations, warranties, covenants and agreements set forth in this Agreement are for the sole benefit of the Parties hereto and their successors and permitted assigns, and they will not be construed as conferring any rights on any other persons other than MODERNA Indemnitees and LONZA Indemnitees pursuant to the indemnification provisions of Sections 16.1 and 16.2.
- c. **Further Assurances.** The Parties shall execute, acknowledge and deliver such further instruments and shall take all such other incidental acts as may be reasonably necessary or appropriate to carry out the purpose and intent of this Agreement.

[REMAINDER OF PAGE INTENTIONALLY LEFT BLANK]

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their duly authorized representatives as of the Effective Date.

MODERNATX, INC.

By: /s/ Stephane Bancel Name: Stephane Bancel
Title: CEO

LONZA SALES LTD.

By: /s/ Albert M. Baehny /s/ Daniel Blaettler

Name: Title:
Albert M. Baehny Daniel Blaettler CEO a.i. and Chairman General Counsel

LONZA LTD.

By: /s/ Albert M. Baehny /s/ Daniel Blaettler

Name: Title:
Albert M. Baehny Daniel Blaettler CEO a.i. and Chairman General Counsel

APPENDIX A-1 STATEMENT OF WORK NR. 1

[TO BE ATTACHED]

APPENDIX A-2 STATEMENT OF WORK NR. 2

[TO BE ATTACHED]

APPENDIX A-3 STATEMENT OF WORK NR. 3

[TO BE ATTACHED]

APPENDIX B TEMPLATE STATEMENT OF WORK

APPENDIX C

EXHIBIT 10.3

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT HAVE BEEN OMITTED AND REPLACED WITH "[***]". SUCH IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS (I) NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF DISCLOSED.

AWARD/CONTRACT		1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)		RATING	PAGE OF PAGES 1 53
2. CONTRACT (Proc Inst Ident) NO. W911QY20C0100		3. EFFECTIVE DATE 09 Aug 2020		4. REQUISITION/PURCHASE REQUEST/PROJECT NO. 0011534693	
5. ISSUED BY W60K ACC-APG NATICK CONTRACTING DIVISION BLDG 1 GENERAL GREENE AVENUE NATICK MA 01760-5011		CODE W911QY	6. ADMINISTERED BY (If other than Item 5) DEFENSE CONTRACT MANAGEMENT AGENCY DCMA BOSTON 495 SUMMER STREET BOSTON MA 02210-2138		CODE S2206A
7. NAME AND ADDRESS OF CONTRACTOR (No., street, city, county, state and zip code) MODERNATX, INC. [***] 200 TECHNOLOGY SQ CAMBRIDGE MA 02139-3578			8. DELIVERY [] FOB ORIGIN [X] OTHER (See below)		
			9. DISCOUNT FOR PROMPT PAYMENT		
CODE 6RP85			FACILITY CODE		10. SUBMIT INVOICES 1 (4 copies unless otherwise specified) TO THE ADDRESS SHOWN IN: Section G
11. SHIP TO/MARK FOR See Schedule		CODE	12. PAYMENT WILL BE MADE BY DEFENSE FINANCE AND ACCOUNTING SERVICE DFAS - COLUMBUS CENTER (HQ0337) NORTH ENTITLEMENT OPERATIONS P.O. BOX 182317 COLUMBUS OH 43218-2266		CODE HQ0337
13. AUTHORITY FOR USING OTHER THAN FULL AND OPEN COMPETITION: [X] 10 U.S.C. 2304(c)(2) [] 41 U.S.C. 253(c)()			14. ACCOUNTING AND APPROPRIATION DATA See Schedule		
15A. ITEM NO.	15B. SUPPLIES/ SERVICES	15C. QUANTITY	15D. UNIT	15E. UNIT PRICE	15F. AMOUNT
SEE SCHEDULE					
15G. TOTAL AMOUNT OF CONTRACT \$1,525,000,000.00					
16. TABLE OF CONTENTS					
(X) SEC.	DESCRIPTION	PAGE(S)	(X) SEC.	DESCRIPTION	PAGE(S)
PART I - THE SCHEDULE			PART II - CONTRACT CLAUSES		
X A	SOLICITATION/ CONTRACT FORM	1 - 2	X I	CONTRACT CLAUSES	45 - 51
X B	SUPPLIES OR SERVICES AND PRICES/ COSTS	3 - 18	PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACH.		
X C	DESCRIPTION/ SPECS./ WORK STATEMENT	19 - 27	X J	LIST OF ATTACHMENTS	52 - 53
X D	PACKAGING AND MARKING	28	PART IV - REPRESENTATIONS AND INSTRUCTIONS		
X E	INSPECTION AND ACCEPTANCE	29 - 30	K	REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS	
X F	DELIVERIES OR PERFORMANCE	31 - 33	L	INST RS., CONDS., AND NOTICES TO OFFERORS	
X G	CONTRACT ADMINISTRATION DATA	34 - 38	M	EVALUATION FACTORS FOR AWARD	
X H	SPECIAL CONTRACT REQUIREMENTS	39 - 44			
CONTRACTING OFFICER WILL COMPLETE ITEM 17 (SEALED-BID OR NEGOTIATED PROCUREMENT) OR 18 (SEALED-BID PROCUREMENT) AS APPLICABLE					
17. [] CONTRACTOR'S NEGOTIATED AGREEMENT (Contractor is required to sign this document and return _____ copies to issuing office.) Contractor agrees to furnish and deliver all items or perform all the services set forth or otherwise identified above and on any continuation sheets for the consideration stated herein. The rights and obligations of the parties to this contract shall be subject to and governed by the following documents: (a) this award/contract, (b) the solicitation, if any, and (c) such provisions, representations, certifications, and specifications, as are attached or incorporated by reference herein. (Attachments are listed herein.)			18. [] SEALED-BID AWARD (Contractor is not required to sign this document.) Your bid on Solicitation Number <u>W911QY20R0043</u> including the additions or changes made by you which additions or changes are set forth in full above, is hereby accepted as to the terms listed above and on any continuation sheets. This award consummates the contract which consists of the following documents: (a) the Government's solicitation and your bid, and (b) this award/contract. No further contractual document is necessary. (Block 18 should be checked only when awarding a sealed-bid contract.)		
19A. NAME AND TITLE OF SIGNER (Type or print) Stéphane Bancel, CEO			20A. NAME OF CONTRACTING OFFICER CONNELL-MAGAW, CAMILLE / BRANCH CHIEF TEL: _____ EMAIL: [***]		
19B. NAME OF CONTRACTOR BY /s/ Stéphane Bancel (Signature of person authorized to sign)		19C. DATE SIGNED 8/11/2020	20B. UNITED STATES OF AMERICA BY /s/ Camille B. Connell-Magaw (Signature of Contracting Officer)		20C. DATE SIGNED 11-Aug-2020

Section A - Solicitation/Contract Form

A.1 The U.S. Army Contracting Command - Aberdeen Proving Ground (ACC-APG), Natick Division has a requirement for up to 500 million SARS-CoV-2 mRNA-1273 Vaccine doses (100 µg) in support of Joint Program Executive Office - Chemical Biological Radiological Nuclear Defense (JPEO-CBRND), the Assistant Secretary for Preparedness and Response (ASPR), and Biomedical Advanced Research and Development Authority (BARDA). All doses of mRNA-1273 Vaccine referenced herein are 100 µg doses. All doses will be delivered in a multi- dose vial with a volume sufficient for 10 doses per vial.

Section B - Supplies or Services and Prices

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0001	SARS-CoV-2 mRNA-1273 Vaccine FFP The contractor shall produce and deliver 100M doses of the SARS-CoV-2 mRNA-1273 Vaccine filled drug product (FDP), IAW Section C, Statement of Work (SOW) and CDRLs (Exhibit A) on this contract. PROJECT: Operation Warp Speed				\$0.00
NET AMT					\$0.00
0001AA	15M Doses FFP FOB: Origin (Shipping Point) PURCHASE REQUEST NUMBER: 0011534693 PROJECT: Operation Warp Speed PSC CD: 6505	15,000,000	Each	\$12.25	\$183,750,000.00
NET AMT					\$183,750,000.00
ACRN AA CIN: GFEB001153469300001					\$183,750,000.00

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0001AB	22M Doses FFP	22,000,000	Each	\$12.25	\$269,500,000.00

FOB: Origin (Shipping Point)
PURCHASE REQUEST NUMBER: 0011534693
PROJECT: Operation Warp Speed
PSC CD: 6505

NET AMT	\$269,500,000.00
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ACRN AB	\$269,500,000.00
CIN: GFEB001153469300002	

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0001AC	30M Doses FFP	30,000,000	Each	\$12.25	\$367,500,000.00

FOB: Destination
PURCHASE REQUEST NUMBER: 0011534693
PROJECT: Operation Warp Speed
PSC CD: 6505

NET AMT	\$367,500,000.00
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ACRN AA	\$367,500,000.00
CIN: GFEB001153469300003	

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0001AD	33M Doses FFP FOB: Destination PURCHASE REQUEST NUMBER: 0011534693 PROJECT: Operation Warp Speed PSC CD: 6505	33,000,000	Each	\$12.25	\$404,250,000.00
NET AMT					\$404,250,000.00
ACRN AA CIN: GFEB5001153469300004					\$404,250,000.00

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0002	Vendor Managed Inventory FFP a. The contractor shall secure, manage and maintain storage for up to 100M doses of mRNA-1273 vaccine and deliver to the designated government facility in accordance with Section F. b. [***] FOB: Destination PROJECT: Operation Warp Speed PSC CD: 6505	1	Job		\$0.00 TBN
NET AMT					\$0.00

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0003	EUA or BLA Incentive FFP This is an incentive CLIN and will be earned only if an Emergency Use Authorization (EUA) or Biologics License Application (BLA) is obtained no later than 31 January 2021. PROJECT: Operation Warp Speed				\$0.00
				NET AMT	\$0.00

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0003AA	EUA or BLA Incentive FFP If earned, this incentive shall be paid at final acceptance of subCLIN 0001AA. FOB: Destination PSC CD: 6505	15,000,000	Each	\$3.00	\$45,000,000.00
				NET AMT	\$45,000,000.00

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0003AB	EUA or BLA Incentive FFP If earned, this incentive shall be paid at final acceptance of subCLIN 0001AB. FOB: Destination PSC CD: 6505	22,000,000	Each	\$3.00	\$66,000,000.00

NET AMT	\$66,000,000.00
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ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0003AC	EUA or BLA Incentive FFP If earned, this incentive shall be paid at final acceptance of subCLIN 0001AC. FOB: Destination PSC CD: 6505	30,000,000	Each	\$3.00	\$90,000,000.00

NET AMT	\$90,000,000.00
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ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0003AD	EUA or BLA Incentive FFP If earned, this incentive shall be paid at final acceptance of subCLIN 0001AD. FOB: Destination PSC CD: 6505	33,000,000	Each	\$3.00	\$99,000,000.00

NET AMT	\$99,000,000.00
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ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0004		1	Job		NSP

Technical Data

FFP

The contractor shall deliver technical Data IAW Contract Data Requirements List (CDRL) IAW deliveries in Section C.4 and Section J, Exhibit A.

FOB: Destination

PROJECT: Operation Warp Speed

PSC CD: 6505

 NET AMT

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
1001					\$0.00
OPTION					

SARS-CoV-2 mRNA-1273 Vaccine

FFP

The contractor shall produce and deliver 100M doses of the SARS-CoV-2 mRNA-1273 Vaccine filled drug product (FDP), IAW Section C, Statement of Work (SOW) and CDRLs (Exhibit A) on this contract.

PROJECT: Operation Warp Speed

 NET AMT

\$0.00

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
1001AA		33,200,000	Each	\$16.50	\$547,800,000.00
OPTION	33.2M Doses				
	FFP				
	a. If executed, the option shall be awarded upon EUA or no later than [***].				
	b. The government shall provide [***] notification to exercise the option.				
	FOB: Destination				
	PROJECT: Operation Warp Speed				
	PSC CD: 6505				

NET AMT	\$547,800,000.00
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ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
1001AB		33,400,000	Each	\$16.50	\$551,100,000.00
OPTION	33.4M Doses				
	FFP				
	a. If executed, the option shall be awarded upon EUA or no later than [***].				
	b. The government shall provide [***] notification to exercise the option.				
	FOB: Destination				
	PROJECT: Operation Warp Speed				
	PSC CD: 6505				

NET AMT	\$551,100,000.00
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ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
1001AC	33.4M Doses	33,400,000	Each	\$16.50	\$551,100,000.00
OPTION	FFP				
	a. If executed, the option shall be awarded upon EUA or no later than [***].				
	b. The government shall provide [***] notification to exercise the option.				
	FOB: Destination				
	PROJECT: Operation Warp Speed				
	PSC CD: 6505				
NET AMT					\$551,100,000.00

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
1002	Vendor Managed Inventory	1	Job		\$0.00 TBN
OPTION	FFP				
	a. The contractor shall secure, manage and maintain storage for up to 100M doses of mRNA-1273 vaccine and deliver to the designated government facility in accordance with Section F.				
	b. [***]				
	FOB: Destination				
	PROJECT: Operation Warp Speed				
	PSC CD: 6505				
NET AMT					\$0.00

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
2001	SARS-CoV-2 mRNA-1273 Vaccine				\$0.00
OPTION	FFP				
	The contractor shall produce and deliver 100M doses of the SARS-CoV-2 mRNA-1273 Vaccine filled drug product (FDP), IAW Section C, Statement of Work (SOW) and CDRLs (Exhibit A) on this contract.				
	PROJECT: Operation Warp Speed				
				NET AMT	\$0.00

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
2001AA	33.4M Doses	33,400,000	Each	\$16.50	\$551,100,000.00
OPTION	FFP				
	a. If executed, the option shall be awarded upon EUA or no later than [***].				
	b. The government shall provide [***] notification to exercise the option.				
	FOB: Destination				
	PROJECT: Operation Warp Speed				
	PSC CD: 6505				
				NET AMT	\$551,100,000.00

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
2001AB	33.4M Doses	33,400,000	Each	\$16.50	\$551,100,000.00
OPTION	FFP				
	a. If executed, the option shall be awarded upon EUA or no later than [***].				
	b. The government shall provide [***] notification to exercise the option.				
	FOB: Destination				
	PROJECT: Operation Warp Speed				
	PSC CD: 6505				
				NET AMT	\$551,100,000.00

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
2001AC	33.2M Doses	33,200,000	Each	\$16.50	\$547,800,000.00
OPTION	FFP				
	a. If executed, the option shall be awarded upon EUA or no later than [***].				
	b. The government shall provide [***] notification to exercise the option.				
	FOB: Destination				
	PROJECT: Operation Warp Speed				
	PSC CD: 6505				
				NET AMT	\$547,800,000.00

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
2002		1	Job		\$0.00 TBN
OPTION	Vendor Managed Inventory FFP a. The contractor shall secure, manage and maintain storage for up to 100M doses of mRNA-1273 vaccine and deliver to the designated government facility in accordance with Section F. b. [***] FOB: Destination PROJECT: Operation Warp Speed PSC CD: 6505				

NET AMT	\$0.00
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ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
3001					\$0.00
OPTION	SARS-CoV-2 mRNA-1273 Vaccine FFP The contractor shall produce and deliver 100M doses of the SARS-CoV-2 mRNA-1273 Vaccine filled drug product (FDP), IAW Section C, Statement of Work (SOW) and CDRLs (Exhibit A) on this contract. PROJECT: Operation Warp Speed				

NET AMT	\$0.00
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ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
3001AA		33,400,000	Each	\$16.50	\$551,100,000.00
OPTION	33.4M Doses				
	FFP				
	a. If executed, the option shall be awarded upon EUA or no later than [***].				
	b. The government shall provide [***] notification to exercise the option.				
	FOB: Destination				
	PROJECT: Operation Warp Speed				
	PSC CD: 6505				

NET AMT	\$551,100,000.00
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ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
3001AB		33,400,000	Each	\$16.50	\$551,100,000.00
OPTION	33.4M Doses				
	FFP				
	a. If executed, the option shall be awarded upon EUA or no later than [***].				
	b. The government shall provide [***] notification to exercise the option.				
	FOB: Destination				
	PROJECT: Operation Warp Speed				
	PSC CD: 6505				

NET AMT	\$551,100,000.00
---------	------------------

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
3001AC	33.2M Doses	33,200,000	Each	\$16.50	\$547,800,000.00
OPTION	FFP				
	a. If executed, the option shall be awarded upon EUA or no later than [***].				
	b. The government shall provide [***] notification to exercise the option.				
	FOB: Destination				
	PROJECT: Operation Warp Speed				
	PSC CD: 6505				
				NET AMT	\$547,800,000.00

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
3002	Vendor Managed Inventory	1	Job		\$0.00 TBN
OPTION	FFP				
	The contractor shall secure, manage and maintain storage for up to 100M doses of mRNA-1273 vaccine and deliver to the designated government facility in accordance with Section F.				
	b. [***]				
	FOB: Destination				
	PROJECT: Operation Warp Speed				
	PSC CD: 6505				
				NET AMT	\$0.00

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
4001	SARS-CoV-2 mRNA-1273 Vaccine				\$0.00
OPTION	FFP				
	The contractor shall produce and deliver 100M doses of the SARS-CoV-2 mRNA-1273 Vaccine filled drug product (FDP), IAW Section C, Statement of Work (SOW) and CDRLs (Exhibit A) on this contract.				
	PROJECT: Operation Warp Speed				
				NET AMT	\$0.00

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
4001AA	33.4M Doses	33,400,000	Each	\$16.50	\$551,100,000.00
OPTION	FFP				
	a. If executed, the option shall be awarded upon EUA or no later than [***].				
	b. The government shall provide [***] notification to exercise the option.				
	FOB: Destination				
	PROJECT: Operation Warp Speed				
	PSC CD: 6505				
				NET AMT	\$551,100,000.00

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
4001AB	33.4M Doses	33,400,000	Each	\$16.50	\$551,100,000.00
OPTION	FFP				
	a. If executed, the option shall be awarded upon EUA or no later than [***].				
	b. The government shall provide [***] notification to exercise the option.				
	FOB: Destination				
	PROJECT: Operation Warp Speed				
	PSC CD: 6505				
				NET AMT	\$551,100,000.00

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
4001AC	33.2M Doses	33,200,000	Each	\$16.50	\$547,800,000.00
OPTION	FFP				
	a. If executed, the option shall be awarded upon EUA or no later than [***].				
	b. The government shall provide [***] notification to exercise the option.				
	FOB: Destination				
	PROJECT: Operation Warp Speed				
	PSC CD: 6505				
				NET AMT	\$547,800,000.00

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
4002		1	Job		\$0.00 TBN
OPTION	Vendor Managed Inventory FFP The contractor shall secure, manage and maintain storage for up to 100M doses of mRNA-1273 vaccine and deliver to the designated government facility in accordance with Section F. b. [***] FOB: Destination PROJECT: Operation Warp Speed PSC CD: 6505				

NET AMT

\$0.00

Section C - Descriptions and Specifications

**STATEMENT OF WORK
LARGE SCALE PRODUCTION OF SARS-CoV-2 VACCINE**

C.1 **SCOPE.** The Department of Defense and Health and Human Services (HHS) require large scale manufacturing of vaccine doses in support of the national emergency response to the Coronavirus Disease 2019 (COVID-19) for the United States Government (USG) and the US population.

C.1.1 **Background.** In December 2019, a novel coronavirus now known as SARS-CoV-2 was first detected in Wuhan, Hubei Province, People's Republic of China, causing outbreaks of the coronavirus disease COVID-19 that has now spread globally. The Secretary of Health and Human Service declared a public health emergency on January 31, 2020, under section 319 of the Public Health Service Act (42 U.S.C. 247d), in response to COVID-19. On March 1, 2020, the President of the United States, pursuant to sections 01 and 301 of the National Emergencies Act (50 U.S.C. 1601 et seq.) and consistent with section 1135 of the Social Security Act (SSA), as amended (42 U.S.C. 1320b-5), proclaimed that the COVID-19 outbreak in the United States constitutes a national emergency.

C.1.1.1 Under Operation Warp Speed (OWS), the Department of Defense and HHS are leading a whole of nation effort to ensure development of promising vaccine, diagnostic and therapeutic candidates and ensure that these medical countermeasures are available in the quantities required to reduce SARS-CoV-2 transmission, identify prior and/or current infection, and improve patient care, thereby mitigating the impact of COVID-19 on the nation and its people. The DoD Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRD) is providing expertise and contracting support to HHS, in compliance with PL 115-92 Authorization Letter for DoD Medical Priorities, through an Interagency Agreement, signed April 23, 2020. As OWS products progress to clinical trials to evaluate the safety and efficacy of vaccines and therapeutics, it is critical that, in parallel, the USG supports large scale manufacturing so that vaccine doses or therapeutic treatment courses are immediately available for nationwide access as soon as a positive efficacy signal is obtained and the medical countermeasures are authorized for widespread use.

C.1.2 **Objective:** The objective of this effort is to obtain the following:

- a. Base Period: Large scale manufacturing of 100 million vaccine doses
- b. Option Period 1: Large scale manufacturing of 100 million vaccine doses
- c. Option Period 2: Large scale manufacturing of 100 million vaccine doses
- d. Option Period 3: Large scale manufacturing of 100 million vaccine doses
- e. Option Period 4: Large scale manufacturing of 100 million vaccine doses

The Base Period is 9 months, with overlapping options for a total of 20 months if all options are exercised.

C.2 **APPLICABLE DOCUMENTS.**

C.2.1 **Federal Documents:**

C.2.1.1 Title 21 Code of Federal Regulations (CFR), Food and Drugs: Part 210, Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs; General; and, Part 211, Current Good Manufacturing Practice In Manufacturing, Processing, Packing, or Holding of Drugs; General.
(https://www.ecfr.gov/cgi-bin/text-idx?SID=a95cab20f443897a400bb7e44a27cf4c&mc=true&tpl=/ecfrbrowse/Title21/21cfrv4_02.tpl#0)

C.3 **REQUIREMENTS.** Independently, and not as an agent of the USG, in accordance with the Proposal submitted by ModernaTX, Inc. in response to Solicitation Number W911QY20R0043, Titled, "Advanced Procurement of mRNA-1273 Vaccine for Prevention of SARS-CoV-2 Coronavirus (COVID-19)", dated July 10, 2020 (and any subsequent USG-approved revisions thereto), the contractor shall provide all necessary services,

qualified personnel, material, equipment and facilities (not otherwise provided by the USG under the terms of this contract) to perform the specific tasks set forth below.

C.3.1 Contract Line Item Number (CLIN) 0001 - Base Period: Large Scale Manufacturing of 100 Million Vaccine Doses.

C.3.1.1 The contractor shall complete all scope required for the production, release and delivery use of 100 million Final Drug Product (FDP) doses of a SARS-CoV-2 mRNA-1273 vaccine. This shall include, the following tasks and other activities reasonably contemplated by such task:

C.3.1.1.1 Storage of FDP doses prior to delivery consistent with all FDA requirements to ensure that the product remains available for use in target populations. Storage and maintenance of the vaccine prior to delivery shall be under conditions and at temperatures necessary to retain stability for use as prescribed in this contract for a period of 12 months. (Based on FDP stability data that supports a 12-month shelf-life, subject to FDA confirmation of the assigned shelf-life.) Ensure requirements of 21CFR207, Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution are met prior to distribution to the CDC. Documents shall be provided under CDRL A002, FDA Interactions and Inspections Documentation.

C.3.1.1.2 cGMP manufacturing of 100 million doses fully compliant with 21 CFR 210 and 211.

C.3.1.1.3 Ensuring that vial labeling and packaging is consistent with FDA guidance for use in target populations and that labeling is updated as appropriate.

C.3.1.1.4 Coordinating with FDA to establish an approved commercial vial label, carton and packaging insert (printed or electronic).

