UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the quarterly period ended June 30, 2021

OR

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

Moderna, Inc.

(Exact Name of Registrant as Specified in Its Charter)

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

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

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

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

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

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

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

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). **Yes** ☐ **No** ☒

As of July 30, 2021, there were 403,646,312 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:

- our activities with respect to our COVID-19 vaccine, and our plans and expectations regarding future generations of our COVID-19 vaccine, including boosters, that we may develop in response to variants of the SARS-CoV-2 virus, ongoing clinical development, manufacturing and supply, pricing, commercialization, if approved, regulatory matters (including dosage for vaccines and authorization or approval for boosters) and third-party and governmental arrangements and potential arrangements;

- our ability to contract with third-party suppliers and manufacturers and their ability to perform adequately, particularly with respect to the timely production and delivery of our COVID-19 vaccine, including any variant booster vaccine candidate, if authorized;

- our ability and the ability of third parties with whom we contract to successfully manufacture our commercial products at scale, as well as drug substances, delivery vehicles, development candidates, and investigational medicines for preclinical and clinical use;

- the scope of protection we are able to establish and maintain for intellectual property rights covering our commercial products, investigational medicines and technology;

- the initiation, timing, progress, results, and cost of our research and development programs and our current and future preclinical studies and clinical trials, including statements regarding the timing of initiation and completion of studies or trials and related preparatory work, the period during which the results of the trials will become available, and our research and development programs;

- the 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 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 our COVID-19 vaccine efforts, particularly 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;

- the ability and willingness of our third-party strategic collaborators to continue research and development activities relating to our development candidates and investigational medicines;

- our ability to obtain and maintain regulatory approval of our investigational medicines;

- our ability to successfully commercialize any future 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;
- 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, and commercialization expertise;
- future agreements with third parties in connection with the 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 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 discussed 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 millions, except per share data)

	June 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 5,603	$ 2,624
Investments	2,387	1,984
Accounts receivable	2,020	1,391
Inventory	643	47
Prepaid expenses and other current assets	316	252
Total current assets	10,969	6,298
Investments, non-current	4,207	639
Property and equipment, net	794	297
Right-of-use assets, operating leases	104	90
Restricted cash, non-current	11	11
Deferred tax assets	66	—
Other non-current assets	2	2
Total assets	$ 16,153	$ 7,337
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 77	$ 18
Accrued liabilities	848	470
Deferred revenue	7,302	3,867
Other current liabilities	613	34
Total current liabilities	8,840	4,389
Deferred revenue, non-current	175	177
Operating lease liabilities, non-current	105	97
Financing lease liabilities, non-current	328	110
Other non-current liabilities	1	3
Total liabilities	9,449	4,776
Commitments and contingencies (Note 12)		
Stockholders' equity:		
Preferred stock, par value $0.0001; 162 shares authorized as of June 30, 2021 and December 31, 2020; no shares issued or outstanding at June 30, 2021 and December 31, 2020	—	—
Common stock, par value $0.0001; 1,600 shares authorized as of June 30, 2021 and December 31, 2020; 403 and 399 shares issued and outstanding as of June 30, 2021 and December 31, 2020, respectively	—	—
Additional paid-in capital	4,931	4,802
Accumulated other comprehensive income	16	3
Retained earnings (accumulated deficit)	1,757	(2,244)
Total stockholders' equity	6,704	2,561
Total liabilities and stockholders' equity	$ 16,153	$ 7,337

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Revenue:				
Product sales	$ 4,197	$ —	$ 5,930	$ —
Grant revenue	139	38	333	42
Collaboration revenue	18	29	28	33
Total revenue	4,354	67	6,291	75
Operating expenses:				
Cost of sales	750	—	943	—
Research and development	421	152	822	267
Selling, general and administrative	121	37	198	61
Total operating expenses	1,292	189	1,963	328
Income (loss) from operations	3,062	(122)	4,328	(253)
Interest income	3	7	7	15
Other expense, net	(2)	(2)	(12)	(3)
Income (loss) before income taxes	3,063	(117)	4,323	(241)
Provision for income taxes	283	—	322	—
Net income (loss)	$ 2,780	$ (117)	$ 4,001	$ (241)
Earnings (loss) per share:				
Basic	$ 6.93	$ (0.31)	$ 9.98	$ (0.66)
Diluted	$ 6.46	$ (0.31)	$ 9.30	$ (0.66)
Weighted average common shares used in calculation of earnings (loss) per share:				
Basic	402	381	401	367
Diluted	431	381	430	367