C.3.1.1.5 Ensuring the product complies with the Drug Supply Chain Security Act (DSCSA), Sections 581-585 of PL 113-54 (Nov. 27, 2013), including product verification, serialization, traceability and detection and response requirements, subject to any exceptions established by or the enforcement discretion of the FDA, including "Exemption from Certain Product Tracing and Product Identification Requirements Under Section 582 of the FD&C Act" (April 2020).

C.3.1.1.6 In coordination with the USG, the contractor shall conduct a demonstration of the vaccine shipping process prior to the first delivery of FDP doses at a time mutually agreed to by the contractor and the USG. Moderna shall provide specifications and details associated with the shipping process and containers (IAW CDRL A005) to enable the USG to adequately plan and prepare for potential distribution of the vaccine.

C.3.1.1.7 Following release of product the contractor shall, promptly deliver product to the designated delivery site via a qualified distribution vendor in accordance with Section F and paragraph C.7 below. In the unforeseen event that a designated delivery site cannot receive product and the contractor provides storage beyond 20 days of product release, the contract will be subject to modification for acceptance purposes.

C.3.1.2 Site Visits and Audits. The contractor shall accommodate periodic or ad hoc site visits by BARDA and FDA representatives for required site visits and audits at facilities used to support this contract throughout the period of performance of the contract.

C.3.1.2.1 BARDA Audits. If issues are identified during an audit, the contractor shall submit a report detailing the finding and corrective action(s) in accordance with CDRL A001.

C.3.1.2.2 FDA Audits. The Contractor shall notify the Contracting Officer and Contracting Officer's Representative (COR) within [***] of a scheduled FDA audit or within [***] of an ad hoc site visitor audit if the FDA does not provide advance notice. The contractor shall provide copies of any FDA Audit Report received from subcontractors that occur as a result of this contract or for this product within [***] of receiving correspondence from the FDA or third party in accordance with CDRL A002. The Contractor shall

provide the Contracting Officer with a plan for addressing areas of nonconformance, if any are identified, within [***] of submittal of the audit report in accordance with CDRL A002.

C.3.1.2.3 FDA Interactions. The contractor shall provide copies of the plan and processes that will ensure the USG has visibility and input on all FDA communications regarding the drugs and biologics for the following, but not limited to: FDA interactions, FDA meetings, communications, submissions, inspections, and enforcement documentation in accordance with CDRL A002.

C.3.2 CLIN 1001 - Option Period 1: Large Scale Manufacturing of 100 Million Vaccine Doses.

C.3.2.1 The contractor shall complete all scope required for the production, release and delivery use of 100 million FDP doses of a SARS-CoV-2 mRNA-1273 vaccine. This shall include the following tasks and other activities reasonably contemplated by such tasks:

C.3.2.1.1 Storage of FDP doses prior to delivery consistent with all FDA requirements to ensure that the product remains available for use in target populations. Storage and maintenance of the vaccine prior to delivery shall be under conditions and at temperatures necessary to retain stability for use as prescribed in this contract for a period of 12 months. (Based on FDP stability data that supports a 12-month shelf-life, subject to FDA confirmation of the assigned shelf-life.) Ensure requirements of 21CFR207, Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution are met prior to distribution to the CDC. Documents shall be provided under CDRL A002, FDA Interactions and Inspections Documentation.

C.3.2.1.2 cGMP manufacturing of 100 million doses, subject to any exceptions established by or the enforcement discretion of the FDA.

C.3.2.1.3 Ensuring that vial labeling and packaging is consistent with FDA guidance for use in target populations and that labeling is updated.

C.3.2.1.4 Ensuring the product complies with the Drug Supply Chain Security Act (DSCSA), Sections 581-585 of PL 113-54 (Nov. 27, 2013), including product verification, serialization, traceability and detection and response requirements subject to any exceptions established by or the enforcement discretion of the FDA.

C.3.2.1.5 Following release of the product the contractor shall deliver the product to the designated distribution site via a qualified distribution vendor in accordance with Section F and paragraph C.7 below. To the extent a natural disaster or other emergency affecting a designated delivery site restricts such site's ability to receive product, the Contractor and the USG will promptly agree on an alternate USG delivery location, or storage as Vendor Managed Inventory (VMI) at the contractor site.

C.3.2.2 Site Visits and Audits. The contractor shall accommodate periodic or ad hoc site visits by BARDA and FDA representatives for required site visits and audits at facilities used to support this contract throughout the period of performance of the contract.

C.3.2.2.1 BARDA Audits. If issues are identified during an audit, the contractor shall submit a report detailing the finding and corrective action(s) in accordance with CDRL A001.

C.3.2.2.2 FDA Audits. The Contractor shall notify the Contracting Officer and COR within [***] of a scheduled FDA audit or within [***] of an ad hoc site visit or audit if the FDA does not provide advance notice. The contractor shall provide copies of any FDA Audit Report received from subcontractors that occur as a result of this contract or for this product within [***] of receiving correspondence from the FDA or third party in accordance with CDRL A015. The Contractor shall provide the Contracting Officer with a plan for addressing areas of nonconformance, if any are identified, within [***] of submittal of the audit report in accordance with CDRL A002.

C.3.2.2.3 FDA Interactions. The contractor shall provide copies of the plan and processes that will ensure the USG has visibility and input on all FDA communications regarding the drugs and biologics for the following, but

not limited to: FDA interactions, FDA meetings, communications, submissions, inspections, and enforcement documentation in accordance with CDRL A002.

C.3.3 CLIN 2001 - Option Period 2: Large Scale Manufacturing of 100 Million Vaccine Doses.

C.3.3.1 The contractor shall complete all scope required for the production, release and delivery use of 100million FDP doses of a SARS-CoV-2 mRNA-1273 vaccine. This shall include the following tasks and other activities reasonably contemplated by such tasks:

C.3.3.1.1 Storage of FDP doses prior to delivery consistent with all FDA requirements to ensure that the product remains available for use in target populations. Storage and maintenance of the vaccine prior to delivery shall be under conditions and at temperatures necessary to retain stability for use as prescribed in this contract for a period of 12 months. (Based on FDP stability data that supports a 12-month shelf-life, subject to FDA confirmation of the assigned shelf-life.) Ensure requirements of 21CFR207, Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution are met prior to distribution to the CDC. Documents shall be provided under CDRL A002, FDA Interactions and Inspections Documentation.

C.3.3.1.2 cGMP manufacturing of 100 million doses, subject to any exceptions established by or the enforcement discretion of the FDA.

C.3.3.1.3 Ensuring that vial labeling and packaging is consistent with FDA guidance for use in target populations and that labeling is updated as appropriate.

C.3.3.1.4 Ensuring that the product complies with the Drug Supply Chain Security Act (DSCSA), Sections 581-585 of PL 113-54 (Nov. 27, 2013), including product verification, serialization, traceability and detection and response requirements, subject to any exceptions established by or the enforcement discretion of the FDA.

C.3.3.1.5 Following release the contractor shall deliver product to the nearest designated distribution site via a qualified distribution vendor in accordance with Section F and paragraph C.7 below. To the extent a natural disaster or other emergency affecting a designated delivery site restricts such site's ability to receive product, the Contractor and the USG will promptly agree on an alternate USG delivery location, or storage as Vendor Managed Inventory (VMI) at the contractor site.

C.3.3.2 Site Visits and Audits. The contractor shall accommodate periodic or ad hoc site visits by BARDA and FDA representatives for required site visits and audits at facilities used to support this contract throughout the period of performance of the contract.

C.3.3.2.1 BARDA Audits. If issues are identified during an audit, the contractor shall submit a report detailing the finding and corrective action(s) in accordance with CDRL A001.

C.3.3.2.2 FDA Audits. The Contractor shall notify the Contracting Officer and COR within [***] of a scheduled FDA audit or within [***] of an ad hoc site visit or audit if the FDA does not provide advance notice. The contractor shall provide copies of any FDA Audit Report received from subcontractors that occur as a result of this contract or for this product within [***] of receiving correspondence from the FDA or third party in accordance with CDRL A002. The Contractor shall provide the Contracting Officer with a plan for addressing areas of nonconformance, if any are identified, within [***] of submittal of the audit report in accordance with CDRL A002.

C.3.3.2.3 FDA Interactions. The contractor shall provide copies of the plan and processes that will ensure the USG has visibility and input on all FDA communications regarding the drugs and biologics for the following, but not limited to: FDA interactions, FDA meetings, communications, submissions, inspections, and enforcement documentation in accordance with CDRL A002.

C.3.4 CLIN 3001 - Option Period 3: Large Scale Manufacturing of 100 Million Vaccine Doses.

C.3.4.1 The contractor shall complete all scope required for the production, release and delivery use of 100 million FDP doses of a SARS-CoV-2 mRNA-1273 vaccine. This shall include the following tasks and other activities reasonably contemplated by such tasks:

C.3.4.1.1 Storage of FDP doses prior to delivery consistent with all FDA requirements to ensure that the product remains available for use in target populations. Storage and maintenance of the vaccine prior to delivery shall be under conditions and at temperatures necessary to retain stability for use as prescribed in this contract for a period of 12 months. (Based on FDP stability data that supports a 12-month shelf-life, subject to FDA confirmation of the assigned shelf-life.) Ensure requirements of 21CFR207, Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution are met prior to distribution to the CDC. Documents shall be provided under CDRL A002, FDA Interactions and Inspections Documentation.

C.3.4.1.2 cGMP manufacturing of 100 million doses, subject to any exceptions established by or the enforcement discretion of the FDA.

C.3.4.1.3 Ensuring that vial labeling and packaging is consistent with FDA guidance for use in target populations and that labeling is updated.

C.3.4.1.4 Ensuring the product complies with the Drug Supply Chain Security Act (DSCSA), Sections 581-585 of PL 113-54 (Nov. 27, 2013), including product verification, serialization, traceability and detection and response requirements subject to any exceptions established by or the enforcement discretion of the FDA.

C.3.4.1.5 Following release of the product the contractor shall deliver the product to the designated distribution site via a qualified distribution vendor in accordance with Section F and paragraph C.7 below. To the extent a natural disaster or other emergency affecting a designated delivery site restricts such site's ability to receive product, the Contractor and the USG will promptly agree on an alternate USG delivery location, or storage as Vendor Managed Inventory (VMI) at the contractor site.

C.3.4.2 Site Visits and Audits. The contractor shall accommodate periodic or ad hoc site visits by BARDA and FDA representatives for required site visits and audits at facilities used to support this contract throughout the period of performance of the contract.

C.3.4.2.1 BARDA Audits. If issues are identified during an audit, the contractor shall submit a report detailing the finding and corrective action(s) in accordance with CDRL A001.

C.3.4.2.2 FDA Audits. The Contractor shall notify the Contracting Officer and COR within [***] of a scheduled FDA audit or within [***] of an ad hoc site visit or audit if the FDA does not provide advance notice. The contractor shall provide copies of any FDA Audit Report received from subcontractors that occur as a result of this contract or for this product within [***] of receiving correspondence from the FDA or third party in accordance with CDRL A015. The Contractor shall provide the Contracting Officer with a plan for addressing areas of nonconformance, if any are identified, within [***] of submittal of the audit report in accordance with CDRL A002.

C.3.4.2.3 FDA Interactions. The contractor shall provide copies of the plan and processes that will ensure the USG has visibility and input on all FDA communications regarding mRNA-1273 for the following, but not limited to: FDA interactions, FDA meetings, communications, submissions, inspections, and enforcement documentation in accordance with CDRL A002.

C.3.5 CLIN 4001 - Option Period 4: Large Scale Manufacturing of 100 Million Vaccine Doses.

C.3.5.1 The contractor shall complete all scope required for the production, release and delivery use of 100 million FDP doses of a SARS-CoV-2 mRNA-1273 vaccine. This shall include the following tasks and other activities reasonably contemplated by such tasks:

C.3.5.1.1 Storage of FDP doses prior to delivery consistent with all FDA requirements to ensure that the product remains available for use in target populations. Storage and maintenance of the vaccine prior to delivery shall be under conditions and at temperatures necessary to retain stability for use as prescribed in this contract for a period of 12 months. (Based on FDP stability data that supports a 12-month shelf-life, subject to FDA confirmation of the assigned shelf-life.) Ensure requirements of 21CFR207, Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution are met prior to distribution to the CDC. Documents shall be provided under CDRL A002, FDA Interactions and Inspections Documentation.

C.3.5.1.2 cGMP manufacturing of 100 million doses, subject to any exceptions established by or the enforcement discretion of the FDA.

C.3.5.1.3 Ensuring that vial labeling and packaging is consistent with FDA guidance for use in target populations and that labeling is updated.

C.3.5.1.4 Ensuring the product complies with the Drug Supply Chain Security Act (DSCSA), Sections 581-585 of PL 113-54 (Nov. 27, 2013), including product verification, serialization, traceability and detection and response requirements subject to any exceptions established by or the enforcement discretion of the FDA.

C.3.5.1.5 Following release of the product the contractor shall deliver the product to the designated distribution site via a qualified distribution vendor in accordance with Section F and paragraph C.7 below. To the extent a natural disaster or other emergency affecting a designated delivery site restricts such site's ability to receive product, the Contractor and the USG will promptly agree on an alternate USG delivery location, or storage as Vendor Managed Inventory (VMI) at the contractor site.

C.3.5.2 Site Visits and Audits. The contractor shall accommodate periodic or ad hoc site visits by BARDA and FDA representatives for required site visits and audits at facilities used to support this contract throughout the period of performance of the contract.

C.3.5.2.1 BARDA Audits. If issues are identified during an audit, the contractor shall submit a report detailing the finding and corrective action(s) in accordance with CDRL A001.

C.3.5.2.2 FDA Audits. The Contractor shall notify the Contracting Officer and COR within [***] of a scheduled FDA audit or within [***] of an ad hoc site visit or audit if the FDA does not provide advance notice. The contractor shall provide copies of any FDA Audit Report received from subcontractors that occur as a result of this contract or for this product within [***] of receiving correspondence from the FDA or third party in accordance with CDRL A015. The Contractor shall provide the Contracting Officer with a plan for addressing areas of nonconformance, if any are identified, within [***] of submittal of the audit report in accordance with CDRL A002.

C.3.5.2.3 FDA Interactions. The contractor shall provide copies of the plan and processes that will ensure the USG has visibility and input on all FDA communications regarding the drugs and biologics for the following, but not limited to: FDA interactions, FDA meetings, communications, submissions, inspections, and enforcement documentation in accordance with CDRL A002.

C.4 **CLIN 0002: Data Deliverables.** The contractor shall provide the following in accordance with the Contract Data Requirements List (CDRL), DD Forms 1423, provided at Appendix A.

C.4.1 Monthly Inventory Report (CDRL A003), detailing at a minimum, raw materials, Bulk mRNA, formulated LNPs, and the fill, finish, and released product.

C.4.2 Quality Management Plan. The contractor shall provide a Quality Management Plan, in accordance with CDRL A004, describing the quality policy and objectives, management review, competencies and training, process document control, feedback, evaluation, corrective action and preventive action, process improvement, measurement, and data analysis processes. The framework is normally divided into infrastructure, senior

management responsibility, resource management, lifecycle management, and quality management system evaluation.

C.4.3 Shipping Documentation (CDRL A005) for all Finished Drug Product (FDP) transferring from the contractor's fill/finish facility to a USG facility. The contractor shall obtain concurrence on planned shipment protocols prior to transport.

C.4.4 Expiring Items Report (CDRL A006) for all FDP in the USG's possession.

C.4.5 Key Personnel Listing (CDRL A007).

C.4.6 Monthly Technical Progress Report (CDRL A008), to include an Integrated Master Schedule, identifying key activities and contract status.

C.4.7 Final Technical Report (CDRL A009), documenting the work performed and results obtained for the entire contract period of performance.

C.4.8 Supply Chain Resiliency Plan (SCRCP). The contractor shall provide, in accordance with CDRL A010 and CDRL Attachment 0001, a comprehensive SCRCP that provides for identification and reporting of critical components associated with the secure supply of drug substance, drug product, and work-in-process through to finished goods, and key equipment suppliers and their locations, including addresses, points of contact, and work performed per location, to include subcontractors.

C.4.9 Risk Management Plan (RMP). The Contractor shall provide an RMP in accordance with CDRL A011 that outlines the impacts of each risk in relation to the cost, schedule, and performance objectives. The plan shall include risk mitigation strategies. Each risk mitigation strategy shall capture how the corrective action will reduce impacts on cost, schedule and performance.

C.4.10 Manufacturing Reports and Dose Tracking. The Contractor shall provide, in accordance with CDRL A013, manufacturing reports and manufacturing dose tracking projections and actuals utilizing the USG-provided "COVID-19 Dose Tracking Template" (CDRL Attachment 0003).

C.4.11 Product Acceptance Report (for each lot of Drug Product). The contractor shall provide, in accordance with CDRL A014, pictures of the drug product with lot number, drug product lot tree, list of associated deviations (from drug substance and product), and a Certificate of Analysis.

C.4.12 Incident Report. The contractor shall communicate to BARDA and document all critical programmatic concerns, issues, or probable risks that have or are likely to significantly impact project schedule and/or cost and/or performance in accordance with CDRL A016. "Significant" is frequently defined as a 10% or greater cost or schedule variance within a control account, but should be confirmed in consultation with the COR. Incidents that present liability to the project even without cost/schedule impact, such as breach of GCP during a clinical study, shall also be reported.

C.4.13 FDA Correspondence. The contractor shall provide any correspondence between Contractor and FDA relevant to the scope of this contract and submit in accordance with CDRL A017.

C.4.14 Press Releases. The contractor shall accurately and factually represent the work conducted under this contract in all press releases. The contractor shall provide an advance copy of any press release in accordance with CDRL A018.

C.4.15 Manufacturing Development Plan. The contractor shall provide a Manufacturing Development Plan, in accordance with CDRL A025, describing the manufacturing process for the drug/biologic product to ensure conformity with §501(a)(2)(B) of the Food, Drug, and Cosmetics Act (FD&C Act, Title 21 United States Code (USC) §351 (a)(2)(B)), regarding good manufacturing practices (GMP).

C.5 Administration.

C.5.1 Post Award Teleconference. The contractor shall host a Post Award Teleconference within 7 calendar days after contract award.

C.5.1.1 The contractor shall provide an Agenda, IAW CDRL A020, detailing the planned activities for the subsequent 30 calendar days and shall discuss agenda items for the Post Award Kickoff Meeting.

C.5.1.2 The contractor shall provide Meeting Minutes IAW CDRL A021.

C.5.2 Post Award Kickoff Meeting. The contracting officer may request the contractor host a contract Kick-Off Meeting within 30 calendar days after contract award via teleconference. The contracting officer shall establish the date and time of the conference and prepare the agenda to include discussion on contract activities and schedule.

C.5.3 Bi-Weekly Teleconference. The contractor shall participate in bi-weekly teleconferences (or more frequent meetings required by the USG if warranted based on contract activities) to discuss performance on the contract.

C.5.4 The contractor shall provide an Agenda, IAW CDRL A020; Meeting Minutes in accordance with CDRL A021; and, Presentation Material in accordance with CDRL A022 for each of the aforementioned teleconferences or meetings throughout the contract period of performance.

C.5.5 Daily "Check-In". The contractor shall participate in a daily "check-in" (via teleconference or email) to address key cost, schedule and technical updates. Daily updates may be shared with senior USG leaders during the COVID-19 response and should be provided on a non-confidential basis, unless the update includes confidential information in which case, the contractor shall provide the update in both confidential and non-confidential formats. Daily check-ins may occur on weekdays, excluding federal holidays. Upon request of the USG, check-ins may also occur on weekends and on federal holidays, provided at least 24 hours' notice.

C.6 Security.

C.6.1 Access and General Protection/Security Policy and Procedures. The contractor shall provide all information required for background checks necessary to access critical information related to OWS, and to meet USG installation access requirements to be accomplished by the installation Director of Emergency Services or Security Office. The contractor employees shall comply with all personnel identity verification requirements as directed by the USG and/or local policy. In addition to the changes otherwise authorized by the changes clause of this contract, should the security status of OWS change the USG may require changes in the contractor's security matters or processes. In addition to the industry standards for employment background checks, the contractor shall be willing to have key individuals, in exceptionally sensitive positions, identified for additional vetting by the United States USG.

C.6.2 Security Program and Plan. The contractor shall implement a comprehensive security program that provides overall protection of personnel, information, data, and facilities associated with fulfilling the USG's requirement. The contractor's security practices and procedures shall be detailed in a Security Plan, in accordance with CDRL A019, and shall demonstrate how the contractor shall meet and adhere to the security requirements outlined in CDRL Attachment 0002. This plan shall be delivered to the USG within 45 days of award, and the USG will review in detail and submit comments within ten (10) business days to the Contracting Officer (CO) to be forwarded to the Contractor. The Contractor shall review the Security Plan comments, and, submit a final Security Plan to the U.S. USG within thirty (30) calendar days after receipt of the comments. The Security Plan shall include a timeline for compliance of all the required security measures outlined in CDRL Attachment 0002.

C.6.3 Operational Security (OPSEC). The contractor shall develop and submit an OPSEC Standard Operating Procedure (SOP) Plan IAW CDRL A024. The contractor shall identify in the SOP/Plan critical information related to this contract, why it needs to be protected, where it is located, who is responsible for it, and how to protect it.

C.7 CLIN 0002 Vendor Managed Inventory (VMI). The Contractor shall provide the capability to store the vaccine for up to 52 weeks, up to 100M doses of mRNA-1273 vaccine, in accordance with product labeling. The contractor shall, in accordance with paragraph C.3.1.1.6, ensure the product storage of FDP doses for up to 12 months prior to delivery consistent with all FDA requirements to ensure that the product remains available for use in target populations. [***]. The contractor shall store the product to insure product quality with audible alarms and contacting. The contractor shall notify the USG within [***] of detection of an incident with the potential to impact product quality, and implement corrective actions to mitigate the incident. . BARDA/JPEO- CBRND personnel may conduct Quality Audits of the storage facility, when deemed necessary. The contractor shall notify the USG of Corrective/Preventive actions within [***] of detection of an incident with potential to impacts product quality. BARDA/JPEO-CBRND personnel may conduct Quality Audits of the storage facility, when deemed necessary.

C.7.1 The USG will provide the contractor advance notice of the required delivery locations for the vaccine. The contractor shall ship mRNA-1273 vaccines to designated locations [***] in the United States. The contractor shall be responsible for shipment of all vaccine product whether acceptance is conducted at origin or destination. [***].

C.7.2 The vaccine product shall be shipped and tracked by the distribution vendor's shipping tracking number, to the USG-designated sites within the continental United States.

C.7.3 [***]. Implementation of a Vendor Managed Inventory Plan/SOP (CDRL A012) shall be provided to the USG. [***]. Notwithstanding either of the foregoing sentences, the contractor shall not be liable for loss of or damage to supplies caused by the negligence of officers, agents, or employees of the USG acting within the scope of their employment.

Section D - Packaging and Marking

D.1 Vaccine markings and labeling will be in accordance with FDA and will be finalized through a contract modification.

Section E - Inspection and Acceptance

INSPECTION AND ACCEPTANCE TERMS

Supplies/services will be inspected/accepted at:

CLIN	INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
0001	N/A	N/A	N/A	N/A
0001AA	Origin	Government	Origin	Government
0001AB	Origin	Government	Origin	Government
0001AC	Destination	Government	Destination	Government
0001AD	Destination	Government	Destination	Government
0002	Destination	Government	Destination	Government
0003	N/A	N/A	N/A	N/A
0003AA	Destination	Government	Destination	Government
0003AB	Destination	Government	Destination	Government
0003AC	Destination	Government	Destination	Government
0003AD	Destination	Government	Destination	Government
0004	Destination	Government	Destination	Government
1001	N/A	N/A	N/A	N/A
1001AA	Destination	Government	Destination	Government
1001AB	Destination	Government	Destination	Government
1001AC	Destination	Government	Destination	Government
1002	Destination	Government	Destination	Government
2001	N/A	N/A	N/A	N/A
2001AA	Destination	Government	Destination	Government
2001AB	Destination	Government	Destination	Government
2001AC	Destination	Government	Destination	Government
2002	Destination	Government	Destination	Government
3001	N/A	N/A	N/A	N/A
3001AA	Destination	Government	Destination	Government
3001AB	Destination	Government	Destination	Government
3001AC	Destination	Government	Destination	Government
3002	Destination	Government	Destination	Government
4001	N/A	N/A	N/A	N/A
4001AA	Destination	Government	Destination	Government
4001AB	Destination	Government	Destination	Government
4001AC	Destination	Government	Destination	Government
4002	Destination	Government	Destination	Government

CLAUSES INCORPORATED BY REFERENCE

52.246-16	Responsibility For Supplies	APR 1984
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E1. Inspection:

Initial quality inspection of Filled Drug Product (FDP) shall occur when the Contractor performs release testing to confirm that products comply with Contractor's release specifications and criteria. Contractor will submit in WAWF to the Contracting Officer or the duly authorized representative of the Government with a Certificate of Analysis for quality inspection of all deliverables. Initial inspection under this contract will be performed at the Contractor's facility, or the subcontractor facility, by the BARDA Contracting Officer Technical Representative (COTR).

Final inspection of product shall occur when the Government inspects each shipment of product delivered to it hereunder for visible damage and quantity within [***] of such delivery. In the event Contractor supplies any product to the Government and it is established that such Product was damaged or does not include the required quantities at the time of delivery, the Government shall promptly notify Contractor in writing within [***]. Final inspection shall be conducted at the CDC location identified as destination.

In the event the USG requires storage of the FDP to a Vendor Managed Inventory (VMI) location, final quantity inspection shall be conducted by submission into WAWF of shipping or other documentation confirming quantity to VMI location. Final physical inspection of the FDP shall be conducted upon receipt of product to USG location.

Inspection of all reports and Contract Data Requirement List (CDRL) under this contract will be performed at Destination by duly authorized representative of the Government.

E.2 Acceptance

a. Acceptance at origin shall occur at [***]. Acceptance at destination shall occur [***]. Regardless of where acceptance occurs, the contractor is responsible for final delivery of Filled Drug Product (FDP) to a government designated CDC location.

b. Acceptance under this agreement will be performed by Army Contracting Command Aberdeen Proving Ground (ACC-APG) Natick Contracting Division (NCD) Contracting Officer.

c. Acceptance of services under VMI SubCLINs (List CLINS) shall occur upon satisfactory physical and quantity inspection of FDP upon delivery at USG designated CDC location.

d. The parties acknowledge that acceptance may depend on the compliance with the Contractor's product specifications. The KO and COR may prior to acceptance consult with FDA under its authority under Public Law 115-92 to determine whether the material to be delivered meets the Contractor's product specifications. To this end, Contractor agrees to provide a letter to FDA authorizing the Government to engage in dialog with FDA about the ultimate compliance of this product with the Contractor's product specifications prior to acceptance. BARDA/COR will accept product according to the approved Product Acceptance Procedure.

Section F - Deliveries or Performance

DELIVERY INFORMATION

CLIN	DELIVERY DATE	QUANTITY	SHIP	TO ADDRESS	DODAAC / CAGE
***	***	***	N/A		N/A
***	***	***	N/A FOB:	Origin (Shipping Point)	
***	***	***	N/A FOB:	Origin (Shipping Point)	
***	***	***	N/A FOB:	Destination	
***	***	***	N/A FOB:	Destination	
***	***	***	N/A FOB:	Destination	
***	***	***	N/A		N/A
***	***	***	N/A FOB:	Destination	
***	***	***	N/A FOB:	Destination	
***	***	***	N/A FOB:	Destination	
***	***	***	N/A FOB: ***	Destination	***
			FOB: Destination		
***	***	***	N/A		N/A
***	***	***	N/A FOB: Destination		

***	***	***	Destination	N/A FOB:	
***	***	***	Destination	N/A FOB:	
***	***	***	Destination	N/A FOB:	
***	***	***	N/A		N/A
***	***	***	N/A FOB:	Destination	
***	***	***	N/A FOB:	Destination	
***	***	***	N/A FOB:	Destination	
***	***	***	N/A FOB:	Destination	
***	***	***	N/A		N/A
***	***	***	N/A FOB:	Destination	
***	***	***	N/A FOB:	Destination	
***	***	***	N/A FOB:	Destination	
***	***	***	N/A		N/A
***	***	***	N/A FOB:	Destination	
***	***	***	N/A FOB:	Destination	
***	***	***	N/A FOB:	Destination	
***	***	***	N/A		N/A
***	***	***	N/A FOB:	Destination	
***	***	***	N/A FOB:	Destination	
***	***	***	N/A FOB:	Destination	
***	***	***	N/A FOB:	Destination	

CLAUSES INCORPORATED BY REFERENCE

52.211-17	Delivery of Excess Quantities	SEP 1989
52.242-15	Stop-Work Order	AUG 1989
52.247-34	F.O.B. Destination	NOV 1991

F.1 The contractor shall ship mRNA-1273 vaccines to designated locations [***] in the United States. The contractor shall be responsible for secure shipment of all vaccine product whether acceptance is conducted at origin or destination.

Section G - Contract Administration Data

ACCOUNTING AND APPROPRIATION DATA

AA: 0212020202120400000664643255 S.0074658.5.6 6100.9000021001
 COST CODE: A5XAH
 AMOUNT: \$955,500,000.00

AB: 0212020202120400000664643255 S.0074658.5.6.1 6100.9000021001
 COST CODE: A5XAH
 AMOUNT: \$269,500,000.00

ACRN	CLIN/SLIN	CIN	AMOUNT
AA	0001AA	GFEB001153469300001	\$183,750,000.00
	0001AC	GFEB001153469300003	\$367,500,000.00
	0001AD	GFEB001153469300004	\$404,250,000.00
AB	0001AB	GFEB001153469300002	\$269,500,000.00

CLAUSES INCORPORATED BY REFERENCE

252.204-7006	Billing Instructions	OCT 2005
252.232-7003	Electronic Submission of Payment Requests and Receiving Reports	DEC 2018

CLAUSES INCORPORATED BY FULL TEXT

252.232-7006 WIDE AREA WORKFLOW PAYMENT INSTRUCTIONS (DEC 2018)

(a) Definitions. As used in this clause—

“Department of Defense Activity Address Code (DoDAAC)” is a six position code that uniquely identifies a unit, activity, or organization.

“Document type” means the type of payment request or receiving report available for creation in Wide Area WorkFlow (WAWF).

“Local processing office (LPO)” is the office responsible for payment certification when payment certification is done external to the entitlement system.

“Payment request” and “receiving report” are defined in the clause at 252.232-7003, Electronic Submission of Payment Requests and Receiving Reports.

(b) Electronic invoicing. The WAWF system provides the method to electronically process vendor payment requests and receiving reports, as authorized by Defense Federal Acquisition Regulation Supplement (DFARS) 252.232-7003, Electronic Submission of Payment Requests and Receiving Reports.

(c) WAWF access. To access WAWF, the Contractor shall—

- (1) Have a designated electronic business point of contact in the System for Award Management at <https://www.sam.gov>; and
- (2) Be registered to use WAWF at <https://wawf.eb.mil/> following the step-by-step procedures for self-registration available at this web site.
- (d) WAWF training. The Contractor should follow the training instructions of the WAWF Web-Based Training Course and use the Practice Training Site before submitting payment requests through WAWF. Both can be accessed by selecting the "Web Based Training" link on the WAWF home page at <https://wawf.eb.mil/>.
- (e) WAWF methods of document submission. Document submissions may be via web entry, Electronic Data Interchange, or File Transfer Protocol.
- (f) WAWF payment instructions. The Contractor shall use the following information when submitting payment requests and receiving reports in WAWF for this contract or task or delivery order:
- (1) Document type. The Contractor shall submit payment requests using the following document type(s):
- COMBO
- (ii) For fixed price line items—
- (A) That require shipment of a deliverable, submit the invoice and receiving report specified by the Contracting Officer.
- Invoice and receiving report document type
- (B) For services that do not require shipment of a deliverable, submit either the Invoice 2in1, which meets the requirements for the invoice and receiving report, or the applicable invoice and receiving report, as specified by the Contracting Officer.
- N/A
- (iii) For customary progress payments based on costs incurred, submit a progress payment request.
- (iv) For performance based payments, submit a performance based payment request.
- (v) For commercial item financing, submit a commercial item financing request.
- (2) Fast Pay requests are only permitted when Federal Acquisition Regulation (FAR) 52.213-1 is included in the contract.
- (3) Document routing. The Contractor shall use the information in the Routing Data Table below only to fill in applicable fields in WAWF when creating payment requests and receiving reports in the system.

Routing Data Table

<i>Field Name in WAWF</i>	<i>Data to be entered in WAWF</i>
Pay Official DoDAAC	HQ0337
Issue By DoDAAC	W911QY
Admin DoDAAC**	S2206A

Inspect By DoDAAC	S2206A / BARDA
Acceptor	W911QY
Ship To	TDB

(4) Payment request. The Contractor shall ensure a payment request includes documentation appropriate to the type of payment request in accordance with the payment clause, contract financing clause, or Federal Acquisition Regulation 52.216-7, Allowable Cost and Payment, as applicable.

(5) Receiving report. The Contractor shall ensure a receiving report meets the requirements of DFARS Appendix F.

(g) WAWF point of contact.

(1) The Contractor may obtain clarification regarding invoicing in WAWF from the following contracting activity's WAWF point of contact.

[***] / DCMA Boston-AFAW, Administrative Contracting Officer / [***]

(2) Contact the WAWF helpdesk at [***], if assistance is needed.

(End of clause)

FOR REFERENCE:

DFARS PGI 204.7108 Payment Instructions Table

https://www.acq.osd.mil/dpap/dars/pgi/pgi_html/current/PGI204_71.htm#payment_instructions

G.1 GOVERNMENT CONTRACT ADMINISTRATION

In no event shall any understanding or agreement, contract modification, change order, or other matter in deviation from the terms of this contract between the Contractor and a person other than the Contracting Officer be effective or binding upon the Government. All such actions must be formalized by a proper contractual document executed by the Contracting Officer.

Procuring Contracting Officer:
[***]
Bldg. 1, General Green Avenue
Natick, MA 017650-5011

Contract Specialist:

[[[
Bldg. 1, General Green Avenue
Natick, MA 017650-5011

G.2 GOVERNMENT TECHNICAL POINT OF CONTACT

[[[
Biologist/Project Officer
200 C Street, NW
Washington, DC 20201

G.3 CONTRACTOR'S CONTRACT ADMINISTRATION

[[[
ModernaTX, Inc.
200 Technology SQ.
Cambridge, MA 02139-3578

G.4 PLACES OF PERFORMANCE

ModernaTX, Inc.
200 Technology SQ.
Cambridge, MA 02139-3578

G.5 NOTIFICATION OF REVISIONS AND CHANGE

Notification of revision or changes to names or email addresses will be provided by official correspondence from the PCO/ACO or office of the PCO/ACO in lieu of a contract modification. This does not apply to any such revisions or changes in the event this contract includes a key personnel clause.

G.6 PERFORMANCE BASED PAYMENT

Performance-based payments (PBP) are authorized under this contract in accordance with FAR 52.232-32. The contractor shall bill for the PBP upon achievement of the completion criteria identified in Attachment 0008, Performance-based Payment Milestone Table. Upon achievement of the completion criteria, the contractor shall bill for the PBP for the base and each option IAW the following schedule:

CLIN	PERIOD	AMOUNT
0001AA	BASE	\$ 90,210,000
0001AA	BASE	\$ 132,308,000
0001AA	BASE	\$ 180,420,000
0001AA	BASE	\$ 198,462,000
TOTAL		\$ 601,400,000
[[[	[[[	[[[
[[[	[[[	[[[
[[[	[[[	[[[
[[[		[[[
[[[	[[[	[[[
[[[	[[[	[[[

***	***	***
***		***

Delivery Invoicing: PBPs are a type of contract financing and are recouped by the Government through deductions of payments otherwise due to the contractor for the partial or complete delivery of contract items. The deductions are made by applying a liquidation rate to the price of delivered contract items. Attachment 0009, Performance-based Payment Milestone Billing Plan, identifies the contractor invoicing schedule for liquidation. The contractor shall submit all invoices IAW Attachment 0009.

Section H - Special Contract Requirements

H.1 Key Personnel

Any key personnel specified in this contract are considered to be essential to work performance. At least thirty (30) calendar days prior to the Contractor voluntarily diverting any of the specified individuals to other programs or contracts the Contractor shall notify the Contracting Officer and shall submit a justification for the diversion or replacement and a request to replace the individual. The request must identify the proposed replacement and provide an explanation of how the replacement's skills, experience, and credentials meet or exceed the requirements of the contract (including, when applicable, Human Subjects Testing requirements). If the employee of the Contractor is terminated for cause or separates from the Contractor voluntarily with less than thirty (30) calendar-day notice, the Contractor shall provide the maximum notice practicable under the circumstances. The Contractor shall not divert, replace, or announce any such change to key personnel without the written consent of the Contracting Officer. The contract will be modified to add or delete key personnel as necessary to reflect the agreement of the parties. The following individuals are determined to be key personnel:

Name	Title
***	***
***	***
***	***
***	***
***	***
***	***
***	***
***	***

H.2 Substitution of Key Personnel

The Contractor agrees to assign to the contract those persons whose resumes/CVs were submitted with the proposal who are necessary to fill the requirements of the contract. No substitutions shall be made except in accordance with this clause.

All requests for substitution must provide a detailed explanation of the circumstance necessitating the proposed substitution, a complete resume for the proposed substitute and any other information requested by the contracting officer to approve or disapprove the proposed substitution. All proposed substitutes must have qualifications that are equal to or higher than the qualifications of the person to be replaced. The contracting officer or authorized representative will evaluate such requests and promptly notify the contractor of his approval or disapproval thereof.

H.3 Disclosure of Information:

Performance under this contract may require the Contractor to access non-public data and information proprietary to a Government agency, another Government Contractor or of such nature that its dissemination or use other than as specified in the work statement would be adverse to the interests of the Government or others. Neither the Contractor, nor Contractor personnel, shall divulge nor release data nor information developed or obtained under performance of this contract, except authorized by Government personnel or upon written approval of the CO which the KO will provide in accordance with OWS or other Government policies and/or guidance. The Contractor shall not use, disclose, or reproduce proprietary data that bears a restrictive legend, other than as specified in this contract, or any information at all regarding this agency.

The Contractor shall comply with all applicable Government requirements for protection of non-public information. Unauthorized disclosure of nonpublic information is prohibited by the Government's rules. Unauthorized disclosure may result in termination of the contract, replacement of a Contractor employee, or other appropriate redress. Neither the Contractor nor the Contractor's employees shall disclose or cause to be disseminated, any information concerning the operations of the activity, which could result in, or increase the likelihood of, the possibility of a breach of the activity's security or interrupt the continuity of its operations.

No information related to data obtained under this contract shall be released or publicized without the prior written consent of the COR, whose approval shall not be unreasonably withheld, conditioned, or delayed, provided that no such consent is required to comply with any law, rule, regulation, court ruling or similar order; for submission to any government entity for submission to any securities exchange on which the Contractor's (or its parent corporation's) securities may be listed for trading; or to third parties relating to securing, seeking, establishing or maintaining regulatory or other legal approvals or compliance, financing and capital raising activities, or mergers, acquisitions, or other business transactions. The exceptions identified in this paragraph apply to all disclosures under this Section H.3 except to the extent that a disclosure is otherwise prohibited by law.

H.4 Publication and Publicity

The contractor shall not release any reports, manuscripts, press releases, or abstracts about the work being performed under this contract without written notice in advance to the Government.

(a) Unless otherwise specified in this contract, the contractor may publish the results of its work under this contract. The contractor shall promptly send a copy of each submission to the COR for security review prior to submission. The contractor shall also inform the COR when the abstract article or other publication is published, and furnish a copy of it as finally published.

(b) Unless authorized in writing by the CO, the contractor shall not display the DoD logo including Operating Division or Staff Division logos on any publications.

(c) The contractor shall not reference the products(s) or services(s) awarded under this contract in commercial advertising, as defined in FAR 31.205-1, in any manner which states or implies DoD approval or endorsement of the product(s) or service(s) provided.

(d) The contractor shall include this clause, including this section (d) in all subcontracts where the subcontractor may propose publishing the results of its work under the subcontract. The contractor shall acknowledge the support of the Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority whenever publicizing the work under this contract in any media by including an acknowledgement substantially as follows:

"This project has been funded in whole or in part with Federal funds from the Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority, under Contract Number W911QY-20-C-0100."

H.5 Confidentiality of Information

a. Confidential information, as used in this article, means non-public information or data of a personal nature about an individual, or proprietary information or data submitted by or pertaining to an institution or organization.

b. The Contracting Officer and the Contractor may, by mutual consent, identify elsewhere in this contract specific information and/or categories of information which the Government will furnish to the Contractor or that the Contractor is expected to generate which is confidential. Similarly, the Contracting Officer and the Contractor may, by mutual consent, identify such confidential information from time to time during the performance of the contract. Failure to agree will be settled pursuant to the "Disputes" clause.

c. If it is established elsewhere in this contract that information to be utilized under this contract, or a portion thereof, is subject to the Privacy Act, the Contractor will follow the rules and procedures of disclosure set forth in the Privacy Act of 1974, 5 U.S.C. 552a, and implementing regulations and policies, with respect to systems of records determined to be subject to the Privacy Act.

d. Confidential information, as defined in paragraph (a) of this article, shall not be disclosed without the prior written consent of the individual, institution, or organization.

e. Whenever the Contractor is uncertain with regard to the proper handling of material under the contract, or if the material in question is subject to the Privacy Act or is confidential information subject to the provisions of this article, the Contractor shall obtain a written determination from the Contracting Officer prior to any release, disclosure, dissemination, or publication.

f. Contracting Officer Determinations will reflect the result of internal coordination with appropriate program and legal officials.

g. The provisions of paragraph (d) of this article shall not apply to conflicting or overlapping provisions in other Federal, State or local laws.

ALL REQUIREMENTS OF THIS SECTION H.5 MUST BE PASSED TO ALL SUB-CONTRACTOR.

H.6 Regulatory Rights

This contract involves supply of a product that requires FDA pre-market approval or clearance before commercial authorization. Contractor is seeking FDA authorization or clearance for the commercialization of mRNA-1273, Moderna vaccine for SARS-CoV-2 Coronavirus (the "Technology"). The Contractor is the Sponsor of the Regulatory Application (an investigational new drug application (IND), investigational device exemption (IDE), emergency use authorization (EUA), new drug application (NDA), biologics license application (BLA), premarket approval application (PMA), or 510(k) pre-market notification filing (510(k)) or another regulatory filing submitted to FDA) for the technology. As the Sponsor of the Regulatory Application to FDA (as the terms "sponsor" and "applicant" are defined or used in at 21 CFR §§3.2(c), 312.5, 600.3(t), 812.2(b), 812 Subpart C, or 814.20), the Contractor has certain standing before the FDA that entitles it to exclusive communications related to the Regulatory Application.

Accordingly, the Contractor and the Government agree to the following:

a. DoD Medical Product Priority. PL 115-92 allows the DoD to request, and FDA to provide, assistance to expedite development of products to diagnose, treat, or prevent serious or life-threatening diseases or conditions facing American military personnel. The contractor recognizes that only the DoD can utilize PL 115-92. As such, the contractor will work proactively with the Government to leverage this law to its maximum potential under this contract. The contractor shall submit Public Law 115-92 Sponsor Authorization Letter that will be delivered to the designated OWS POC(s) within 30 days of award.

[***]

H.7 Performance Based Payment Liquidated under Termination

Performance Based Payments (PBPs) have been authorized as a method of financing under this contract. In the event the Moderna's mRNA-1273 COVID Vaccine is unsuccessful in its bid to obtain EUA or FDA approval, the Government may issue a Termination for Convenience (T4C) in whole or in part, on this contract. Upon notice of a T4C, the contractor shall submit a termination settlement proposal, IAW FAR 52.249-2, Termination for Convenience of the Government (Fixed-Price).

H.8 Public Readiness and Emergency Preparedness (PREP) Act:

In accordance with the Public Readiness and Emergency Preparedness Act ("PREP Act"), Pub. L. No. 109-148, Division C, Section 2, as amended (codified at 42 U.S.C. § 247d-6d and 42 U.S.C. § 247d-6e), as well as the Secretary of HHS's Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 15198 (Mar. 17, 2020, effective Feb. 4, 2020), and amended on April 15, 2020, 85 Fed. Reg. 21012 (together, the "Prep Act Declaration"):

- (i) This Agreement is being entered into for purposes of facilitating the manufacture, testing, development, distribution, administration, and use of "Covered Countermeasures" for responding to the COVID-19 public health emergency, in accordance with Section VI of the PREP Act Declaration;
- (ii) Contractor's performance of this Agreement falls within the scope of the "Recommended Activities" for responding to the COVID-19 public health emergency, to the extent it is in accordance with Section III of the PREP Act Declaration; and
- (iii) Contractor is a "Covered Person" to the extent it is a person defined in Section V of the PREP Act Declaration.

Therefore, in accordance with Sections IV and VII of the PREP Act Declaration as well as the PREP Act (42 U.S.C. § 247d-6d), the Department of Defense contracting via assisted acquisition on behalf of the HHS, expressly acknowledges and agrees that the HHS Declaration cited above, specifically its language providing immunity from suit and liability is applicable to this acquisition as long as Contractor's activities fall within the terms and conditions of the PREP Act and the PREP Act Declaration.

The Government may not use, or authorize the use of, any products or materials provided under this contract, unless such use occurs in the United States (or a U.S. territory where U.S. law applies such as embassies, military and NATO installations) and is protected from liability under a declaration issued under the PREP Act, or a successor COVID-19 PREP Act Declaration of equal or greater scope. Any use where the application of the PREP Act is in question will be discussed with Moderna prior to use and, if the parties disagree on such use, the dispute will be resolved according to the "Disputes Clause" (52.233-1)

The items and technology covered by this Contract are being developed for both civil and military applications.

[***]

H.10 Ensuring Sufficient Supply of the Product

1. In recognition of the Government's significant funding for the development and manufacturing of the product in this contract and the Government's need to provide sufficient quantities of a COVID-19 vaccine to protect the United States population, the Government shall have the remedy described in this section to ensure sufficient supply of the product to meet the needs of the public health or national security. This remedy is not available to the Government unless and until both of the following conditions ((a) and (b)) are met:

- a. Moderna gives written notice, required to be submitted to the Government no later than [***], of:
 - i. any formal management decision to terminate manufacturing of this product vaccine prior to delivery of any doses to USG under this contract, including all exercised options, other than as a result of clinical failure, or serious technical or safety reasons or;
 - ii. any formal management decision to discontinue sale of this product vaccine to the Government prior to delivery of any doses to USG under this contract, including all exercised options, other than as a result of clinical failure, or serious technical or safety reasons; or
 - iii. any filing that anticipates Federal bankruptcy protection; and
 - b. Moderna has submitted an Emergency Use Authorization application under §564 of the FD&C Act or a biologics license application provisions of §351(a) of the Public Health Service Act (PHSA).
2. If both conditions listed in section 1 occur, Moderna, upon the request of the Government, shall provide the following items necessary for the Government to pursue manufacturing of this product vaccine with a third party for exclusive sale to the U.S. Government:
- a. a writing evidencing a non-exclusive, nontransferable, irrevocable (except for cause), royalty-free paid-up license to practice or have practiced for or on behalf of the U.S. Government any Moderna Background Patent, Copyright, other Moderna Intellectual Property, Moderna Know-How, Moderna Technical Data rights necessary to manufacture doses of the mRNA-1273 vaccine;
 - b. necessary FDA regulatory filings or authorizations owned or controlled by Moderna related to this product vaccine and any confirmatory instrument pertaining thereto; and
 - c. any outstanding Deliverables contemplated or materials purchased under this contract.
3. This remedy will remain available until the end of the contract.