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Net income (loss)	$ 2,780	$ (117)	$ 4,001	$ (241)
Other comprehensive income (loss), net of taxes:				
Available-for-sales securities:				
Unrealized (losses) gains on available-for-sale debt securities	(5)	13	(7)	5
Less: net realized (gains) losses on available-for-sale securities reclassified in net income (loss)	(1)	1	(1)	1
Net (decrease) increase from available-for-sale debt securities	(6)	14	(8)	6
Cash flow hedges:				
Unrealized gains on derivative instruments	21	—	21	—
Total other comprehensive income	15	14	13	6
Comprehensive income (loss)	$ 2,795	$ (103)	$ 4,014	$ (235)

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

MODERNA, INC.
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
FOR THE THREE MONTHS AND SIX MONTHS ENDED JUNE 30, 2021 AND 2020
(Unaudited, in millions)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Retained Earnings (Accumulated Deficit)	Total Stockholders' Equity
	Shares	Amount				
Balance at March 31, 2021	401	$ —	$ 4,860	$ 1	$ (1,023)	$ 3,838
Exercise of options to purchase common stock	2	—	31	—	—	31
Purchase of common stock under employee stock purchase plan	—	—	5	—	—	5
Stock-based compensation	—	—	35	—	—	35
Other comprehensive income, net of tax	—	—	—	15	—	15
Net income	—	—	—	—	2,780	2,780
Balance at June 30, 2021	403	$ —	$ 4,931	$ 16	$ 1,757	$ 6,704

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at March 31, 2020	370	$ —	$ 3,268	$ (6)	$ (1,621)	$ 1,641
Proceeds from public offering of common stock, net of issuance costs of $1	18	—	1,303	—	—	1,303
Exercise of options to purchase common stock	5	—	78	—	—	78
Purchase of common stock under employee stock purchase plan	—	—	3	—	—	3
Stock-based compensation	—	—	25	—	—	25
Other comprehensive income, net of tax	—	—	—	14	—	14
Net loss	—	—	—	—	(117)	(117)
Balance at June 30, 2020	393	$ —	$ 4,677	$ 8	$ (1,738)	$ 2,947

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Retained Earnings (Accumulated Deficit)	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2020	399	$ —	$ 4,802	$ 3	$ (2,244)	$ 2,561
Exercise of options to purchase common stock	4	—	59	—	—	59
Purchase of common stock under employee stock purchase plan	—	—	5	—	—	5
Stock-based compensation	—	—	65	—	—	65
Other comprehensive income, net of tax	—	—	—	13	—	13
Net income	—	—	—	—	4,001	4,001
Balance at June 30, 2021	403	$ —	$ 4,931	$ 16	$ 1,757	$ 6,704

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2019	337	$ —	$ 2,670	$ 2	$ (1,497)	$ 1,175
Proceeds from public offering of common stock, net of issuance costs of $2	48	—	1,853	—	—	1,853
Exercise of options to purchase common stock	8	—	106	—	—	106
Purchase of common stock under employee stock purchase plan	—	—	3	—	—	3
Stock-based compensation	—	—	45	—	—	45
Other comprehensive income, net of tax	—	—	—	6	—	6
Net loss	—	—	—	—	(241)	(241)
Balance at June 30, 2020	393	$ —	$ 4,677	$ 8	$ (1,738)	$ 2,947