[***]

H.12 Transportation to Final Destination

During the course of performance under this contract, the Government may require storage of the filled drug product (FDP) before delivery to the final government location. In these circumstances, the Government will accept FDP at the contractor facility (Origin). The contractor; however, shall continue to be responsible for secure delivery of the vaccine to its final destination as identified on this contract. [***].

H.13 Validation of IP/Data

The Parties acknowledge that background intellectual property and technical data assertions have been made and evaluated by the parties. The parties agree that, should additional information relevant to these assertions become available, the parties will reevaluate said assertions as necessary in the future.

H.14 Novation

Upon Moderna, US, Inc.'s registration in the System for Award Management, the Government will, at the Contractor's request, complete a novation of this Contract to recognize Moderna US, Inc. as a counterparty instead of Moderna TX, Inc. This novation will be completed through a modification executed by the Government that identifies Moderna US, Inc. as the contracting party for all purposes as if it had originally executed the Contract.

Section I - Contract Clauses

CLAUSES INCORPORATED BY REFERENCE

52.202-1	Definitions	JUN 2020
52.203-3	Gratuities	APR 1984
52.203-5	Covenant Against Contingent Fees	MAY 2014
52.203-6	Restrictions On Subcontractor Sales To The Government	JUN 2020
52.203-7	Anti-Kickback Procedures	JUN 2020
52.203-8	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity	MAY 2014
52.203-10	Price Or Fee Adjustment For Illegal Or Improper Activity	MAY 2014
52.203-12	Limitation On Payments To Influence Certain Federal Transactions	JUN 2020
52.203-13	Contractor Code of Business Ethics and Conduct	JUN 2020
52.203-17	Contractor Employee Whistleblower Rights and Requirement To Inform Employees of Whistleblower Rights	JUN 2020
52.204-1	Approval of Contract	DEC 1989
52.204-4	Printed or Copied Double-Sided on Postconsumer Fiber Content Paper	MAY 2011
52.204-10	Reporting Executive Compensation and First-Tier Subcontract Awards	JUN 2020
52.204-13	System for Award Management Maintenance	OCT 2018
52.204-18	Commercial and Government Entity Code Maintenance	JUL 2016
52.204-19	Incorporation by Reference of Representations and Certifications.	DEC 2014
52.204-23	Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities.	JUL 2018
52.204-25	Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment.	AUG 2019
52.209-6	Protecting the Government's Interest When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment	JUN 2020
52.209-10	Prohibition on Contracting With Inverted Domestic Corporations	NOV 2015
52.210-1	Market Research	JUN 2020
52.215-2	Audit and Records--Negotiation	JUN 2020
52.215-8	Order of Precedence--Uniform Contract Format	OCT 1997
52.215-11	Price Reduction for Defective Certified Cost or Pricing Data--Modifications	JUN 2020
52.215-13	Subcontractor Certified Cost or Pricing Data--Modifications	JUN 2020
52.215-14	Integrity of Unit Prices	JUN 2020
52.215-15	Pension Adjustments and Asset Reversions	OCT 2010
52.215-18	Reversion or Adjustment of Plans for Postretirement Benefits (PRB) Other than Pensions	JUL 2005
52.215-19	Notification of Ownership Changes	OCT 1997
52.215-21	Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data -- Modifications	JUN 2020
52.217-4	Evaluation Of Options Exercised At The Time Of Contract Award	JUN 1988
52.217-7	Option For Increased Quantity-Separately Priced Line Item	MAR 1989
52.217-8	Option To Extend Services	NOV 1999
52.219-8	Utilization of Small Business Concerns	OCT 2018

52.219-28	Post-Award Small Business Program Rerepresentation	MAY 2020
52.222-1	Notice To The Government Of Labor Disputes	FEB 1997
52.222-3	Convict Labor	JUN 2003
52.222-19	Child Labor -- Cooperation with Authorities and Remedies	JAN 2020
52.222-21	Prohibition Of Segregated Facilities	APR 2015
52.222-26	Equal Opportunity	SEP 2016
52.222-35	Equal Opportunity for Veterans	JUN 2020
52.222-36	Equal Opportunity for Workers with Disabilities	JUN 2020
52.222-37	Employment Reports on Veterans	JUN 2020
52.222-40	Notification of Employee Rights Under the National Labor Relations Act	DEC 2010
52.222-50	Combating Trafficking in Persons	JAN 2019
52.222-54	Employment Eligibility Verification	OCT 2015
52.223-6	Drug-Free Workplace	MAY 2001
52.223-18	Encouraging Contractor Policies To Ban Text Messaging While Driving	JUN 2020
52.225-13	Restrictions on Certain Foreign Purchases	JUN 2008
52.227-1	Authorization and Consent	JUN 2020
52.227-1 Alt I	Authorization And Consent (JUN 2020) - Alternate I	APR 1984
52.227-2	Notice And Assistance Regarding Patent And Copyright Infringement	JUN 2020
52.227-11	Patent Rights--Ownership By The Contractor	MAY 2014
52.232-9	Limitation On Withholding Of Payments	APR 1984
52.232-17	Interest	MAY 2014
52.232-23	Assignment Of Claims	MAY 2014
52.232-25	Prompt Payment	JAN 2017
52.232-33	Payment by Electronic Funds Transfer--System for Award Management	OCT 2018
52.232-39	Unenforceability of Unauthorized Obligations	JUN 2013
52.232-40	Providing Accelerated Payments to Small Business Subcontractors	DEC 2013
52.233-1	Disputes	MAY 2014
52.233-3	Protest After Award	AUG 1996
52.233-4	Applicable Law for Breach of Contract Claim	OCT 2004
52.242-13	Bankruptcy	JUL 1995
52.243-1	Changes--Fixed Price	AUG 1987
52.243-7	Notification Of Changes	JAN 2017
52.244-5	Competition In Subcontracting	DEC 1996
52.245-9	Use And Charges	APR 2012
52.249-2	Termination For Convenience Of The Government (Fixed-Price)	APR 2012
52.249-8	Default (Fixed-Price Supply & Service)	APR 1984
52.249-14	Excusable Delays	APR 1984
252.203-7000	Requirements Relating to Compensation of Former DoD Officials	SEP 2011
252.203-7002	Requirement to Inform Employees of Whistleblower Rights	SEP 2013
252.203-7003	Agency Office of the Inspector General	AUG 2019
252.211-7003	Item Unique Identification and Valuation	MAR 2016
252.222-7006	Restrictions on the Use of Mandatory Arbitration Agreements	DEC 2010
252.225-7048	Export-Controlled Items	JUN 2013
252.227-7013	Rights in Technical Data--Noncommercial Items	FEB 2014
252.227-7014	Rights in Noncommercial Computer Software and Noncommercial Computer Software Documentation	FEB 2014
252.227-7016	Rights in Bid or Proposal Information	JAN 2011

252.227-7017	Identification and Assertion of Use, Release, or Disclosure Restrictions	JAN 2011
252.227-7019	Validation of Asserted Restrictions--Computer Software	SEP 2016
252.227-7028	Technical Data or Computer Software Previously Delivered to the Government	JUN 1995
252.227-7030	Technical Data--Withholding Of Payment	MAR 2000
252.227-7037	Validation of Restrictive Markings on Technical Data	SEP 2016
252.232-7007	Limitation Of Government's Obligation	APR 2014
252.244-7000	Subcontracts for Commercial Items	JUN 2013

CLAUSES INCORPORATED BY FULL TEXT

52.217-9 OPTION TO EXTEND THE TERM OF THE CONTRACT (MAR 2000)

(a) The Government may extend the term of this contract by written notice to the Contractor within 5 days for; provided that the Government gives the Contractor a preliminary written notice of its intent to extend at least 30 days for Options 1 and 2, 60 days for Option 3 and 4 before the contract expires. The preliminary notice does not commit the Government to an extension.

(b) If the Government exercises this option, the extended contract shall be considered to include this option clause.

(c) The total duration of this contract, including the exercise of any options under this clause, shall not exceed 20 months.

(End of clause)

52.232-32 PERFORMANCE-BASED PAYMENTS (APR 2012)

(a) Amount of payments and limitations on payments. Subject to such other limitations and conditions as are specified in this contract and this clause, the amount of payments and limitations on payments shall be specified in the contract's description of the basis for payment.

(b) Contractor request for performance-based payment. The Contractor may submit requests for payment of performance-based payments not more frequently than monthly, in a form and manner acceptable to the Contracting Officer. Unless otherwise authorized by the Contracting Officer, all performance-based payments in any period for which payment is being requested shall be included in a single request, appropriately itemized and totaled. The Contractor's request shall contain the information and certification detailed in paragraphs (l) and (m) of this clause.

(c) Approval and payment of requests.

(1) The Contractor shall not be entitled to payment of a request for performance-based payment prior to successful accomplishment of the event or performance criterion for which payment is requested. The Contracting Officer shall determine whether the event or performance criterion for which payment is requested has been successfully accomplished in accordance with the terms of the contract. The Contracting Officer may, at any time, require the Contractor to substantiate the successful performance of any event or performance criterion which has been or is represented as being payable.

(2) A payment under this performance-based payment clause is a contract financing payment under the Prompt Payment clause of this contract and not subject to the interest penalty provisions of the Prompt Payment Act. The designated payment office will pay approved requests on the 30th day after receipt of the request for performance-based payment by the designated payment office. However, the designated payment office is not required to provide

payment if the Contracting Officer requires substantiation as provided in paragraph (c)(1) of this clause, or inquiries into the status of an event or performance criterion, or into any of the conditions listed in paragraph (e) of this clause, or into the Contractor certification. The payment period will not begin until the Contracting Officer approves the request.

(3) The approval by the Contracting Officer of a request for performance-based payment does not constitute an acceptance by the Government and does not excuse the Contractor from performance of obligations under this contract.

(d) Liquidation of performance-based payments.

(1) Performance-based finance amounts paid prior to payment for delivery of an item shall be liquidated by deducting a percentage or a designated dollar amount from the delivery payment. If the performance-based finance payments are on a delivery item basis, the liquidation amount for each such line item shall be the percent of that delivery item price that was previously paid under performance-based finance payments or the designated dollar amount. If the performance-based finance payments are on a whole contract basis, liquidation shall be by either predesignated liquidation amounts or a liquidation percentage.

(2) If at any time the amount of payments under this contract exceeds any limitation in this contract, the Contractor shall repay to the Government the excess. Unless otherwise determined by the Contracting Officer, such excess shall be credited as a reduction in the unliquidated performance-based payment balance(s), after adjustment of invoice payments and balances for any retroactive price adjustments.

(e) Reduction or suspension of performance-based payments. The Contracting Officer may reduce or suspend performance-based payments, liquidate performance-based payments by deduction from any payment under the contract, or take a combination of these actions after finding upon substantial evidence any of the following conditions:

(1) The Contractor failed to comply with any material requirement of this contract (which includes paragraphs(h) and (i) of this clause).

(2) Performance of this contract is endangered by the Contractor's --

(i) Failure to make progress; or

(ii) Unsatisfactory financial condition.

(3) The Contractor is delinquent in payment of any subcontractor or supplier under this contract in the ordinary course of business.

(f) Title.

(1) Title to the property described in this paragraph (f) shall vest in the Government. Vestiture shall be immediately upon the date of the first performance-based payment under this contract, for property acquired or produced before that date. Otherwise, vestiture shall occur when the property is or should have been allocable or properly chargeable to this contract

(2) "Property," as used in this clause, includes all of the following described items acquired or produced by the Contractor that are or should be allocable or properly chargeable to this contract under sound and generally accepted accounting principles and practices:

(i) Parts, materials, inventories, and work in process;

(ii) Special tooling and special test equipment to which the Government is to acquire title;

(iii) Nondurable (i.e., noncapital) tools, jigs, dies, fixtures, molds, patterns, taps, gauges, test equipment and other similar manufacturing aids, title to which would not be obtained as special tooling under subparagraph (f)(2)(ii) of this clause; and

(iv) Drawings and technical data, to the extent the Contractor or subcontractors are required to deliver them to the Government by other clauses of this contract.

(3) Although title to property is in the Government under this clause, other applicable clauses of this contract (e.g., the termination or clauses) shall determine the handling and disposition of the property.

(4) The Contractor may sell any scrap resulting from production under this contract, without requesting the Contracting Officer's approval, provided that any significant reduction in the value of the property to which the Government has title under this clause is reported in writing to the Contracting Officer.

(5) In order to acquire for its own use or dispose of property to which title is vested in the Government under this clause, the Contractor shall obtain the Contracting Officer's advance approval of the action and the terms. If approved, the basis for payment (the events or performance criteria) to which the property is related shall be deemed to be not in compliance with the terms of the contract and not payable (if the property is part of or needed for performance), and the Contractor shall refund the related performance-based payments in accordance with paragraph (d) of this clause.

(6) When the Contractor completes all of the obligations under this contract, including liquidation of all performance-based payments, title shall vest in the Contractor for all property (or the proceeds thereof) not --

(i) Delivered to, and accepted by, the Government under this contract; or

(ii) Incorporated in supplies delivered to, and accepted by, the Government under this contract and to which title is vested in the Government under this clause.

(7) The terms of this contract concerning liability for Government-furnished property shall not apply to property to which the Government acquired title solely under this clause.

(g) Risk of loss. Before delivery to and acceptance by the Government, the Contractor shall bear the risk of loss for property, the title to which vests in the Government under this clause, except to the extent the Government expressly assumes the risk. If any property is lost (see 45.101), the basis of payment (the events or performance criteria) to which the property is related shall be deemed to be not in compliance with the terms of the contract and not payable (if the property is part of or needed for performance), and the Contractor shall refund the related performance-based payments in accordance with paragraph (d) of this clause.

(h) Records and controls. The Contractor shall maintain records and controls adequate for administration of this clause. The Contractor shall have no entitlement to performance-based payments during any time the Contractor's records or controls are determined by the Contracting Officer to be inadequate for administration of this clause.

(i) Reports and Government access. The Contractor shall promptly furnish reports, certificates, financial statements, and other pertinent information requested by the Contracting Officer for the administration of this clause and to determine that an event or other criterion prompting a financing payment has been successfully accomplished. The Contractor shall give the Government reasonable opportunity to examine and verify the Contractor's records and to examine and verify the Contractor's performance of this contract for administration of this clause.

(j) Special terms regarding default. If this contract is terminated under the Default clause,

(1) the Contractor shall, on demand, repay to the Government the amount of unliquidated performance-based payments, and

(2) title shall vest in the Contractor, on full liquidation of all performance-based payments, for all property for which

the Government elects not to require delivery under the Default clause of this contract. The Government shall be liable for no payment except as provided by the Default clause.

(k) Reservation of rights.

(1) No payment or vesting of title under this clause shall --

(i) Excuse the Contractor from performance of obligations under this contract; or

(ii) Constitute a waiver of any of the rights or remedies of the parties under the contract.

(2) The Government's rights and remedies under this clause --

(i) Shall not be exclusive, but rather shall be in addition to any other rights and remedies provided by law or this contract; and

(ii) Shall not be affected by delayed, partial, or omitted exercise of any right, remedy, power, or privilege, nor shall such exercise or any single exercise preclude or impair any further exercise under this clause or the exercise of any other right, power, or privilege of the Government.

(l) Content of Contractor's request for performance-based payment. The Contractor's request for performance-based payment shall contain the following:

(1) The name and address of the Contractor;

(2) The date of the request for performance-based payment;

(3) The contract number and/or other identifier of the contract or order under which the request is made;

(4) Such information and documentation as is required by the contract's description of the basis for payment; and

(5) A certification by a Contractor official authorized to bind the Contractor, as specified in paragraph (m) of this clause.

(m) Content of Contractor's certification. As required in paragraph (l)(5) of this clause, the Contractor shall make the following certification in each request for performance-based payment:

I certify to the best of my knowledge and belief that --

(1) This request for performance-based payment is true and correct; this request (and attachments) has been prepared from the books and records of the Contractor, in accordance with the contract and the instructions of the Contracting Officer;

(2) (Except as reported in writing on _____), all payments to subcontractors and suppliers under this contract have been paid, or will be paid, currently, when due in the ordinary course of business;

(3) There are no encumbrances (except as reported in writing on _____) against the property acquired or produced for, and allocated or properly chargeable to, the contract which would affect or impair the Government's title;

(4) There has been no materially adverse change in the financial condition of the Contractor since the submission by the Contractor to the Government of the most recent written information dated _____; and

(5) After the making of this requested performance-based payment, the amount of all payments for each deliverable item for which performance-based payments have been requested will not exceed any limitation in the contract, and

the amount of all payments under the contract will not exceed any limitation in the contract.

(End of Clause)

52.252-2 CLAUSES INCORPORATED BY REFERENCE (FEB 1998)

This contract incorporates one or more clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this/these address(es):

<https://www.acquisition.gov/content/regulations>

(End of clause)

52.252-6 AUTHORIZED DEVIATIONS IN CLAUSES (APR 1984)

(a) The use in this solicitation or contract of any Federal Acquisition Regulation (48 CFR Chapter 1) clause with an authorized deviation is indicated by the addition of "(DEVIATION)" after the date of the clause.

(b) The use in this solicitation or contract of any Defense Federal Acquisition Regulation Supplement (48 CFR Chapter 2) clause with an authorized deviation is indicated by the addition of "(DEVIATION)" after the name of the regulation.

(End of clause)

Section J - List of Documents, Exhibits and Other Attachments

Document Type	Description	Page #	Date
Exhibit A	CDRLs	14	18 July 2020
Attachment 0001	Supply Chain Resiliency Plan for CDRL A010	2	23 July 2020
Attachment 0002	Security Plan	6	23 July 2020
Attachment 0003	Dose Tracking Template Draft Moderna	Excel	15 July 2020
Attachment 0004	Data Rights	1	7 August 2020
Attachment 0005	***	1	7 August 2020
Attachment 0006	ModernaTx, Inc. Background Intellectual Property	2	6 August 2020
Attachment 0007	Performance Base Payment Milestone Schedule	1	7 August 2020
Attachment 0008	Performance Base Payment Milestone Billing Plan	15	7 August 2020

Exhibit A
Contract Data Requirements List (CDRL)

Data Item #	Title of Data Item	Subtitle	Date
A001	Quality Audit Finding and Response Record (QAFRR)	BARDA Audit Findings Report	18-Jul-20
A002	Quality Audit Finding and Response Record (QAFRR)	FDA Audit Findings Report	18-Jul-20
A003	Contractor Furnished Material (CFM) Report	Monthly Inventory Report	18-Jul-20
A004	Quality Program Plan	Quality Program Plan	18-Jul-20
A005	Task Directive Documentation	Shipping Documentation - Finished Drag Products (FDP)	18-Jul-20
A006	Task Directive Documentation	Expiring Item Report	18-Jul-20
A007	Contractor's Personnel Roster	Key Personnel Listing	18-Jul-20
A008	Status Report	Monthly Technical Progress Report	18-Jul-20
A009	Contract Summary Report	Final Technical Report	18-Jul-20
A010	Supply Chain Risk Management Plan	Supply Chain Resiliency Plan (SCRP)	18-Jul-20
A011	Contractor's Risk Management Plan	Risk Management Plan (RMP)	18-Jul-20
A012	Research and Development of Medical Products Regulated by the U.S. Food and Drug Administration	Vendor Managed Inventory Plan/SOP	18 Jul 20
A013	Internal Contractor Technical Data	Manufacturing Reports and Dose Tracking Projections/Actuals	18-Jul-20
A014	Certificate of Compliance (Analysis)	Product Acceptance Report	18-Jul-20
A015	N/A	-	-
A016	Accident Incident Report	Incident Report	18-Jul-20
A017	Internal Contractor Technical Data Report	FDA Correspondence	18-Jul-20
A018	Acquisition Support Documentation	Press Releases	18-Jul-20
A019	Contractor's Standard Operating Procedures	Security Plan	18-Jul-20
A020	Conference Agenda	Conference Agenda	18-Jul-20

A021	Report, Record of Meeting/Minutes	Meeting Minutes	18-Jul-20
A022	Presentation Material	Presentation Material	18-Jul-20
A023	N/A	-	-
A024	Operations Security (OPSEC) Plan	Operational Security (OPSEC) SOP/Plan	18 Jul 20
A025	Research and Development of Medical Products Regulated by the U.S. Food & Drug Administration (FDA)	Manufacturing Development Plan	18 Jul 20

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT HAVE BEEN OMITTED AND REPLACED WITH “[***]”. SUCH IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS (I) NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF DISCLOSED.

Section J

Title	Description	Page	Date
Exhibit A	Contract Data Requirement List (CDRL)	15	18 July 2020
Attachment 0001	Supply Chain Resiliency Plan for CDRL A010	2	23 July 2020
Attachment 0002	Security Plan	6	23 July 2020
Attachment 0003	Dose Tracking Template Draft Moderna	Excel	15 July 2020
Attachment 0004	Data Rights	2	7 August 2020
Attachment 0005	[***]	1	7 August 2020
Attachment 0006	ModernaTx, Inc. Background Intellectual Property	2	6 August 2020
Attachment 0007	Performance Based Payment Milestone Schedule	1	7 August 2020
Attachment 0008	Performance Based Payment Milestone Billing Plan	15	7 August 2020

Contract Data Requirements List (CDRLs)

Exhibit A

As of 18 July 2020

CONTRACT DATA REQUIREMENTS LIST (2 Data Items)					Form Approved OMB No. 0704-0188			
The public reporting burden for this collection of information is estimated to average 220 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden, to the Department of Defense, Executive Services Directorate (0704-0188). Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. Please do not return your form to the above organization. Send completed form to the Government Issuing Contracting Officer for the Contract/PR No. listed in Block E.								
A. CONTRACT LINE ITEM NO. 0002		B. EXHIBIT A		C. CATEGORY: TDP TM Other General/Admin Data				
D. SYSTEM/ITEM LARGE SCALE PRODUCTION OF SARS-CoV-2 VACCINE		E. CONTRACT/PR NO. W911QY-20-C-0100		F. CONTRACTOR Moderna TX, Inc.				
1. DATA ITEM NO. A001		2. TITLE OF DATA ITEM Quality Audit Finding and Response Record (QAFRR)		3. SUBTITLE BARDA Audit Findings Report				17. Price Group
4. AUTHORITY (Data Acquisition Document No.) DI-SESS-81923		5. CONTRACT REFERENCE C.3.1.2.1, C.3.2.2.1, C.3.3.2.1		6. REQUIRING OFFICE ASPR BARDA				18. Estimated Total Price
7. DD 250 REQ N/A	9. DIST STATEMENT REQUIRED C	10. FREQUENCY ASREQ	12. DATE OF FIRST SUBMISSION Refer to Block 16	14. DISTRIBUTION				
8. APP CODE A		11. AS OF DATE 0	13. DATE OF SUBSEQUENT SUBMISSION Refer to Block 16	a. ADDRESSEE	b. COPIES			
16. REMARKS 4. The Data Item Description (DID) may be obtained from http://quicksearch.dia.mil/ . The contractor shall detail the findings and corrective action(s). 8. The US Government (USG) will respond with comments or approval within 10 calendar days after receipt. 9. Distribution Statement C: Distribution authorized to U.S. Government agencies and their Contractors (Administrative or Operational Use). Determination made July 18, 2020. Distribution guidance is included in DoD Instruction 5230.24. 12. Submit within 10 business days of an Audit. 13. The contractor shall incorporate USG comments and provide a final report to the USG upon completion of corrective action. 14. Submit as an electronic file in Microsoft Office (i.e. Word, Excel, Power Point) via email to the BARDA representative: Marva Taylor ([***]) and the Contracting Officer** (KO), Danny Soto ([***]). LT: Letter of Transmittal (via email).					Draft	Final		
				ASPR BARDA*	1	1	0	
				CCAP-SCN**	LT	1	0	
				15. TOTAL →				
1. DATA ITEM NO. A002		2. TITLE OF DATA ITEM Research and Development of Medical Products Regulated by the U.S. Food & Drug Administration		3. SUBTITLE FDA Interactions and Inspections Documents				17. Price Group
4. AUTHORITY (Data Acquisition Document No.) DI-TCSP-82040 (Tailored)		5. CONTRACT REFERENCE C.3.1.2.2, C.3.2.2.2, C.3.3.2.2		6. REQUIRING OFFICE ASPR BARDA				18. Estimated Total Price
7. DD 250 REQ N/A	9. DIST STATEMENT REQUIRED C	10. FREQUENCY ASREQ	12. DATE OF FIRST SUBMISSION Refer to Block 16	14. DISTRIBUTION				
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				ASPR BARDA*	1	1	0	
				CCAP-SCN**	1	1	0	
				15. TOTAL →				2
G. PREPARED BY Pamela Serra		H. DATE July 18, 2020		I. APPROVED BY Marva Taylor		J. DATE July 18, 2020		

CONTRACT DATA REQUIREMENTS LIST (2 Data Items)						Form Approved OMB No. 0704-0188								
The public reporting burden for this collection of information is estimated to average 220 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden, to the Department of Defense, Executive Services Directorate (0704-0188). Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. Please do not return your form to the above organization. Send completed form to the Government Issuing Contracting Officer for the Contract/PR No. listed in Block E.														
A. CONTRACT LINE ITEM NO. 0002		B. EXHIBIT A		C. CATEGORY: TDP TM Other General/Admin Data										
D. SYSTEM/ITEM LARGE SCALE PRODUCTION OF SARS-CoV-2 VACCINE		E. CONTRACT/PR NO. W911QY-20-C-0100			F. CONTRACTOR Moderna TX, Inc.									
1. DATA ITEM NO. A003		2. TITLE OF DATA ITEM Contractor Furnished Material (CFM) Report			3. SUBTITLE Monthly Inventory Report			17. Price Group						
4. AUTHORITY (Data Acquisition Document No.) DI-MGMT-82049		5. CONTRACT REFERENCE C.4.1			6. REQUIRING OFFICE ASPR BARDA			18. Estimated Total Price						
7. DD 250 REQ NO NO		9. DIST STATEMENT REQUIRED C		10. FREQUENCY MTHLY		12. DATE OF FIRST SUBMISSION Refer to Block 16		14. DISTRIBUTION						
8. APP CODE NA		11. AS OF DATE N		13. DATE OF SUBSEQUENT SUBMISSION Refer to Block 16		<table border="1"> <tr> <td rowspan="2">a. ADDRESSEE</td> <td colspan="3">b. COPIES</td> </tr> <tr> <td>Draft</td> <td>Reg</td> <td>Repro</td> </tr> </table>			a. ADDRESSEE	b. COPIES			Draft	Reg
a. ADDRESSEE	b. COPIES													
	Draft	Reg	Repro											
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				CCAP-SCN**		0	LT	0						
				15. TOTAL →				1	1	0				
1. DATA ITEM NO. A004		2. TITLE OF DATA ITEM Research and Development of Medical Products Regulated by the U.S. Food & Drug Administration			3. SUBTITLE Quality Management Plan			17. Price Group						
4. AUTHORITY (Data Acquisition Document No.) DI-TSP-82040 (Tailored)		5. CONTRACT REFERENCE C.4.18			6. REQUIRING OFFICE ASPR BARDA			18. Estimated Total Price						
7. DD 250 REQ N/A		9. DIST STATEMENT REQUIRED C		10. FREQUENCY ASREQ		12. DATE OF FIRST SUBMISSION Refer to Block 16		14. DISTRIBUTION						
8. APP CODE A		11. AS OF DATE 0		13. DATE OF SUBSEQUENT SUBMISSION Refer to Block 16		<table border="1"> <tr> <td rowspan="2">a. ADDRESSEE</td> <td colspan="3">b. COPIES</td> </tr> <tr> <td>Draft</td> <td>Re g</td> <td>Repro</td> </tr> </table>			a. ADDRESSEE	b. COPIES			Draft	Re g
a. ADDRESSEE	b. COPIES													
	Draft	Re g	Repro											
16. REMARKS 4. The Data Item Description (DID) may be obtained from http://quicksearch.dla.mil/ . Page 10, paragraph f.(2) applies. 8. The US Government (USG) will respond with comments or approval within 10 calendar days after receipt. 9. Distribution Statement C: Distribution authorized to U.S. Government agencies and their Contractors (Administrative or Operational Use). Determination made July 18, 2020. Distribution guidance is included in DoD Instruction 5230.24. 12. Submit within 30 calendar days after contract award. 13. The contractor shall incorporate USG comments and resubmit within 10 calendar days after receipt. 14. Submit as an electronic file in Microsoft Office (i.e. Word, Excel, Power Point) via email to the BARDA representative: Marva Taylor ([***]) and the Contracting Officer** (KO), Danny Soto ([***]). LT: Letter of Transmittal (via email).				ASPR BARDA*		1	1	0						
				CCAP-SCN**		LT	LT	0						
				15. TOTAL →				1	1	0				
G. PREPARED BY Pamela Serra		H. DATE July 18, 2020		I. APPROVED BY Marva Taylor		J. DATE July 18, 2020								

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CONTRACT DATA REQUIREMENTS LIST (2 Data Items)					Form Approved OMB No. 0704-0188			
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A. CONTRACT LINE ITEM NO. 0002			B. EXHIBIT A		C. CATEGORY: TDP ☐ TM ☐ Other General/Admin Data ☐			
D. SYSTEM/ITEM LARGE SCALE PRODUCTION OF SARS-CoV-2 VACCINE			E. CONTRACT/PR NO. W911QY-20-C-0100		F. CONTRACTOR Moderna TX, Inc.			
1. DATA ITEM NO. A006		2. TITLE OF DATA ITEM Task Directive Documentation			3. SUBTITLE Expiring Items Report			17. Price Group
4. AUTHORITY (Data Acquisition Document No.) DI-SESS-82206 (Tailored)			5. CONTRACT REFERENCE C.4.3		6. REQUIRING OFFICE ASPR BARDA			18. Estimated Total Price
7. DD 250 REQ NA	9. DIST STATEMENT REQUIRED C	10. FREQUENCY ASREQ	12. DATE OF FIRST SUBMISSION Refer to Block 16		14. DISTRIBUTION			
8. APP CODE NO		11. AS OF DATE NA	13. DATE OF SUBSEQUENT SUBMISSION Refer to Block 16					
16. REMARKS 4. The Data Item Description (DID) may be obtained from http://quicksearch.dla.mil/ . Only paragraph cc applies. 9. Distribution Statement C: Distribution authorized to U.S. Government agencies and their Contractors (Administrative or Operational Use). Determination made July 18, 2020. Distribution guidance is included in DoD Instruction 5230.24. 12. & 13. Submit 30 calendar days prior to product expiration throughout contract period of performance. 14. Submit as an electronic file in Microsoft Office (i.e. Word, Excel, Power Point) via email to the BARDA representative: Marva Taylor ([***]) and the Contracting Officer** (KO), Danny Soto ([***]). LT: Letter of Transmittal (via email).					a. ADDRESSEE	b. COPIES		
						Draft	Reg	Repro
					ASPR BARDA*	0	1	0
					CCAP-SCN**	0	LT	0
					15. TOTAL →			
1. DATA ITEM NO. A007		2. TITLE OF DATA ITEM Contractor's Personnel Roster			3. SUBTITLE Key Personnel Listing			17. Price Group
4. AUTHORITY (Data Acquisition Document No.) DI-MGMT-81834A			5. CONTRACT REFERENCE C.4.5		6. REQUIRING OFFICE ASPR BARDA			18. Estimated Total Price
7. DD 250 REQ N/A	9. DIST STATEMENT REQUIRED C	10. FREQUENCY ASREQ	12. DATE OF FIRST SUBMISSION Refer to Block 16		14. DISTRIBUTION			
8. APP CODE A		11. AS OF DATE 0	13. DATE OF SUBSEQUENT SUBMISSION Refer to Block 16					
16. REMARKS 4. The Data Item Description (DID) may be obtained from http://quicksearch.dla.mil/ . 8. The US Government (USG) will respond with comments or approval within 10 calendar days after receipt. 9. Distribution Statement C: Distribution authorized to U.S. Government agencies and their Contractors (Administrative or Operational Use). Determination made July 18, 2020. Distribution guidance is included in DoD Instruction 5230.24. 12. Submit with Technical Proposal. 13. The contractor shall incorporate USG comments and resubmit to the USG within 10 calendar days after receipt. Resubmit for any changes to key personnel. 14. Submit as an electronic file in Microsoft Office (i.e. Word, Excel, Power Point) via email to the BARDA representative: Marva Taylor ([***]) and the Contracting Officer** (KO), Danny Soto ([***]). LT: Letter of Transmittal (via email).					a. ADDRESSEE	b. COPIES		
						Draft	Reg	Repro
					ASPR BARDA*	1	1	0
					CCAP-SCN**	0	LT	0
					15. TOTAL →			
G. PREPARED BY Pamela Serra		H. DATE July 18, 2020		I. APPROVED BY Marva Taylor		J. DATE July 18, 2020		

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CONTRACT REQUIREMENTS LIST <i>(2 Data Items)</i>					<i>Form Approved OMB No. 0704-0188</i>						
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A. CONTRACT LINE ITEM NO. 0002		B. EXHIBIT A		C. CATEGORY: TDP TM Other General/Admin Data							
D. SYSTEM/ITEM LARGE SCALE PRODUCTION OF SARS-CoV-2 VACCINE		E. CONTRACT/PR NO. W911QY-20-C-0100		F. CONTRACTOR Moderna TX, Inc.							
1. DATA ITEM NO. A009		2. TITLE OF DATA ITEM Contract Summary Report		3. SUBTITLE Final Technical Report							
4. AUTHORITY (Data Acquisition Document No.) DI-ADNM-80447A		5. CONTRACT REFERENCE C.4.7		6. REQUIRING OFFICE ASPR BARDA							
7. DD 250 REQ N/A		9. DIST STATEMENT REQUIRED C		10. FREQUENCY R/ASR		14. DISTRIBUTION					
8. APP CODE A		11. AS OF DATE 0		13. DATE OF FIRST SUBMISSION Refer to Block 16							
16. REMARKS 4. The Data Item Description (DID) may be obtained from http://quicksearch.dla.mil/ . The final report shall be marked as "Final". A cover letter with the report shall contain a summary (not to exceed 200 words) of salient results achieved during the performance of the contract and be structured in the following format: Identify doses accepted by the Government in previous submissions. a. Cover page to include the contract number, contract title, performance period covered, Contractor's name and address, telephone number, fax number, email address and submission date. b. SECTION I: EXECUTIVE SUMMARY - Summarize the purpose and scope of the contract effort including a summary of the major accomplishments relative to the specific activities set forth in the Statement of Work. c. SECTION II: RESULTS - A detailed description of the work performed related to WBS and Gantt chart, the results obtained, and the impact of the results on the scientific and/or public health community including a listing of all manuscripts (published and in preparation) and abstracts presented during the entire period of performance and a summary of all inventions. 8. The US Government (USG) will respond with comments or approval within 30 calendar days after receipt of first draft report and within 15 calendar days of second submission. 9. Distribution Statement C: Distribution authorized to U.S. Government agencies and their Contractors (Administrative or Operational Use). Determination made July 18, 2020. Distribution guidance is included in DoD Instruction 5230.24. 12. Submit Draft Report 75 calendar days prior to end of contract. Submit Final Report 30 calendar days after contract award. 13. The contractor shall incorporate USG comments and resubmit to the USG within 30 calendar days after receipt for first submission and within 10 calendar days after second submission. 14. Submit as an electronic file in Microsoft Office (i.e. Word, Excel, Power Point) via email to the BARDA representative: Marva Taylor ([***]) and the Contracting Officer** (KO), Danny Soto ([***]). LT: Letter of Transmittal (via email).				a. ADDRESSEE		b. COPIES					
						Draft		Final			
						Reg		Repro			
				ASPR BARDA*		1		1		0	
				CCAP-SCN**		1		1		0	
15. TOTAL →				2		2		0			
1. DATA ITEM NO. A010		2. TITLE OF DATA ITEM Supply Chain Risk Management Plan		3. SUBTITLE Supply Chain Resiliency Plan (SCRCP)		17. Price Group					
4. AUTHORITY (Data Acquisition Document No.) DI-MGMT-82256		5. CONTRACT REFERENCE C.4.8		6. REQUIRING OFFICE ASPR BARDA		18. Estimated Total Price					
7. DD 250 REQ N/A		9. DIST STATEMENT REQUIRED C		10. FREQUENCY ASREQ							
8. APP CODE A		11. AS OF DATE 0		13. DATE OF FIRST SUBMISSION Refer to Block 16		14. DISTRIBUTION					
				13. DATE OF SUBSEQUENT SUBMISSION Refer to Block 16							
16. REMARKS 4. The Data Item Description (DID) may be obtained from http://quicksearch.dla.mil/ . SPECIFIC CONTENT INSTRUCTIONS ARE PROVIDED AT ATTACHMENT 0001 TO THIS CDRL. 8. The US Government (USG) will respond with comments or approval within 10 calendar days after receipt. 9. Distribution Statement C: Distribution authorized to U.S. Government agencies and their Contractors (Administrative or Operational Use). Determination made July 18, 2020. Distribution guidance is included in DoD Instruction 5230.24. 12. Submit with 30 Calendar days after contract award. 13. The contractor shall incorporate USG comments and resubmit to the USG within 7 calendar days after receipt. Submit any and all proposed revisions to the Plan for USG approval 10 calendar days prior to implementation. 14. Submit as an electronic file in Microsoft Office (i.e. Word, Excel, Power Point) via email to the BARDA representative: Marva Taylor ([***]) and the Contracting Officer** (KO), Danny Soto ([***]). LT: Letter of Transmittal (via email).				a. ADDRESSEE		b. COPIES					
						Draft		Final			
						Reg		Repro			
				ASPR BARDA*		1		1		0	
				CCAP-SCN**		LT		LT		0	
15. TOTAL →				1		1		0			
G. PREPARED BY Pamela Serra		H. DATE July 18, 2020		I. APPROVED BY Marva Taylor		J. DATE July 18, 2020					

CONTRACT DATA REQUIREMENTS LIST (2 Data Items)						Form Approved OMB No. 0704-0188	
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A. CONTRACT LINE ITEM NO. 0002		B. EXHIBIT A		C. CATEGORY: TDP TM Other General/Admin Data			
D. SYSTEM/ITEM LARGE SCALE PRODUCTION OF SARS-CoV-2 VACCINE		E. CONTRACT/PR NO. W911QY-20-C-0100		F. CONTRACTOR Moderna TX, Inc.			
1. DATA ITEM NO. A011		2. TITLE OF DATA ITEM Research and Development of Medical Products Regulated by the U.S. Food and Drug Administration		3. SUBTITLE Risk Management Plan (RMP)			17. Price Group
4. AUTHORITY (Data Acquisition Document No.) DI-TCSP-82040 (Tailored)		5. CONTRACT REFERENCE C.4.9		6. REQUIRING OFFICE ASPR BARDA			18. Estimated Total Price
7. DD 250 REQ N/A	9. DIST STATEMENT REQUIRED C	10. FREQUENCY R/ASR	12. DATE OF FIRST SUBMISSION Refer to Block 16	14. DISTRIBUTION			
8. APP CODE A		11. AS OF DATE 0	13. DATE OF SUBSEQUENT SUBMISSION Refer to Block 16	a. ADDRESSEE	b. COPIES		
					Draft	Final Reg	Repro
16. REMARKS 4. The Data Item Description (DID) may be obtained from http://quicksearch.dla.mil/ . Page 29, Paragraph (4) applies. 8. The US Government (USG) will respond with comments or approval within 7 calendar days after receipt. 9. Distribution Statement C: Distribution authorized to U.S. Government agencies and their Contractors (Administrative or Operational Use). Determination made July 18, 2020. Distribution guidance is included in DoD Instruction 5230.24. 12. Submit within XX calendar days after contract award. 13. The contractor shall incorporate USG comments and resubmit to the USG within 20 calendar days after receipt. Submit updates to the RMP concurrent with Monthly Progress Report. (CDRL A008). The contractor may choose to notify the USG up to two times every three months if there are no changes from the prior submission, and not submit an update. 14. Submit as an electronic file in Microsoft Office (i.e. Word, Excel, Power Point) via email to the BARDA representative: Marva Taylor ([***]) and the Contracting Officer** (KO), Danny Soto ([***]). LT: Letter of Transmittal (via email).				ASPR BARDA*	1	1	0
				CCAP-SCN**	1	1	0
				15. TOTAL →			
1. DATA ITEM NO. A012		2. TITLE OF DATA ITEM Research and Development of Medical Products Regulated by the U.S. Food and Drug Administration		3. SUBTITLE Vendor Managed Inventory Plan/SOP			17. Price Group
4. AUTHORITY (Data Acquisition Document No.) DI-TCSP-82040 (Tailored)		5. CONTRACT REFERENCE C.7.1		6. REQUIRING OFFICE ASPR BARDA			18. Estimated Total Price
7. DD 250 REQ N/A	9. DIST STATEMENT REQUIRED C	10. FREQUENCY R/ASR	12. DATE OF FIRST SUBMISSION Refer to Block 16	14. DISTRIBUTION			
8. APP CODE A		11. AS OF DATE 0	13. DATE OF SUBSEQUENT SUBMISSION Refer to Block 16	a. ADDRESSEE	b. COPIES		
					Draft	Final Reg	Repro
16. REMARKS 4. The Data Item Description (DID) may be obtained from http://quicksearch.dla.mil/ . Page 11, paragraph (13) applies and Page 29, Paragraph (4) applies. (Subparagraphs (a) through (c) do not apply.) 8. The US Government (USG) will respond with comments or approval within 7 calendar days after receipt. 9. Distribution Statement C: Distribution authorized to U.S. Government agencies and their Contractors (Administrative or Operational Use). Determination made July 18, 2020. Distribution guidance is included in DoD Instruction 5230.24. 12. Submit within 45 calendar days after contract award. 13. The contractor shall incorporate USG comments and resubmit to the USG within 20 calendar days after receipt. Resubmit for any changes to the USG-approved Plan/SOP. 14. Submit as an electronic file in Microsoft Office (i.e. Word, Excel, Power Point) via email to the BARDA representative: Marva Taylor ([***]) and the Contracting Officer** (KO), Danny Soto ([***]). LT: Letter of Transmittal (via email).				ASPR BARDA*	1	1	0
				CCAP-SCN**	1	1	0
				15. TOTAL →			
G. PREPARED BY Pamela Serra		H. DATE July 18, 2020		I. APPROVED BY Marva Taylor		J. DATE July 18, 2020	

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CONTRACT DATA REQUIREMENTS LIST (2 Data Items)										Form Approved OMB No. 0704-0188					
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A. CONTRACT LINE ITEM NO. 0002			B. EXHIBIT A		C. CATEGORY: TDP TM Other General/Admin Data										
D. SYSTEM/ITEM LARGE SCALE PRODUCTION OF SARS-CoV-2 VACCINE			E. CONTRACT/PR NO. W911QY-20-C-0100			F. CONTRACTOR Moderna TX, Inc.									
1. DATA ITEM NO. A015		2. TITLE OF DATA ITEM NOT USED				3. SUBTITLE				17. Price Group					
4. AUTHORITY (Data Acquisition Document No.)				5. CONTRACT REFERENCE		6. REQUIRING OFFICE A				18. Estimated Total Price					
7. DD 250 REQ		9. DIST STATEMENT REQUIRED		10. FREQUENCY		12. DATE OF FIRST SUBMISSION		14. DISTRIBUTION							
8. APP CODE				11. AS OF DATE		13. DATE OF SUBSEQUENT SUBMISSION		a. ADDRESSEE		b. COPIES					
								Draft		Final					
										Reg					
										Repro					
16. REMARKS NOT USED															
								15. TOTAL →							
1. DATA ITEM NO. A016		2. TITLE OF DATA ITEM Accident Incident Report				3. SUBTITLE Incident Report		17. Price Group							
4. AUTHORITY (Data Acquisition Document No.) DI-MGMT-82188				5. CONTRACT REFERENCE C.4.12		6. REQUIRING OFFICE ASPR BARDA				18. Estimated Total Price					
7. DD 250 REQ N/A		9. DIST STATEMENT REQUIRED		10. FREQUENCY ASREQ		12. DATE OF FIRST SUBMISSION Refer to Block 16		14. DISTRIBUTION							
8. APP CODE A		C		11. AS OF DATE N/A		13. DATE OF SUBSEQUENT SUBMISSION Refer to Block 16		a. ADDRESSEE		b. COPIES					
								Draft		Final					
										Reg					
										Repro					
16. REMARKS 4. The Data Item Description (DID) may be obtained from http://quicksearch.dla.mil/ . 9. Distribution Statement C: Distribution authorized to U.S. Government agencies and their Contractors (Administrative or Operational Use). Determination made July 18, 2020. Distribution guidance is included in DoD Instruction 5230.24. 12. Submit with 48 hours of activity or incident or within 24 hours for a security activity or incident. 13. Submit additional updates within 48 hours of additional developments. If corrective action is deemed necessary by the USG, the Contractor shall address in writing, its consideration of concerns raised within 5 business days of receipt. 14. Provide via telephone with written follow-ups and corrective actions to the COR and Contracting Officer. Provide write-up as an electronic file in Microsoft Office (i.e. Word, Excel, Power Point) via email to the BARDA representative: Marva Taylor ([***]) and the Contracting Officer** (KO), Danny Soto ([***]). LT: Letter of Transmittal (via email).								ASPR BARDA*		1		1		0	
								CCAP-SCN**		1		LT		0	
15. TOTAL →								1		1					
G. PREPARED BY Pamela Serra				H. DATE July 18, 2020		I. APPROVED BY Marva Taylor		J. DATE July 18, 2020							