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

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

	Six Months Ended June 30,	
	2021	**2020**
Operating activities		
Net income (loss)	$ 4,001	$ (241)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Stock-based compensation	65	45
Depreciation and amortization	84	15
Amortization/accretion of investments	13	2
Deferred income taxes	(72)	—
Changes in assets and liabilities:		
Accounts receivable	(629)	(28)
Prepaid expenses and other assets	(110)	(12)
Inventory	(596)	—
Right-of-use assets, operating leases	(14)	(12)
Accounts payable	44	12
Accrued liabilities	367	20
Deferred revenue	3,433	51
Operating lease liabilities	8	14
Other liabilities	440	4
Net cash provided by (used in) operating activities	7,034	(130)
Investing activities		
Purchases of marketable securities	(6,559)	(903)
Proceeds from maturities of marketable securities	860	517
Proceeds from sales of marketable securities	1,706	108
Purchases of property and equipment	(65)	(25)
Net cash used in investing activities	(4,058)	(303)
Financing activities		
Proceeds from public offerings of common stock, net of issuance costs	—	1,853
Proceeds from issuance of common stock through equity plans, net	64	106
Changes in financing lease liabilities	(62)	—
Net cash provided by financing activities	2	1,959
Net increase in cash, cash equivalents and restricted cash	2,978	1,526
Cash, cash equivalents and restricted cash, beginning of year	2,636	248
Cash, cash equivalents and restricted cash, end of period	$ 5,614	$ 1,774
Non-cash investing and financing activities		
Purchases of property and equipment included in accounts payable and accrued liabilities	$ 45	$ 9
Right-of-use assets obtained through finance lease modifications and reassessments	$ 363	$ 14
Right-of-use assets obtained in exchange for financing lease liabilities	$ 126	$ —

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, our, 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 vaccines and therapeutics for infectious diseases, immuno-oncology, rare diseases, autoimmune and cardiovascular diseases, independently and with our strategic collaborators.

On December 18, 2020, we received an Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA) for the emergency use of the Moderna COVID-19 Vaccine (also referred to as mRNA-1273) in individuals 18 years of age or older. We have also received authorization for our COVID-19 vaccine from health agencies in more than 50 countries and from the World Health Organization. Additional authorizations are currently under review in other countries. In addition, we have received authorization for our COVID-19 vaccine for use in adolescents in the European Union and Japan and have pending applications for authorization to administer the vaccine to adolescents with regulatory agencies in the United States and other countries. On June 1, 2021, we initiated the rolling submission process with the U.S. FDA for a Biologics License Application for our COVID-19 vaccine, and we currently anticipate completing our submission in August 2021.

As of June 30, 2021, we had 24 mRNA development programs in our portfolio with 14 having entered the clinic. We have incurred significant expenses in connection with the discovery, development and commercialization of our products, and we expect to continue to incur significant expenses for the foreseeable future. We anticipate that our expenses will increase significantly in connection with the ongoing development and commercialization of our COVID-19 vaccine and ongoing activities to support our platform research, drug discovery and clinical development, including development of any new generations of boosters and vaccines against variants of SARS-CoV-2, infrastructure and Research Engine and Early Development Engine (which includes our Moderna Technology Center), digital infrastructure, creation of a portfolio of intellectual property, and administrative support. We may finance our future cash needs that exceed our operating costs 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.

We believe that our cash, cash equivalents, and investments as of June 30, 2021 will be sufficient to enable us to fund our projected operations through at least the next 12 months from the issuance of these financial statements. We are subject to numerous risks and uncertainties associated with pharmaceutical development and commercialization, and we are unable to predict the timing or amount of expenses or if we will be able to maintain profitability. If we 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, 2020 (2020 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 2020 Form 10-K.

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

The significant accounting policies used in preparation of these condensed consolidated financial statements for the three and six months ended June 30, 2021 are consistent with those described in our 2020 Form 10-K.

Use of Estimates

We have made estimates and judgments affecting the amounts reported in our condensed consolidated financial statements and the accompanying notes. We base our estimates on historical experience and 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 at the date of the financial statements and the reported amounts of revenues and expenses during the reporting periods that are not readily apparent from other sources. Significant estimates relied upon in preparing these financial statements include, but are not limited to, critical accounting policies or estimates related to revenue recognition, research and development expenses, stock-based compensation, leases, fair value of financial instruments, derivative financial instruments, inventory, useful lives of property and equipment, income taxes and our valuation allowance on our deferred tax assets. The actual results that we experience may differ materially from our estimates.