CONTRACT DATA REQUIREMENTS LIST (2 Data Items)					Form Approved OMB No. 0704-0188					
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A. CONTRACT LINE ITEM NO. 0002		B. EXHIBIT A		C. CATEGORY: TDP TM Other General/Admin Data						
D. SYSTEM/ITEM LARGE SCALE PRODUCTION OF SARS-CoV-2 VACCINE		E. CONTRACT/PR NO. W911QY-20-C-0100			F. CONTRACTOR Moderna TX, Inc.					
1. DATA ITEM NO. A017		2. TITLE OF DATA ITEM Research and Development of Medical Products Regulated by the U.S. Food and Drug Administration			3. SUBTITLE FDA Correspondence					
4. AUTHORITY (Data Acquisition Document No.) DI-TCSF-82040 (Tailored)		5. CONTRACT REFERENCE C.4.13			6. REQUIRING OFFICE ASPR BARDA					
7. DD 250 REQ N/A		9. DIST STATEMENT REQUIRED C		10. FREQUENCY ASREQ		12. DATE OF FIRST SUBMISSION Refer to Block 16				
8. APP CODE A		11. AS OF DATE 0		13. DATE OF SUBSEQUENT SUBMISSION Refer to Block 16		14. DISTRIBUTION				
16. REMARKS 4. The Data Item Description (DID) may be obtained from http://quicksearch.dla.mil/ . 8. The US Government (USG) will respond with comments or approval within 10 business days after receipt. 9. Distribution Statement C: Distribution authorized to U.S. Government agencies and their Contractors (Administrative or Operational Use). Determination made July 18, 2020. Distribution guidance is included in DoD Instruction 5230.24. 12. Submit within 2 business days of receipt of FDA correspondence. 13. The contractor shall incorporate USG comments and resubmit concurrent with FDA submission or no later than 1 calendar day of its submission to FDA. 14. Submit as an electronic file in Microsoft Office (i.e. Word, Excel, Power Point) via email to the BARDA representative: Marva Taylor (****) and the Contracting Officer** (KO), Danny Soto (****). LT: Letter of Transmittal (via email).						a. ADDRESSEE			b. COPIES	
						Draft			Final	
						Reg			Repro	
						0			1	
15. TOTAL →						0 1 0				
1. DATA ITEM NO. A018		2. TITLE OF DATA ITEM Acquisition Support Documentation			3. SUBTITLE Press Releases					
4. AUTHORITY (Data Acquisition Document No.) DI-MGMT-81607		5. CONTRACT REFERENCE C.4.14			6. REQUIRING OFFICE ASPR BARDA					
7. DD 250 REQ N/A		9. DIST STATEMENT REQUIRED C		10. FREQUENCY ASREQ		12. DATE OF FIRST SUBMISSION Refer to Block 16				
8. APP CODE A		11. AS OF DATE 0		13. DATE OF SUBSEQUENT SUBMISSION Refer to Block 16		14. DISTRIBUTION				
16. REMARKS 4. The Data Item Description (DID) may be obtained from http://quicksearch.dla.mil/ . Only paragraphs 3.e, 3.f and 3.g apply. 9. Distribution Statement C: Distribution authorized to U.S. Government agencies and their Contractors (Administrative or Operational Use). Determination made July 18, 2020. Distribution guidance is included in DoD Instruction 5230.24. 12. Submit no less than 5 business days prior to the issuance of the press release. 13. Submit any final press releases no later than one (1) calendar day prior to its release. 14. Submit as an electronic file in Microsoft Office (i.e. Word, Excel, Power Point) via email to the BARDA representative: Marva Taylor (****) and the Contracting Officer** (KO), Danny Soto (****). LT: Letter of Transmittal (via email).						a. ADDRESSEE			b. COPIES	
						Draft			Final	
						Reg			Repro	
						1			1	
15. TOTAL →						1 1 0				
G. PREPARED BY Pamela Serra		H. DATE July 18, 2020		I. APPROVED BY Marva Taylor		J. DATE July 18, 2020				

CONTRACT DATA REQUIREMENTS LIST (2 Data Items)				Form Approved OMB No. 0704-0188			
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A. CONTRACT LINE ITEM NO. 0002		B. EXHIBIT A		C. CATEGORY: TDP TM Other General/Admin Data			
D. SYSTEM/ITEM LARGE SCALE PRODUCTION OF SARS-CoV-2 VACCINE		E. CONTRACT/PR NO. W911QY-20-C-0100		F. CONTRACTOR Moderna TX, Inc.			
1. DATA ITEM NO. A019		2. TITLE OF DATA ITEM Contractor's Standard Operating Procedures		3. SUBTITLE Security Plan			
4. AUTHORITY (Data Acquisition Document No.) DI-MGMT-81580		5. CONTRACT REFERENCE C.6		6. REQUIRING OFFICE ASPR BARDA			
7. DD 250 REQ N/A		9. DIST STATEMENT REQUIRED C		10. FREQUENCY R/ASR		12. DATE OF FIRST SUBMISSION Refer to Block 16	
8. APP CODE A		11. AS OF DATE N/A		13. DATE OF SUBSEQUENT SUBMISSION Refer to Block 16		14. DISTRIBUTION	
16. REMARKS 4. The Data Item Description (DID) may be obtained from http://quicksearch.dla.mil/ . 8. The US Government (USG) will respond with comments or approval within 15 calendar days after receipt. 9. Distribution Statement C: Distribution authorized to U.S. Government agencies and their Contractors (Administrative or Operational Use). Determination made July 18, 2020. Distribution guidance is included in DoD Instruction 5230.24. 12. Submit within 45 calendar days after contract award. 13. The contractor shall incorporate USG comments and resubmit to the USG within 10 calendar days after receipt. Resubmit for any and all revisions for USG approval. 14. Submit as an electronic file in Microsoft Office (i.e. Word, Excel, Power Point) via email to the BARDA representative: Marva Taylor ([***]) and the Contracting Officer** (KO), Danny Soto ([***]). LT: Letter of Transmittal (via email).				a. ADDRESSEE		b. COPIES	
15. TOTAL →				2		2	
1. DATA ITEM NO. A020		2. TITLE OF DATA ITEM Conference Agenda		3. SUBTITLE Agenda			
4. AUTHORITY (Data Acquisition Document No.) DI-ADMIN-81249B		5. CONTRACT REFERENCE C.5.11, C.5.4		6. REQUIRING OFFICE ASPR BARDA			
7. DD 250 REQ N/A		9. DIST STATEMENT REQUIRED C		10. FREQUENCY ASREQ		12. DATE OF FIRST SUBMISSION Refer to Block 16	
8. APP CODE A		11. AS OF DATE 0		13. DATE OF SUBSEQUENT SUBMISSION Refer to Block 16		14. DISTRIBUTION	
16. REMARKS 4. The Data Item Description (DID) may be obtained from http://quicksearch.dla.mil/ . 8. Post Award Teleconference: The USG will respond with comments or approval within 1 calendar days after receipt. Kickoff Meeting: The USG will respond with comments or approval within 3 calendar days after receipt. 9. Distribution Statement C: Distribution authorized to U.S. Government agencies and their Contractors (Administrative or Operational Use). Determination made July 18, 2020. Distribution guidance is included in DoD Instruction 5230.24. 12. Post Award Teleconference: Submit at least 3 business days prior to conduct of meeting and establish a teleconference number, unless otherwise provided by the USG. Kickoff Meeting: Submit at least 5 business days prior to conduct of meeting. 13. The contractor shall incorporate USG comments and distribute agenda at least 2 business days prior to meeting. 14. Submit as an electronic file in Microsoft Office (i.e. Word, Excel, Power Point) via email to the BARDA representative: Marva Taylor ([***]) and the Contracting Officer** (KO), Danny Soto ([***]). LT: Letter of Transmittal (via email).				a. ADDRESSEE		b. COPIES	
15. TOTAL →				1		2	
G. PREPARED BY Pamela Serra		H. DATE July 18, 2020		I. APPROVED BY Marva Taylor		J. DATE July 18, 2020	

CONTRACT DATA REQUIREMENTS LIST (2 Data Items)					Form Approved OMB No. 0704-0188			
The public reporting burden for this collection of information is estimated to average 220 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden, to the Department of Defense, Executive Services Directorate (0704-0188). Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. Please do not return your form to the above organization. Send completed form to the Government Issuing Contracting Officer for the Contract/PR No. listed in Block E.								
A. CONTRACT LINE ITEM NO. 0002		B. EXHIBIT A		C. CATEGORY: TDP TM Other General/Admin Data				
D. SYSTEM/ITEM LARGE SCALE PRODUCTION OF SARS-CoV-2 VACCINE		E. CONTRACT/PR NO. W911QY-20-C-0100			F. CONTRACTOR Moderna TX, Inc.			
1. DATA ITEM NO. A021		2. TITLE OF DATA ITEM Report, Record of Meeting/Minutes			3. SUBTITLE Meeting Minutes			
4. AUTHORITY (Data Acquisition Document No.) DI-ADNM-81505		5. CONTRACT REFERENCE C.4.12, C.5.4			6. REQUIRING OFFICE ASPR BARDA			
7. DD 250 REQ N/A		9. DIST STATEMENT REQUIRED C		10. FREQUENCY ASREQ		12. DATE OF FIRST SUBMISSION Refer to Block 16		
8. APP CODE A		11. AS OF DATE 0		13. DATE OF SUBSEQUENT SUBMISSION Refer to Block 16		14. DISTRIBUTION		
16. REMARKS 4. The Data Item Description (DID) may be obtained from http://quicksearch.dla.mil/ . 8. The US Government (USG) will respond with comments or approval within 10 calendar days after receipt. 9. Distribution Statement C: Distribution authorized to U.S. Government agencies and their Contractors (Administrative or Operational Use). Determination made July 18, 2020. Distribution guidance is included in DoD Instruction 5230.24. 12. Submit within 3 calendar days after conduct of meeting. 13. Post Award Teleconference: The contractor shall incorporate USG comments and resubmit to the USG within 3 business day after receipt and within 10 business days for Kickoff Meeting. 14. Submit as an electronic file in Microsoft Office (i.e. Word, Excel, Power Point) via email to the BARDA representative: Marva Taylor ([***]) and the Contracting Officer** (KO), Danny Soto ([***]). LT: Letter of Transmittal (via email).					a. ADDRESSEE		b. COPIES	
					Draft		Final Reg Repro	
					ASPR BARDA*		1 1 0	
					CCAP-SCN**		LT 1 0	
					15. TOTAL →		2 2 0	
1. DATA ITEM NO. A022		2. TITLE OF DATA ITEM Presentation Material			3. SUBTITLE Presentation Material			
4. AUTHORITY (Data Acquisition Document No.) DI-ADNM-81373		5. CONTRACT REFERENCE C.5.4			6. REQUIRING OFFICE ASPR BARDA			
7. DD 250 REQ N/A		9. DIST STATEMENT REQUIRED C		10. FREQUENCY ASREQ		12. DATE OF FIRST SUBMISSION Refer to Block 16		
8. APP CODE A		11. AS OF DATE N/A		13. DATE OF SUBSEQUENT SUBMISSION Refer to Block 16		14. DISTRIBUTION		
16. REMARKS 4. The Data Item Description (DID) may be obtained from http://quicksearch.dla.mil/ . 8. The US Government (USG) will respond with comments or approval within 5 calendar days after receipt. 9. Distribution Statement C: Distribution authorized to U.S. Government agencies and their Contractors (Administrative or Operational Use). Determination made July 18, 2020. Distribution guidance is included in DoD Instruction 5230.24. 12. Submit concurrent with Agenda (CDRL A020). 13. The contractor shall incorporate USG comments and resubmit to the USG within 5 calendar days after receipt. 14. Submit as an electronic file in Microsoft Office (i.e. Word, Excel, Power Point) via email to the BARDA representative: Marva Taylor ([***]) and the Contracting Officer** (KO), Danny Soto ([***]). LT: Letter of Transmittal (via email).					a. ADDRESSEE		b. COPIES	
					Draft		Final Reg Repro	
					ASPR BARDA*		1 1 0	
					CCAP-SCN**		1 1 0	
					15. TOTAL →		2 2 0	
G. PREPARED BY Pamela Serra		H. DATE July 18, 2020		I. APPROVED BY Marva Taylor		J. DATE July 18, 2020		

CONTRACT DATA REQUIREMENTS LIST (2 Data Items)										Form Approved OMB No. 0704-0188			
The public reporting burden for this collection of information is estimated to average 220 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden, to the Department of Defense, Executive Services Directorate (0704-0188). Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. Please do not return your form to the above organization. Send completed form to the Government Issuing Contracting Officer for the Contract/PR No. listed in Block E.													
A. CONTRACT LINE ITEM NO. 0002			B. EXHIBIT A		C. CATEGORY: TDP TM Other General/Admin Data								
D. SYSTEM/ITEM LARGE SCALE PRODUCTION OF SARS-CoV-2 VACCINE			E. CONTRACT/PR NO. W911QY-20-C-0100			F. CONTRACTOR Moderna TX, Inc.							
1. DATA ITEM NO. A023		2. TITLE OF DATA ITEM NOT USED				3. SUBTITLE				17. Price Group			
4. AUTHORITY (Data Acquisition Document No.)				5. CONTRACT REFERENCE		6. REQUIRING OFFICE A				18. Estimated Total Price			
7. DD 250 REQ		9. DIST STATEMENT REQUIRED		10. FREQUENCY		12. DATE OF FIRST SUBMISSION		14. DISTRIBUTION					
8. APP CODE				11. AS OF DATE		13. DATE OF SUBSEQUENT SUBMISSION		a. ADDRESSEE		b. COPIES			
										Draft Reg Final Repro			
16. REMARKS NOT USED													
												15. TOTAL →	
1. DATA ITEM NO. A024		2. TITLE OF DATA ITEM Operations Security (OPSEC) Plan				3. SUBTITLE Operational Security Plan (OPSEC) SOP/Plan		17. Price Group					
4. AUTHORITY (Data Acquisition Document No.) DI-MGMT-80934C				5. CONTRACT REFERENCE C.6.3		6. REQUIRING OFFICE ASPR BARDA				18. Estimated Total Price			
7. DD 250 REQ N/A		9. DIST STATEMENT REQUIRED		10. FREQUENCY ASREQ		12. DATE OF FIRST SUBMISSION Refer to Block 16		14. DISTRIBUTION					
8. APP CODE A		C		11. AS OF DATE 0		13. DATE OF SUBSEQUENT SUBMISSION Refer to Block 16		a. ADDRESSEE		b. COPIES			
										Draft Reg Final Repro			
16. REMARKS 4. The Data Item Description (DID) may be obtained from http://quicksearch.dia.mil/ . 8. The US Government (USG) will respond with comments or approval within 10 calendar days after receipt. 9. Distribution Statement C: Distribution authorized to U.S. Government agencies and their Contractors (Administrative or Operational Use). Determination made July 18, 2020. Distribution guidance is included in DoD Instruction 5230.24. 12. Submit within 90 calendar days of contract award. 13. The contractor shall incorporate USG comments and revisions within 10 calendar days after receipt. Resubmit for any revisions to the UGS-approved SOP/Plan. 14. Submit as an electronic file in Microsoft Office (i.e. Word, Excel, Power Point) via email to the BARDA representative: Marva Taylor ([**]) and the Contracting Officer** (KO), Danny Soto ([**]). LT: Letter of Transmittal (via email).						ASPR BARDA*		1		1		0	
						CCAP-SCN**		LT		1		0	
												15. TOTAL →	
G. PREPARED BY Pamela Serra				H. DATE July 18, 2020		I. APPROVED BY Marva Taylor		J. DATE July 18, 2020					

			15. TOTAL →	2	2	0
G. PREPARED BY Pamela Serra	H. DATE July 18, 2020	I. APPROVED BY Marva Taylor	J. DATE July 18, 2020			

INSTRUCTIONS FOR COMPLETING DD FORM 1423

(See DoD 5010.12-M for detailed instructions.)

FOR GOVERNMENT PERSONNEL

Item A. Self-explanatory.

Item B. Self-explanatory.

Item C. Mark (X) appropriate category: TDP - Technical Data Package; TM - Technical Manual; Other - other category of data, such as "Provisioning," "Configuration Management," etc.

Item D. Enter name of system/item being acquired that data will support.

Item E. Self-explanatory (to be filled in after contract award).

Item F. Self-explanatory (to be filled in after contract award).

Item G. Signature of preparer of CDRL.

Item H. Date CDRL was prepared.

Item I. Signature of CDRL approval authority.

Item J. Date CDRL was approved.

Item 1. See DoD FAR Supplement Subpart 4.71 for proper numbering.

Item 2. Enter title as it appears on data acquisition document cited in Item 4.

Item 3. Enter subtitle of data item for further definition of data item (optional entry).

Item 4. Enter Data Item Description (DID) number, military specification number, or military standard number listed in DoD 5010.12-L (AMSDL), or one-time DID number, that defines data content and format requirements.

Item 5. Enter reference to tasking in contract that generates requirement for the data item (e.g., Statement of Work paragraph number).

Item 6. Enter technical office responsible for ensuring adequacy of the data item.

Item 7. Specify requirement for inspection/acceptance of the data item by the Government.

Item 8. Specify requirement for approval of a draft before preparation of the final data item.

Item 9. For technical data, specify requirement for contractor to mark the appropriate distribution statement on the data (ref. DoDD 5230.24).

Item 10. Specify number of times data items are to be delivered.

Item 11. Specify as-of date of data item, when applicable.

Item 12. Specify when first submittal is required.

Item 13. Specify when subsequent submittals are required, when applicable.

Item 14. Enter addressees and number of draft/final copies to be delivered

FOR THE CONTRACTOR

Item 17. Specify appropriate price group from one of the following groups of effort in developing estimated prices for each data item listed on the DD Form 1423.

- a. Group I. Definition - Data which is not otherwise essential to the contractor's performance of the primary contracted effort (production, development, testing, and administration) but which is required by DD Form 1423.

Estimated Price - Costs to be included under Group I are those applicable to preparing and assembling the data item in conformance with Government requirements, and the administration and other expenses related to reproducing and delivering such data items to the Government.

- b. Group II. Definition - Data which is essential to the performance of the primary contracted effort but the contractor is required to perform additional work to conform to Government requirements with regard to depth of content, format, frequency of submittal, preparation, control, or quality of the data item.

Estimated Price - Costs to be included under Group II are those incurred over and above the cost of the essential data item without conforming to Government requirements, and the administrative and other expenses related to reproducing and delivering such data item to the Government.

- c. Group III. Definition - Data which the contractor must develop for his internal use in performance of the primary contracted effort and does not require any substantial change to conform to Government requirements with regard to depth of content, format, frequency of submittal, preparation, control, and quality of the data item.

Estimated Price - Costs to be included under Group III are the administrative and other expenses related to reproducing and delivering such data item to the Government.

- d. Group IV. Definition - Data which is developed by the contractor as part of his normal operating procedures and his effort in supplying these data to the Government is minimal.

Estimated Price - Group IV items should normally be shown on the DD Form 1423 at no cost.

Item 18. For each data item, enter an amount equal to that portion of the total price which is estimated to be attributable to the production or development for the Government of that item of data. These estimated data prices shall be developed only from those costs which will be incurred as a direct result of the requirement to supply the data, over and above

to each addressee. Explain reproducible copies in Item 16.

Item 15. Enter total number of draft/final copies to be delivered.

Item 16. Use for additional/clarifying information for Items 1 through 15. Examples are: Tailoring of documents cited in Item 4; Clarification of submittal dates in Items 12 and 13; Explanation of reproducible copies in Item 14.; Desired medium for delivery of the data item.

those costs which would otherwise be incurred in performance of the contract if no data were required. The estimated data prices shall not include any amount for rights in data. The Government's right to use the data shall be governed by the pertinent provisions of the contract.

Supply Chain Resiliency Plan for CDRL A010

Attachment 0001

As of 23 July 2020

**ATTACHMENT 0001
TO
CONTRACT DATA REQUIREMENTS
LIST A010**

Supply Chain Resiliency Plan

The contractor shall provide a comprehensive Supply Chain Resiliency Plan that provides for identification and reporting of critical components associated with the secure supply of drug substance, drug product, and work-in-process through to finished goods.

1. A critical component is defined as any material that is essential to the product or the manufacturing process associated with that product. Included in the definition are consumables and disposables associated with manufacturing. NOT included in the definition are facility and capital equipment.

Consideration of critical components includes the evaluation and potential impact of raw materials, excipients, active ingredients, substances, pieces, parts, software, firmware, labeling, assembly, testing, analytical and environmental componentry, reagents, or utility materials which are used in the manufacturing of a drug, cell banks, seed stocks, devices and key processing components and equipment. A clear example of a critical component is one where a sole supplier is utilized.

2. The contractor shall identify key equipment suppliers, their locations, local resources, and the associated control processes at the time of award. This document shall address planning and scheduling for active pharmaceutical ingredients, upstream, downstream, component assembly, finished drug product and delivery events as necessary for the delivery of product.

- a) Communication for these requirements shall be updated as part of an annual review, or as necessary, as part of regular contractual communications.
- b) For upstream and downstream processing, both single-use and re-usable in-place processing equipment, and manufacturing disposables also shall be addressed. For finished goods, the inspection, labeling, packaging, and associated machinery shall be addressed taking into account capacity capabilities.
- c) The focus on the aspects of resiliency shall be on critical components and aspects of complying with the contractual delivery schedule. Delivery methods shall be addressed, inclusive of items that are foreign-sourced, both high and low volume, which would significantly affect throughput and adherence to the contractually agreed deliveries.

3. The contractor shall articulate in the plan, the methodology for inventory control, production planning, scheduling processes and ordering mechanisms, as part of those agreed deliveries.

- a) Production rates and lead times shall be understood and communicated to the HHS/ASPR/BARDA Contracting Officer or the Contracting Officer's Representative as necessary.
- b) Production throughput critical constraints should be well understood by activity and by design, and communicated to contractual personnel. As necessary, communication should focus on identification, exploitation, elevation, and secondary constraints of throughput, as appropriate.

4. Reports for critical items should include the following information:

- a) Critical Material
- b) Primary vendor and secondary vendor, if applicable
- c) Supplier, Manufacturing / Distribution Location
- d) Supplier Lead Time
- e) Shelf Life
- f) Transportation / Shipping restrictions

- g) Comparability studies, if applicable
- h) Amount of material (dose equivalent) in inventory

Security Plan

Attachment 0002

As of 23 July 2020

ATTACHMENT 0002

**CONTRACT DATA REQUIREMENTS
LIST A019**

BARDA SECURITY REQUIREMENTS

The contractor shall provide a Security Plan which shall address the following:

[***]

Data Rights

Attachment 0004

As of 7 August 2020

Data Rights Restrictions

Limited Rights Data

The following are Moderna's technical data assertions required by DFAR 252.227-7017 ("Identification and assertion of use, release, or disclosure restrictions"). Notwithstanding any contrary representation by the Contractor on the System for Award Management or any contrary provision in the contract, the following categories of information developed exclusively at private expense will, if provided to the Government, be considered limited rights data subject to the restrictions specified in DFAR 227.7013. These restrictions apply to any component of information covered by this provision, regardless of whether a component is included in a contract deliverable. The Government will, as applicable, retain government purpose rights or unlimited rights in technical data generated in performance or included in a deliverable as required by DFARS 252.227-7013 or another applicable data rights clause to the extent that any component of such technical data (i) was developed in whole or in part with Government funds, (ii) pertains to an item developed in whole in part with Government funds, or (iii) was first produced in performance of a Government contract subject to FAR 52.227-14. Nothing in this Contract or this Attachment affects any data rights that the Government may already have under prior agreements between Moderna and the Government, including with respect to Agreement Nos. [***] The Government will not reverse engineer or otherwise evaluate materials provided under this Contract to reproduce the type of information described below without Moderna's prior written consent.

[***]	[***]	[***]	[***]
[***] [***] [***] [***] [***] [***]	[***] [***] [***] [***] [***] [***]	[***]	[***]
[***]	[***]	[***]	[***]

August 7, 2020

W911QY-20-C-0100
Data Rights
Attachment 0004

***	***	***	***
***	***	***	***
***	***	***	***
***	***	***	***
***	***	***	***

Attachment 0005

As of 7 August 2020

W911QY-20-C-0100

Attachment 0005

Page 1 of 2

August 7, 2020

W911QY-20-C-0100

Attachment 0005

Moderna Tx, Inc. Background Intellectual Property

Attachment 0006

As of 6 August 2020

Description of Moderna, Inc. Representative Intellectual Property

[**]

Description of Moderna, Inc. Representative Intellectual Property

***]

Performance Based Payment (PBP) Milestone Schedule

Attachment 0007

As of 7 August

CLIN	Milestone	Severable/ Cumulative	Price	Milestone Completion Verification Method
001				Moderna shall provide: 1) written confirmation from the CMO network that sufficient capacity has been reserved; and, 2) written confirmation of reservation of sufficient raw materials along with a manufacturing schedule.
	Capacity and Raw Material Reservation	Severable	\$601,400,000	
***	***	***	***	***
***	***	***	***	***

Performance Base Payment (PBP) Milestone Billing Plan

Attachment 0008

As of 7 August 2020

W911QY-20-C-0100
PBP Milestone Billing Plan
Attachment 0008

[***]

[***]

[***]

[***]

ACTIVE/105609518.1

W911QY-20-C-0100
PBP Milestone Billing Plan
Attachment 0008



[***]

CERTAIN CONFIDENTIAL PORTIONS OF THIS EXHIBIT HAVE BEEN OMITTED AND REPLACED WITH "[***]". SUCH IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS (I) NOT MATERIAL AND (II) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF DISCLOSED.

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT		1. CONTRACT ID CODE	PAGE OF PAGES
			1 16
2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. (If applicable)
		0011534693	
6. ISSUED BY	CODE W911QY	7. ADMINISTERED BY (If other than item 6)	CODE S2206A
W60K ACC-APG NATICK DIVISION BLDG 1 GENERAL GREENE AVENUE NATICK MA 01760-5011		DEFENSE CONTRACT MANAGEMENT AGENCY DCMA BOSTON 495 SUMMER STREET BOSTON MA 02210-2138	
8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code)		9A. AMENDMENT OF SOLICITATION NO.	
MODERNA US INC [***] 200 TECHNOLOGY SQ CAMBRIDGE MA 02139-3578		9B. DATED (SEE ITEM 11)	
		X 10A. MOD. OF CONTRACT/ORDER NO. W911QY20C0100	
		10B. DATED (SEE ITEM 13)	
		X 09-Aug-2020	
CODE 8PTMO	FACILITY CODE		
11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS			
The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offer is extended, is not extended.			
Offer must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment, (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.			
12. ACCOUNTING AND APPROPRIATION DATA (If required)			
13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.			
A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.			
B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(B).			
X C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF: Mutual Agreement of the parties, FAR 43.103(a)(3) & H.14, Novation			
D. OTHER (Specify type of modification and authority)			
E. IMPORTANT: Contractor is not, X is required to sign this document and return 1 copies to the issuing office.			
14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.) Modification Control Number: dsoto202575			
The purpose of this modification is to			
1. Novation Change from Moderna TX to Moderna US			
2. Section C make administrative revisions to correct type-o and update company name			
3. Section G update company name, correct type-o in subCLINs, and revise WAWF Clause inspect by from S2206A to W911QY			
4. Section I add FAR 52.204-25 and update information in FAR 252.232-7007			
5. Section J revised page number on Exhibits and Attachments			
The total obligated amount and contract price remains the unchanged.			
Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.			
15A. NAME AND TITLE OF SIGNER (Type or print)		16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)	
Stephane Bancel, CEO		CAMILLE B. CONNELL-MAGAW TEL: [***] EMAIL: [***]	
15B. CONTRACTOR/OFFEROR	(Signature of person authorized to sign)	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA BY
/s/ Stephane Bancel		9/4/2020	

/s/ Camille B. Connell-Magaw

(Signature of Contracting Officer)

16C. DATE
SIGNED

9/08/2020

EXCEPTION TO SF 30
APPROVED BY OIRM 11-84

30-105-04

STANDARD FORM 30 (Rev. 10-83)
Prescribed by GSA FAR (48
CFR) 53.243

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

SUMMARY OF CHANGES

SECTION C - DESCRIPTIONS AND SPECIFICATIONS

The following have been modified:

**STATEMENT OF WORK
LARGE SCALE PRODUCTION OF SARS-CoV-2 VACCINE**

C.1 **SCOPE.** The Department of Defense and Health and Human Services (HHS) require large scale manufacturing of vaccine doses in support of the national emergency response to the Coronavirus Disease 2019 (COVID-19) for the United States Government (USG) and the US population.

C.1.1 **Background.** In December 2019, a novel coronavirus now known as SARS-CoV-2 was first detected in Wuhan, Hubei Province, People's Republic of China, causing outbreaks of the coronavirus disease COVID-19 that has now spread globally. The Secretary of Health and Human Service declared a public health emergency on January 31, 2020, under section 319 of the Public Health Service Act (42 U.S.C. 247d), in response to COVID-19. On March 1, 2020, the President of the United States, pursuant to sections 01 and 301 of the National Emergencies Act (50 U.S.C. 1601 et seq.) and consistent with section 1135 of the Social Security Act (SSA), as amended (42 U.S.C. 1320b-5), proclaimed that the COVID-19 outbreak in the United States constitutes a national emergency.

C.1.1.1 Under Operation Warp Speed (OWS), the Department of Defense and HHS are leading a whole of nation effort to ensure development of promising vaccine, diagnostic and therapeutic candidates and ensure that these medical countermeasures are available in the quantities required to reduce SARS-CoV-2 transmission, identify prior and/or current infection, and improve patient care, thereby mitigating the impact of COVID-19 on the nation and its people. The DoD Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRD) is providing expertise and contracting support to HHS, in compliance with PL 115-92 Authorization Letter for DoD Medical Priorities, through an Interagency Agreement, signed April 23, 2020. As OWS products progress to clinical trials to evaluate the safety and efficacy of vaccines and therapeutics, it is critical that, in parallel, the USG supports large scale manufacturing so that vaccine doses or therapeutic treatment courses are immediately available for nationwide access as soon as a positive efficacy signal is obtained and the medical countermeasures are authorized for widespread use.

C.1.2 **Objective:** The objective of this effort is to obtain the following:

- a. Base Period: Large scale manufacturing of 100 million vaccine doses
- b. Option Period 1: Large scale manufacturing of 100 million vaccine doses
- c. Option Period 2: Large scale manufacturing of 100 million vaccine doses
- d. Option Period 3: Large scale manufacturing of 100 million vaccine doses
- e. Option Period 4: Large scale manufacturing of 100 million vaccine doses

The Base Period is 9 months, with overlapping options for a total of 20 months if all options are exercised.

C.2 **APPLICABLE DOCUMENTS.**

C.2.1 **Federal Documents:**

C.2.1.1 Title 21 Code of Federal Regulations (CFR), Food and Drugs: Part 210, Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs; General; and, Part 211, Current Good Manufacturing Practice In Manufacturing, Processing, Packing, or Holding of Drugs; General.

(https://www.ecfr.gov/cgi-bin/text-idx?SID=a95cab20f443897a400bb7e44a27cf4c&mc=true&tpl=/ecfrbrowse/Title21/21cfrv4_02.tpl#0)

C.3 **REQUIREMENTS.** Independently, and not as an agent of the USG, in accordance with the Proposal submitted by **Moderna US, Inc.** in response to Solicitation Number W911QY20R0043, Titled, "Advanced Procurement of mRNA-1273 Vaccine for Prevention of SARS-CoV-2 Coronavirus (COVID-19)", dated July 10, 2020 (and any subsequent USG-approved revisions thereto), the contractor shall provide all necessary services, qualified personnel, material, equipment and facilities (not otherwise provided by the USG under the terms of this contract) to perform the specific tasks set forth below.

C.3.1 **Contract Line Item Number (CLIN) 0001 - Base Period: Large Scale Manufacturing of 100 Million Vaccine Doses.**

C.3.1.1 The contractor shall complete all scope required for the production, release and delivery use of 100 million Final Drug Product (FDP) doses of a SARS-CoV-2 mRNA-1273 vaccine. This shall include, the following tasks and other activities reasonably contemplated by such task:

C.3.1.1.1 Storage of FDP doses prior to delivery consistent with all FDA requirements to ensure that the product remains available for use in target populations. Storage and maintenance of the vaccine prior to delivery shall be under conditions and at temperatures necessary to retain stability for use as prescribed in this contract for a period of 12 months. (Based on FDP stability data that supports a 12-month shelf-life, subject to FDA confirmation of the assigned shelf-life.) Ensure requirements of 21CFR207, Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution are met prior to distribution to the CDC. Documents shall be provided under CDRL A002, FDA Interactions and Inspections Documentation.

C.3.1.1.2 cGMP manufacturing of 100 million doses fully compliant with 21 CFR 210 and 211.

C.3.1.1.3 Ensuring that vial labeling and packaging is consistent with FDA guidance for use in target populations and that labeling is updated as appropriate.

C.3.1.1.4 Coordinating with FDA to establish an approved commercial vial label, carton and packaging insert (printed or electronic).

C.3.1.1.5 Ensuring the product complies with the Drug Supply Chain Security Act (DSCSA), Sections 581-585 of PL 113-54 (Nov. 27, 2013), including product verification, serialization, traceability and detection and response requirements, subject to any exceptions established by or the enforcement discretion of the FDA, including "Exemption from Certain Product Tracing and Product Identification Requirements Under Section 582 of the FD&C Act" (April 2020).

C.3.1.1.6 In coordination with the USG, the contractor shall conduct a demonstration of the vaccine shipping process prior to the first delivery of FDP doses at a time mutually agreed to by the contractor and the USG. Moderna shall provide specifications and details associated with the shipping process and containers (IAW CDRL A005) to enable the USG to adequately plan and prepare for potential distribution of the vaccine.

C.3.1.1.7 Following release of product the contractor shall, promptly deliver product to the designated delivery site via a qualified distribution vendor in accordance with Section F and paragraph C.7 below. In the unforeseen event that a designated delivery site cannot receive product and the contractor provides storage beyond 20 days of product release, the contract will be subject to modification for acceptance purposes.

C.3.1.2 **Site Visits and Audits.** The contractor shall accommodate periodic or ad hoc site visits by BARDA and FDA representatives for required site visits and audits at facilities used to support this contract throughout the period of performance of the contract.

C.3.1.2.1 **BARDA Audits.** If issues are identified during an audit, the contractor shall submit a report detailing the finding and corrective action(s) in accordance with CDRL A001.

C.3.1.2.2 FDA Audits. The Contractor shall notify the Contracting Officer and Contracting Officer's Representative (COR) within [***] of a scheduled FDA audit or within [***] of an ad hoc site visit or audit if the FDA does not provide advance notice. The contractor shall provide copies of any FDA Audit Report received from subcontractors that occur as a result of this contract or for this product within [***] of receiving correspondence from the FDA or third party in accordance with CDRL A002. The Contractor shall provide the Contracting Officer with a plan for addressing areas of nonconformance, if any are identified, within [***] of submittal of the audit report in accordance with CDRL A002.

C.3.1.2.3 FDA Interactions. The contractor shall provide copies of the plan and processes that will ensure the USG has visibility and input on all FDA communications regarding the drugs and biologics for the following, but not limited to: FDA interactions, FDA meetings, communications, submissions, inspections, and enforcement documentation in accordance with CDRL A002.

C.3.2 CLIN 1001 - Option Period 1: Large Scale Manufacturing of 100 Million Vaccine Doses.

C.3.2.1 The contractor shall complete all scope required for the production, release and delivery use of 100 million FDP doses of a SARS-CoV-2 mRNA-1273 vaccine. This shall include the following tasks and other activities reasonably contemplated by such tasks:

C.3.2.1.1 Storage of FDP doses prior to delivery consistent with all FDA requirements to ensure that the product remains available for use in target populations. Storage and maintenance of the vaccine prior to delivery shall be under conditions and at temperatures necessary to retain stability for use as prescribed in this contract for a period of 12 months. (Based on FDP stability data that supports a 12-month shelf-life, subject to FDA confirmation of the assigned shelf-life.) Ensure requirements of 21CFR207, Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution are met prior to distribution to the CDC. Documents shall be provided under CDRL A002, FDA Interactions and Inspections Documentation.

C.3.2.1.2 cGMP manufacturing of 100 million doses, subject to any exceptions established by or the enforcement discretion of the FDA.

C.3.2.1.3 Ensuring that vial labeling and packaging is consistent with FDA guidance for use in target populations and that labeling is updated.

C.3.2.1.4 Ensuring the product complies with the Drug Supply Chain Security Act (DSCSA), Sections 581-585 of PL 113-54 (Nov. 27, 2013), including product verification, serialization, traceability and detection and response requirements subject to any exceptions established by or the enforcement discretion of the FDA.

C.3.2.1.5 Following release of the product the contractor shall deliver the product to the designated distribution site via a qualified distribution vendor in accordance with Section F and paragraph C.7 below. To the extent a natural disaster or other emergency affecting a designated delivery site restricts such site's ability to receive product, the Contractor and the USG will promptly agree on an alternate USG delivery location, or storage as Vendor Managed Inventory (VMI) at the contractor site.

C.3.2.2 Site Visits and Audits. The contractor shall accommodate periodic or ad hoc site visits by BARDA and FDA representatives for required site visits and audits at facilities used to support this contract throughout the period of performance of the contract.

C.3.2.2.1 BARDA Audits. If issues are identified during an audit, the contractor shall submit a report detailing the finding and corrective action(s) in accordance with CDRL A001.

C.3.2.2.2 FDA Audits. The Contractor shall notify the Contracting Officer and COR within [***] of a scheduled FDA audit or within [***] of an ad hoc site visit or audit if the FDA does not provide advance notice. The contractor shall provide copies of any FDA Audit Report received from subcontractors that occur as a result of this contract or for this product within [***] of receiving correspondence from the FDA or third party in

accordance with CDRL A015. The Contractor shall provide the Contracting Officer with a plan for addressing areas of nonconformance, if any are identified, within [***] of submittal of the audit report in accordance with CDRL A002.

C.3.2.2.3 FDA Interactions. The contractor shall provide copies of the plan and processes that will ensure the USG has visibility and input on all FDA communications regarding the drugs and biologics for the following, but not limited to: FDA interactions, FDA meetings, communications, submissions, inspections, and enforcement documentation in accordance with CDRL A002.

C.3.3 CLIN 2001 - Option Period 2: Large Scale Manufacturing of 100 Million Vaccine Doses.

C.3.3.1 The contractor shall complete all scope required for the production, release and delivery use of 100 million FDP doses of a SARS-CoV-2 mRNA-1273 vaccine. This shall include the following tasks and other activities reasonably contemplated by such tasks:

C.3.3.1.1 Storage of FDP doses prior to delivery consistent with all FDA requirements to ensure that the product remains available for use in target populations. Storage and maintenance of the vaccine prior to delivery shall be under conditions and at temperatures necessary to retain stability for use as prescribed in this contract for a period of 12 months. (Based on FDP stability data that supports a 12-month shelf-life, subject to FDA confirmation of the assigned shelf-life.) Ensure requirements of 21CFR207, Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution are met prior to distribution to the CDC. Documents shall be provided under CDRL A002, FDA Interactions and Inspections Documentation.

C.3.3.1.2 cGMP manufacturing of 100 million doses, subject to any exceptions established by or the enforcement discretion of the FDA.

C.3.3.1.3 Ensuring that vial labeling and packaging is consistent with FDA guidance for use in target populations and that labeling is updated as appropriate.

C.3.3.1.4 Ensuring that the product complies with the Drug Supply Chain Security Act (DSCSA), Sections 581-585 of PL 113-54 (Nov. 27, 2013), including product verification, serialization, traceability and detection and response requirements, subject to any exceptions established by or the enforcement discretion of the FDA.

C.3.3.1.5 Following release the contractor shall deliver product to the nearest designated distribution site via a qualified distribution vendor in accordance with Section F and paragraph C.7 below. To the extent a natural disaster or other emergency affecting a designated delivery site restricts such site's ability to receive product, the Contractor and the USG will promptly agree on an alternate USG delivery location, or storage as Vendor Managed Inventory (VMI) at the contractor site.

C.3.3.2 Site Visits and Audits. The contractor shall accommodate periodic or ad hoc site visits by BARDA and FDA representatives for required site visits and audits at facilities used to support this contract throughout the period of performance of the contract.

C.3.3.2.1 BARDA Audits. If issues are identified during an audit, the contractor shall submit a report detailing the finding and corrective action(s) in accordance with CDRL A001.

C.3.3.2.2 FDA Audits. The Contractor shall notify the Contracting Officer and COR within [***] of a scheduled FDA audit or within [***] of an ad hoc site visit or audit if the FDA does not provide advance notice. The contractor shall provide copies of any FDA Audit Report received from subcontractors that occur as a result of this contract or for this product within [***] of receiving correspondence from the FDA or third party in accordance with CDRL A002. The Contractor shall provide the Contracting Officer with a plan for addressing areas of nonconformance, if any are identified, within [***] of submittal of the audit report in accordance with CDRL A002.

C.3.3.2.3 FDA Interactions. The contractor shall provide copies of the plan and processes that will ensure the USG has visibility and input on all FDA communications regarding the drugs and biologics for the following, but not limited to: FDA interactions, FDA meetings, communications, submissions, inspections, and enforcement documentation in accordance with CDRL A002.

C.3.4 CLIN 3001 - Option Period 3: Large Scale Manufacturing of 100 Million Vaccine Doses

C.3.4.1 The contractor shall complete all scope required for the production, release and delivery use of 100 million FDP doses of a SARS-CoV-2 mRNA-1273 vaccine. This shall include the following tasks and other activities reasonably contemplated by such tasks:

C.3.4.1.1 Storage of FDP doses prior to delivery consistent with all FDA requirements to ensure that the product remains available for use in target populations. Storage and maintenance of the vaccine prior to delivery shall be under conditions and at temperatures necessary to retain stability for use as prescribed in this contract for a period of 12 months. (Based on FDP stability data that supports a 12-month shelf-life, subject to FDA confirmation of the assigned shelf-life.) Ensure requirements of 21CFR207, Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution are met prior to distribution to the CDC. Documents shall be provided under CDRL A002, FDA Interactions and Inspections Documentation.

C.3.4.1.2 cGMP manufacturing of 100 million doses, subject to any exceptions established by or the enforcement discretion of the FDA.

C.3.4.1.3 Ensuring that vial labeling and packaging is consistent with FDA guidance for use in target populations and that labeling is updated.

C.3.4.1.4 Ensuring the product complies with the Drug Supply Chain Security Act (DSCSA), Sections 581-585 of PL 113-54 (Nov. 27, 2013), including product verification, serialization, traceability and detection and response requirements subject to any exceptions established by or the enforcement discretion of the FDA.

C.3.4.1.5 Following release of the product the contractor shall deliver the product to the designated distribution site via a qualified distribution vendor in accordance with Section F and paragraph C.7 below. To the extent a natural disaster or other emergency affecting a designated delivery site restricts such site's ability to receive product, the Contractor and the USG will promptly agree on an alternate USG delivery location, or storage as Vendor Managed Inventory (VMI) at the contractor site.

C.3.4.2 Site Visits and Audits. The contractor shall accommodate periodic or ad hoc site visits by BARDA and FDA representatives for required site visits and audits at facilities used to support this contract throughout the period of performance of the contract.

C.3.4.2.1 BARDA Audits. If issues are identified during an audit, the contractor shall submit a report detailing the finding and corrective action(s) in accordance with CDRL A001.

C.3.4.2.2 FDA Audits. The Contractor shall notify the Contracting Officer and COR within [***] of a scheduled FDA audit or within [***] of an ad hoc site visit or audit if the FDA does not provide advance notice. The contractor shall provide copies of any FDA Audit Report received from subcontractors that occur as a result of this contract or for this product within [***] of receiving correspondence from the FDA or third party in accordance with CDRL A015. The Contractor shall provide the Contracting Officer with a plan for addressing areas of nonconformance, if any are identified, within [***] of submittal of the audit report in accordance with CDRL A002.

C.3.4.2.3 FDA Interactions. The contractor shall provide copies of the plan and processes that will ensure the USG has visibility and input on all FDA communications regarding mRNA-1273 for the following, but not limited to: FDA interactions, FDA meetings, communications, submissions, inspections, and enforcement documentation in accordance with CDRL A002.

C.3.5 CLIN 4001 - Option Period 4: Large Scale Manufacturing of 100 Million Vaccine Doses.

C.3.5.1 The contractor shall complete all scope required for the production, release and delivery use of 100 million FDP doses of a SARS-CoV-2 mRNA-1273 vaccine. This shall include the following tasks and other activities reasonably contemplated by such tasks:

C.3.5.1.1 Storage of FDP doses prior to delivery consistent with all FDA requirements to ensure that the product remains available for use in target populations. Storage and maintenance of the vaccine prior to delivery shall be under conditions and at temperatures necessary to retain stability for use as prescribed in this contract for a period of 12 months. (Based on FDP stability data that supports a 12-month shelf-life, subject to FDA confirmation of the assigned shelf-life.) Ensure requirements of 21CFR207, Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution are met prior to distribution to the CDC. Documents shall be provided under CDRL A002, FDA Interactions and Inspections Documentation.

C.3.5.1.2 cGMP manufacturing of 100 million doses, subject to any exceptions established by or the enforcement discretion of the FDA.

C.3.5.1.3 Ensuring that vial labeling and packaging is consistent with FDA guidance for use in target populations and that labeling is updated.

C.3.5.1.4 Ensuring the product complies with the Drug Supply Chain Security Act (DSCSA), Sections 581-585 of PL 113-54 (Nov. 27, 2013), including product verification, serialization, traceability and detection and response requirements subject to any exceptions established by or the enforcement discretion of the FDA.

C.3.5.1.5 Following release of the product the contractor shall deliver the product to the designated distribution site via a qualified distribution vendor in accordance with Section F and paragraph C.7 below. To the extent a natural disaster or other emergency affecting a designated delivery site restricts such site's ability to receive product, the Contractor and the USG will promptly agree on an alternate USG delivery location, or storage as Vendor Managed Inventory (VMI) at the contractor site.

C.3.5.2 Site Visits and Audits. The contractor shall accommodate periodic or ad hoc site visits by BARDA and FDA representatives for required site visits and audits at facilities used to support this contract throughout the period of performance of the contract.

C.3.5.2.1 BARDA Audits. If issues are identified during an audit, the contractor shall submit a report detailing the finding and corrective action(s) in accordance with CDRL A001.

C.3.5.2.2 FDA Audits. The Contractor shall notify the Contracting Officer and COR within [***] of a scheduled FDA audit or within [***] of an ad hoc site visit or audit if the FDA does not provide advance notice. The contractor shall provide copies of any FDA Audit Report received from subcontractors that occur as a result of this contract or for this product within [***] of receiving correspondence from the FDA or third party in accordance with CDRL A015. The Contractor shall provide the Contracting Officer with a plan for addressing areas of nonconformance, if any are identified, within [***] of submittal of the audit report in accordance with CDRL A002.

C.3.5.2.3 FDA Interactions. The contractor shall provide copies of the plan and processes that will ensure the USG has visibility and input on all FDA communications regarding the drugs and biologics for the following, but not limited to: FDA interactions, FDA meetings, communications, submissions, inspections, and enforcement documentation in accordance with CDRL A002.

C.4 CLIN 0002: Data Deliverables. The contractor shall provide the following in accordance with the Contract Data Requirements List (CDRL), DD Forms 1423, provided at Appendix A.

C.4.1 Monthly Inventory Report (CDRL A003), detailing at a minimum, raw materials, Bulk mRNA, formulated LNPs, and the fill, finish, and released product.

C.4.2 Quality Management Plan. The contractor shall provide a Quality Management Plan, in accordance with CDRL A004, describing the quality policy and objectives, management review, competencies and training, process document control, feedback, evaluation, corrective action and preventive action, process improvement, measurement, and data analysis processes. The framework is normally divided into infrastructure, senior management responsibility, resource management, lifecycle management, and quality management system evaluation.

C.4.3 Shipping Documentation (CDRL A005) for all Finished Drug Product (FDP) transferring from the contractor's fill/finish facility to a USG facility. The contractor shall obtain concurrence on planned shipment protocols prior to transport.

C.4.4 Expiring Items Report (CDRL A006) for all FDP in the USG's possession.

C.4.5 Key Personnel Listing (CDRL A007).

C.4.6 Monthly Technical Progress Report (CDRL A008), to include an Integrated Master Schedule, identifying key activities and contract status.

C.4.7 Final Technical Report (CDRL A009), documenting the work performed and results obtained for the entire contract period of performance.

C.4.8 Supply Chain Resiliency Plan (SCRCP). The contractor shall provide, in accordance with CDRL A010 and CDRL Attachment 0001, a comprehensive SCRCP that provides for identification and reporting of critical components associated with the secure supply of drug substance, drug product, and work-in-process through to finished goods, and key equipment suppliers and their locations, including addresses, points of contact, and work performed per location, to include subcontractors.

C.4.9 Risk Management Plan (RMP). The Contractor shall provide an RMP in accordance with CDRL A011 that outlines the impacts of each risk in relation to the cost, schedule, and performance objectives. The plan shall include risk mitigation strategies. Each risk mitigation strategy shall capture how the corrective action will reduce impacts on cost, schedule and performance.

C.4.10 Manufacturing Reports and Dose Tracking. The Contractor shall provide, in accordance with CDRL A013, manufacturing reports and manufacturing dose tracking projections and actuals utilizing the USG-provided "COVID-19 Dose Tracking Template" (CDRL Attachment 0003).

C.4.11 Product Acceptance Report (for each lot of Drug Product). The contractor shall provide, in accordance with CDRL A014, pictures of the drug product with lot number, drug product lot tree, list of associated deviations (from drug substance and product), and a Certificate of Analysis.

C.4.12 Incident Report. The contractor shall communicate to BARDA and document all critical programmatic concerns, issues, or probable risks that have or are likely to significantly impact project schedule and/or cost and/or performance in accordance with CDRL A016. "Significant" is frequently defined as a 10% or greater cost or schedule variance within a control account, but should be confirmed in consultation with the COR. Incidents that present liability to the project even without cost/schedule impact, such as breach of GCP during a clinical study, shall also be reported.

C.4.13 FDA Correspondence. The contractor shall provide any correspondence between Contractor and FDA relevant to the scope of this contract and submit in accordance with CDRL A017.

C.4.14 Press Releases. The contractor shall accurately and factually represent the work conducted under this contract in all press releases. The contractor shall provide an advance copy of any press release in accordance with CDRL A018.

C.4.15 **Manufacturing Development Plan.** The contractor shall provide a Manufacturing Development Plan, in accordance with CDRL A025, describing the manufacturing process for the drug/biologic product to ensure conformity with §501(a)(2)(B) of the Food, Drug, and Cosmetics Act (FD&C Act, Title 21 United States Code (USC) §351 (a)(2)(B)), regarding good manufacturing practices (GMP).

C.5 Administration.

C.5.1 **Post Award Teleconference.** The contractor shall host a Post Award Teleconference within 15 7 calendar days after contract award.

C.5.1.1 The contractor shall provide an Agenda, IAW CDRL A020, detailing the planned activities for the subsequent 30 calendar days and shall discuss agenda items for the Post Award Kickoff Meeting.

C.5.1.2 The contractor shall provide Meeting Minutes IAW CDRL A021.

C.5.2 **Post Award Kickoff Meeting.** The contracting officer may request the contractor host a contract Kick-Off Meeting within 30 calendar days after contract award via teleconference. The contracting officer shall establish the date and time of the conference and prepare the agenda to include discussion on contract activities and schedule.

C.5.3 **Bi-Weekly Teleconference.** The contractor shall participate in bi-weekly teleconferences (or more frequent meetings required by the USG if warranted based on contract activities) to discuss performance on the contract.

C.5.4 The contractor shall provide an Agenda, IAW CDRL A020; Meeting Minutes in accordance with CDRL A021; and, Presentation Material in accordance with CDRL A022 for each of the aforementioned teleconferences or meetings throughout the contract period of performance.

C.5.5 **Daily "Check-In".** The contractor shall participate in a daily "check-in" (via teleconference or email) to address key cost, schedule and technical updates. Daily updates may be shared with senior USG leaders during the COVID- 19 response and should be provided on a non-confidential basis, unless the update includes confidential information in which case, the contractor shall provide the update in both confidential and non-confidential formats. Daily check-ins may occur on weekdays, excluding federal holidays. Upon request of the USG, check-ins may also occur on weekends and on federal holidays, provided at least 24 hours' notice.

C.6 Security.

C.6.1 **Access and General Protection/Security Policy and Procedures.** The contractor shall provide all information required for background checks necessary to access critical information related to OWS, and to meet USG installation access requirements to be accomplished by the installation Director of Emergency Services or Security Office. The contractor employees shall comply with all personnel identity verification requirements as directed by the USG and/or local policy. In addition to the changes otherwise authorized by the changes clause of this contract, should the security status of OWS change the USG may require changes in the contractor's security matters or processes. In addition to the industry standards for employment background checks, the contractor shall be willing to have key individuals, in exceptionally sensitive positions, identified for additional vetting by the United States USG.

C.6.2 **Security Program and Plan.** The contractor shall implement a comprehensive security program that provides overall protection of personnel, information, data, and facilities associated with fulfilling the USG's requirement. The contractor's security practices and procedures shall be detailed in a Security Plan, in accordance with CDRL A019, and shall demonstrate how the contractor shall meet and adhere to the security requirements outlined in CDRL Attachment 0002. This plan shall be delivered to the USG within 45 days of award, and the USG will review in detail and submit comments within ten (10) business days to the Contracting Officer (CO) to be forwarded to the Contractor. The Contractor shall review the Security Plan comments, and, submit a final Security Plan to the U.S. USG within thirty (30) calendar days after receipt of the comments. The Security Plan shall include a timeline for compliance of all the required security measures outlined in CDRL Attachment 0002.

C.6.3 Operational Security (OPSEC). The contractor shall develop and submit an OPSEC Standard Operating Procedure (SOP)/Plan IAW CDRL A024. The contractor shall identify in the SOP/Plan critical information related to this contract, why it needs to be protected, where it is located, who is responsible for it, and how to protect it.

C.7 **CLIN 0002 Vendor Managed Inventory (VMI)**. The Contractor shall provide the capability to store the vaccine for up to 52 weeks, up to 100M doses of mRNA-1273 vaccine, in accordance with product labeling. The contractor shall, in accordance with paragraph C.3.1.1.6, ensure the product storage of FDP doses for up to 12 months prior to delivery consistent with all FDA requirements to ensure that the product remains available for use in target populations. [***] The contractor shall store the product to insure product quality with audible alarms and contacting. The contractor shall notify the USG within [***] of detection of an incident with the potential to impact product quality, and implement corrective actions to mitigate the incident. . BARDA/JPEO- CBRND personnel may conduct Quality Audits of the storage facility, when deemed necessary. The contractor shall notify the USG of Corrective/Preventive actions within [***] of detection of an incident with potential to impacts product quality. BARDA/JPEO-CBRND personnel may conduct Quality Audits of the storage facility, when deemed necessary.

C.7.1 The USG will provide the contractor advance notice of the required delivery locations for the vaccine. The contractor shall ship mRNA-1273 vaccines to designated locations in up to [***] in the United States. The contractor shall be responsible for shipment of all vaccine product whether acceptance is conducted at origin or destination. [***]

C.7.2 The vaccine product shall be shipped and tracked by the distribution vendor's shipping tracking number, to the USG-designated sites within the continental United States.

C.7.3 [***] Implementation of a Vendor Managed Inventory Plan/SOP (CDRL A012) shall be provided to the USG. [***] Notwithstanding either of the foregoing sentences, the contractor shall not be liable for loss of or damage to supplies caused by the negligence of officers, agents, or employees of the USG acting within the scope of their employment.

SECTION G - CONTRACT ADMINISTRATION DATA

The following have been modified:

G.1 GOVERNMENT CONTRACT ADMINISTRATION

In no event shall any understanding or agreement, contract modification, change order, or other matter in deviation from the terms of this contract between the Contractor and a person other than the Contracting Officer be effective or binding upon the Government. All such actions must be formalized by a proper contractual document executed by the Contracting Officer.

Procuring Contracting Officer:
Camille Connell-Magaw / [***] / [***]
[***]
[***]

Contract Specialist:
Danny Soto / [***] / [***]
[***]
[***]

G.2 GOVERNMENT TECHNICAL POINT OF CONTACT

Marva Taylor / [***] / [***]
Biologist/Project Officer
[***]
[***]

G.3 CONTRACTOR'S CONTRACT ADMINISTRATION

[***]
ModernaTX, Inc.
200 Technology SQ.
Cambridge, MA 02139-3578

G.4 PLACES OF PERFORMANCE

Moderna US, Inc.
200 Technology SQ.
Cambridge, MA 02139-3578

G.5 NOTIFICATION OF REVISIONS AND CHANGE

Notification of revision or changes to names or email addresses will be provided by official correspondence from the PCO/ACO or office of the PCO/ACO in lieu of a contract modification. This does not apply to any such revisions or changes in the event this contract includes a key personnel clause.

G.6 PERFORMANCE BASED PAYMENT

Performance-based payments (PBP) are authorized under this contract in accordance with FAR 52.232-32. The contractor shall bill for the PBP upon achievement of the completion criteria identified in Attachment 0007, Performance-based Payment Milestone Table. Upon achievement of the completion criteria, the contractor shall bill for the PBP for the base and each option IAW the following schedule:

CLIN	PERIOD	AMOUNT
0001AA	BASE	\$ 90,210,000
0001AB	BASE	\$ 132,308,000
0001AC	BASE	\$ 180,420,000
0001AD	BASE	\$ 198,462,000
TOTAL		\$ 601,400,000
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]		[***]
[***]	[***]	[***]

***	***	***
***	***	***
***		***

Delivery Invoicing: PBPs are a type of contract financing and are recouped by the Government through deductions of payments otherwise due to the contractor for the partial or complete delivery of contract items. The deductions are made by applying a liquidation rate to the price of delivered contract items. Attachment 0008, Performance-based Payment Milestone Billing Plan, identifies the contractor invoicing schedule for liquidation. The contractor shall submit all invoices IAW Attachment 0008.

252.232-7006 WIDE AREA WORKFLOW PAYMENT INSTRUCTIONS (DEC 2018)

(a) Definitions. As used in this clause--

“Department of Defense Activity Address Code (DoDAAC)” is a six position code that uniquely identifies a unit, activity, or organization.

“Document type” means the type of payment request or receiving report available for creation in Wide Area WorkFlow (WAWF).

“Local processing office (LPO)” is the office responsible for payment certification when payment certification is done external to the entitlement system.

“Payment request” and “receiving report” are defined in the clause at 252.232-7003, Electronic Submission of Payment Requests and Receiving Reports.

(b) Electronic invoicing. The WAWF system provides the method to electronically process vendor payment requests and receiving reports, as authorized by Defense Federal Acquisition Regulation Supplement (DFARS) 252.232-7003, Electronic Submission of Payment Requests and Receiving Reports.

(c) WAWF access. To access WAWF, the Contractor shall—

(1) Have a designated electronic business point of contact in the System for Award Management at <https://www.sam.gov>; and

(2) Be registered to use WAWF at <https://wawf.eb.mil/> following the step-by-step procedures for self-registration available at this web site.

(d) WAWF training. The Contractor should follow the training instructions of the WAWF Web-Based Training Course and use the Practice Training Site before submitting payment requests through WAWF. Both can be accessed by selecting the “Web Based Training” link on the WAWF home page at <https://wawf.eb.mil/>.

(e) WAWF methods of document submission. Document submissions may be via web entry, Electronic Data Interchange, or File Transfer Protocol.

(f) WAWF payment instructions. The Contractor shall use the following information when submitting payment requests and receiving reports in WAWF for this contract or task or delivery order:

(1) Document type. The Contractor shall submit payment requests using the following document type(s):

COMBO

(ii) For fixed price line items—

(A) That require shipment of a deliverable, submit the invoice and receiving report specified by the Contracting Officer.

Invoice and receiving report document type

(B) For services that do not require shipment of a deliverable, submit either the Invoice 2in1, which meets the requirements for the invoice and receiving report, or the applicable invoice and receiving report, as specified by the Contracting Officer.

N/A

(iii) For customary progress payments based on costs incurred, submit a progress payment request.

(iv) For performance based payments, submit a performance based payment request.

(v) For commercial item financing, submit a commercial item financing request.

(2) Fast Pay requests are only permitted when Federal Acquisition Regulation (FAR) 52.213-1 is included in the contract.

(3) Document routing. The Contractor shall use the information in the Routing Data Table below only to fill in applicable fields in WAWF when creating payment requests and receiving reports in the system.

Routing Data Table

<i>Field Name in WAWF</i>	<i>Data to be entered in WAWF</i>
Pay Official DoDAAC	HQ0337
Issue By DoDAAC	W911QY
Admin DoDAAC**	S2206A
Inspect By DoDAAC	W911QY / BARDA
Acceptor	W911QY
Ship To	TDB

(4) Payment request. The Contractor shall ensure a payment request includes documentation appropriate to the type of payment request in accordance with the payment clause, contract financing clause, or Federal Acquisition Regulation 52.216-7, Allowable Cost and Payment, as applicable.

(5) Receiving report. The Contractor shall ensure a receiving report meets the requirements of DFARS Appendix F.

(g) WAWF point of contact.

(1) The Contractor may obtain clarification regarding invoicing in WAWF from the following contracting activity's WAWF point of contact.

Orlando Ortiz / DCMA Boston-AFAW, Administrative Contracting Officer / [***]

(2) Contact the WAWF helpdesk at 866-618-5988, if assistance is needed.

(End of clause)

FOR REFERENCE:

DFARS PGI 204.7108 Payment Instructions Table

https://www.acq.osd.mil/dpap/dars/pgi/pgi_html/current/PGI204_71.htm#payment_instructions

SECTION I - CONTRACT CLAUSES

The following have been added by reference:

52.204-25	Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment.	AUG 2020
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The following have been modified:

252.232-7007 LIMITATION OF GOVERNMENT'S OBLIGATION (APR 2014)

(a) Contract line item 0003 is incrementally funded. For this item, the sum of \$0.00 of the total price is presently available for payment and allotted to this contract. An allotment schedule is set forth in paragraph (j) of this clause.

(b) For item(s) identified in paragraph (a) of this clause, the Contractor agrees to perform up to the point at which the total amount payable by the Government, including reimbursement in the event of termination of those item(s) for the Government's convenience, approximates the total amount currently allotted to the contract. The Contractor is not authorized to continue work on those item(s) beyond that point. The Government will not be obligated in any event to reimburse the Contractor in excess of the amount allotted to the contract for those item(s) regardless of anything to the contrary in the clause entitled "TERMINATION FOR THE CONVENIENCE OF THE GOVERNMENT." As used in this clause, the total amount payable by the Government in the event of termination of applicable contract line item(s) for convenience includes costs, profit and estimated termination settlement costs for those item(s).

- (c) Notwithstanding the dates specified in the allotment schedule in paragraph (j) of this clause, the Contractor will notify the Contracting Officer in writing at least ninety days prior to the date when, in the Contractor's best judgment, the work will reach the point at which the total amount payable by the Government, including any cost for termination for convenience, will approximate 85 percent of the total amount then allotted to the contract for performance of the applicable item(s). The notification will state (1) the estimated date when that point will be reached and (2) an estimate of additional funding, if any, needed to continue performance of applicable line items up to the next scheduled date for allotment of funds identified in paragraph (j) of this clause, or to a mutually agreed upon substitute date. The notification will also advise the Contracting Officer of the estimated amount of additional funds that will be required for the timely performance of the item(s) funded pursuant to this clause, for subsequent period as may be specified in the allotment schedule in paragraph (j) of this clause, or otherwise agreed to by the parties. If after such notification additional funds are not allotted by the date identified in the Contractor's notification, or by an agreed substitute date, the Contracting Officer will terminate any item(s) for which additional funds have not been allotted, pursuant to the clause of this contract entitled "TERMINATION FOR THE CONVENIENCE OF THE GOVERNMENT".
- (d) When additional funds are allotted for continued performance of the contract line item(s) identified in paragraph (a) of this clause, the parties will agree as to the period of contract performance which will be covered by the funds. The provisions of paragraph (b) through (d) of this clause will apply in like manner to the additional allotted funds and agreed substitute date, and the contract will be modified accordingly.
- (e) If, solely by reason of failure of the Government to allot additional funds, by the dates indicated below, in amounts sufficient for timely performance of the contract line item(s) identified in paragraph (a) of this clause, the Contractor incurs additional costs or is delayed in the performance of the work under this contract and if additional funds are allotted, an equitable adjustment will be made in the price or prices (including appropriate target, billing, and ceiling prices where applicable) of the item(s), or in the time of delivery, or both. Failure to agree to any such equitable adjustment hereunder will be a dispute concerning a question of fact within the meaning of the clause entitled "disputes."
- (f) The Government may at any time prior to termination allot additional funds for the performance of the contract line item(s) identified in paragraph (a) of this clause.
- (g) The termination provisions of this clause do not limit the rights of the Government under the clause entitled "DEFAULT." The provisions of this clause are limited to work and allotment of funds for the contract line item(s) set forth in paragraph (a) of this clause. This clause no longer applies once the contract is fully funded except with regard to the rights or obligations of the parties concerning equitable adjustments negotiated under paragraphs (d) or (e) of this clause.
- (h) Nothing in this clause affects the right of the Government to this contract pursuant to the clause of this contract entitled "TERMINATION FOR CONVENIENCE OF THE GOVERNMENT."
- (i) Nothing in this clause shall be construed as authorization of voluntary services whose acceptance is otherwise prohibited under 31 U.S.C. 1342.
-

(j) The parties contemplate that the Government will allot funds to this contract in accordance with the following schedule:

On execution of contract \$0.00

Upon successful completion of CLIN 0003 \$300,000,000

(End of clause)

SECTION J - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

The following have been modified:

Document Type	Description	Page #	Date
Exhibit A	CDRLs	15	18 July 2020
Attachment 0001	Supply Chain Resiliency Plan for CDRL A010	3	23 July 2020
Attachment 0002	Security Plan	7	23 July 2020
Attachment 0003	Dose Tracking Template Draft Moderna	Excel	15 July 2020
Attachment 0004	Data Rights	3	7 August 2020
Attachment 0005	***]	2	7 August 2020
Attachment 0006	ModernaTx, Inc. Background Intellectual Property	3	6 August 2020
Attachment 0007	Performance Base Payment Milestone Schedule	2	7 August 2020
Attachment 0008	Performance Base Payment Milestone Billing Plan	16	7 August 2020

(End of Summary of Changes)

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT		1. CONTRACT ID CODE	PAGE OF PAGES
		1	3

2. AMENDMENT/MODIFICATION NO.	EFFECTIVE DATE 11-Sep-2020	4. REQUISITION/PURCHASE REQ. NO. 0011534693
6. ISSUED BY W6QK ACC-APG NATICK DIVISION BLDG 1 GENERAL GREENE AVENUE NATICK MA 01760-5011	CODE W911QY	5. PROJECT NO. (If applicable)
	7. ADMINISTERED BY (If other than item 6) DEFENSE CONTRACT MANAGEMENT AGENCY DCMA BOSTON 495 SUMMER STREET BOSTON MA 02210-2138	CODE S2206A

8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code) MODERNA US, INC. [***] 200 TECHNOLOGY SQ CAMBRIDGE MA 02139-3578	9A. AMENDMENT OF SOLICITATION NO. 9B. DATED (SEE ITEM 11) X 10A. MOD. OF CONTRACT/ORDER NO. W911QY20C0100 10B. DATED (SEE ITEM 13) X 09-Aug-2020
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CODE 8PTM0	FACILITY CODE	
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11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offer is extended, is not extended.

Offer must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended by one of the following methods:
(a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required)

13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS.
IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.

B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(B).

X C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:
45 CFR part 101, Health Resources and Priorities Allocations System (HRPAS)

D. OTHER (Specify type of modification and authority)

E. IMPORTANT: Contractor is not, X is required to sign this document and return 1 copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)
Modification Control Number: tscott202802

OBLIGATION AMOUNT: \$0.00

See Block 14 continuation page

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (Type or print) Stephane BANCEL, CEO	16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print) Christine F. Sordillo [***] TEL: [***] EMAIL:
15B. CONTRACTOR/OFFEROR	16B. UNITED STATES OF AMERICA
15C. DATE SIGNED 9/10/2020	16C. DATE SIGNED 11 Sept 2020

/s/ Stephane Bancel (Signature of person authorized to sign)	BY /s/ Christine F. Sordillo (Signature of Contracting Officer)	
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EXCEPTION TO SF 30 APPROVED BY OIRM 11-84	30-105-04	STANDARD FORM 30 (Rev. 10-83) Prescribed by GSA FAR (48 CFR) 53.243
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SECTION SF 30 BLOCK 14 CONTINUATION PAGE

SUMMARY OF CHANGES

SECTION SF 30 - BLOCK 14 CONTINUATION PAGE

The following have been added by full text:

The purpose of this modification is to:

1. Add a Health Resources Priorities and Allocations System (HRPAS) priority rating of DO-HR to this contract:

This is a DO rated contract for the purpose of emergency preparedness and the Contractor shall follow all the provisions of the Health Resources Priorities and Allocations System regulation (45 CFR Part 101). If the contractor needs to utilize industrial resources to fulfill this rated order for a health resource, it is authorized pursuant to 45 CFR §101.36(b) to place the same priority rating and program identification symbol for health resources on its orders for industrial resources with its suppliers.

2. Add a Defense Priorities and Allocation System (DPAS) priority rating of DO-C9 to this contract to act as the equivalent to the HRPAS priority rating of DO-HR.
3. Add FAR 52.211-15, Defense Priority and Allocation Requirements

This is a rated order certified for national defense, emergency preparedness, and energy program use, and the Contractor shall follow all the requirements of the Defense Priorities and Allocations System regulation (15 CFR 700).

4. Add Attachment 0009 - HRPAS Moderna Letter to Section J

The total funded amount and total contract price remain unchanged.

SECTION A - SOLICITATION/CONTRACT FORM

The DPAS code DO-C9 has been added.

The contractor organization has changed from

MODERNATX, INC.

[***]

200 TECHNOLOGY SQ
CAMBRIDGE MA 02139-3578

to

MODERNA US, INC.

[***]

200 TECHNOLOGY SQ
CAMBRIDGE MA 02139-3578

SECTION I - CONTRACT CLAUSES

The following have been added by full text:

52.211-15 DEFENSE PRIORITY AND ALLOCATION REQUIREMENTS (APR 2008)

This is a rated order certified for national defense, emergency preparedness, and energy program use, and the Contractor shall follow all the requirements of the Defense Priorities and Allocations System regulation (15 CFR 700).

(End of clause)

SECTION J - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

The following have been modified:

Document Type	Description	Page #	Date
Exhibit A	CDRLs	15	18 July 2020
Attachment 0001	Supply Chain Resiliency Plan for CDRL A010	3	23 July 2020
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Attachment 0007	Performance Base Payment Milestone Schedule	2	7 August 2020
Attachment 0008	Performance Base Payment Milestone Billing Plan	16	7 August 2020
Attachment 0009	HRPAS Moderna Letter	1	3 September 2020

(End of Summary of Changes)

CERTIFICATION PURSUANT TO RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

CERTIFICATIONS

I, Stéphane Bancel, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Moderna, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: October 30, 2020

By: /s/ Stéphane Bancel

Stéphane Bancel

Chief Executive Officer

(Principal Executive Officer)

CERTIFICATION PURSUANT TO RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

CERTIFICATIONS

I, David W. Meline, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Moderna, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: October 30, 2020

By: /s/ David W. Meline
 David W. Meline
 Chief Financial Officer
 (Principal Financial Officer)

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350
AS ADOPTED PURSUANT TO SECTION 906
OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report on Form 10-Q of Moderna, Inc. (the “Company”) for the period ended September 30, 2020 as filed with the Securities and Exchange Commission on the date hereof (the “Report”), we, Stéphane Bancel, Chief Executive Officer of the Company, and David W. Meline, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of our knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: October 30, 2020

By: /s/ Stéphane Bancel
Stéphane Bancel
Chief Executive Officer
(Principal Executive Officer)

Date: October 30, 2020

By: /s/ David W. Meline
David W. Meline
Chief Financial Officer
(Principal Financial Officer)