Comprehensive Income (Loss)

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

The components of accumulated other comprehensive income for the three and six months ended June 30, 2021 were as follows (in millions):

	Unrealized Loss on Available-for-Sale Debt Securities	Net Unrealized Gains on Derivatives Designated As Hedging Instruments	Total
Accumulated other comprehensive income, balance at December 31, 2020	$ 3	$ —	$ 3
Other comprehensive loss	(2)	—	(2)
Accumulated other comprehensive income, balance at March 31, 2021	1	—	1
Other comprehensive (loss) income	(6)	21	15
Accumulated other comprehensive income, balance at June 30, 2021	$ (5)	$ 21	$ 16

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 millions):

	June 30,	
	2021	2020
Cash and cash equivalents	$ 5,603	$ 1,762
Restricted cash	—	1
Restricted cash, non-current	11	11
Total cash, cash equivalents and restricted cash shown in the condensed consolidated statements of cash flows	$ 5,614	$ 1,774

Recently Issued Accounting Standards Not Yet Adopted

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 condensed consolidated financial statements and disclosures.

3. Product Sales

In December 2020, we began selling our COVID-19 vaccine to the U.S. Government and international governments. Under the supply agreements with these governments, we received or billed for upfront deposits for our future vaccine supply, which are initially recorded as deferred revenue. We recognize revenue based on the fixed price per dose when control of the product has transferred and customer acceptance has occurred as applicable, unless such acceptance provisions are deemed perfunctory.

Product sales by customer geographic location was as follows (in millions):

	Three Months Ended June 30, 2021	Six Months Ended June 30, 2021
United States	$ 2,093	$ 3,451
Rest of world	2,104	2,479
Total	$ 4,197	$ 5,930

There were no product sales for the three and six months ended June 30, 2020. As of June 30, 2021, we had one commercial product authorized for use, our COVID-19 vaccine.

As of June 30, 2021 and December 31, 2020, we had deferred revenue of $7.2 billion and $3.8 billion, respectively, related to customer deposits, classified as current deferred revenue in our condensed consolidated balance sheets. Timing of product manufacturing, delivery, and receipt of marketing approval will determine the period in which revenue is recognized.

4. 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 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 June 30, 2021, we have earned the committed funding of $5 million. An additional $51 million funding would be 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 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 $472 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. We further amended the agreement in March 2021 to provide for an additional commitment of $63 million to further support late-stage clinical development, including Phase 2/3 mRNA-1273 pediatric studies. In April 2021, we entered into a further amendment to the BARDA agreement, increasing the amount of potential reimbursements by $236 million in connection with costs associated with the Phase 3 clinical trials for mRNA-1273 and pharmacovigilance efforts. The maximum award from BARDA, inclusive of the March 2021 and April 2021 amendments, was approximately $1.3 billion. Under the terms of the agreement, BARDA will fund the advancement of mRNA-1273 to FDA licensure. All contract options have been exercised. As of June 30, 2021, the remaining available funding, net of revenue earned, was $421 million.

In September 2016, we received from BARDA an award of up to $126 million, subsequently adjusted to $117 million in 2021, to help fund our Zika vaccine program. Three of the four contract options have been exercised. As of June 30, 2021, the remaining available funding, net of revenue earned, was $59 million, with an additional $8 million available if the final contract option is exercised.

In January 2016, we entered a global health project framework agreement with the Bill and Melinda Gates Foundation (Gates Foundation) to advance mRNA-based development projects for various infectious diseases, including human immunodeficiency virus (HIV). As of June 30, 2021, the available funding, net of revenue earned, was $10 million, with up to an additional $80 million available, if additional follow-on projects are approved.

The following table summarizes grant revenue as of and for the periods presented (in millions):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
BARDA	$ 134	$ 37	$ 326	$ 40
Other grant revenue	5	1	7	2
Total grant revenue	$ 139	$ 38	$ 333	$ 42

5. Collaboration Agreements

We have entered into collaboration agreements with strategic collaborators to accelerate the discovery and advancement of potential mRNA medicines across therapeutic areas. As of June 30, 2021 and December 31, 2020, we had collaboration agreements with AstraZeneca plc (AstraZeneca), Merck & Co., Inc (Merck), Vertex Pharmaceuticals Incorporated and Vertex Pharmaceuticals (Europe) Limited (together, Vertex), and Chiesi Farmaceutici S.P.A. (Chiesi). Please refer to our 2020 Form 10-K under the heading "Third-Party Strategic Alliances" and Note 5 to our consolidated financial statements for further description of each of the collaboration agreements.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
Collaboration Revenue by Strategic Collaborator:	2021	2020	2021	2020
AstraZeneca	$ 4	$ 16	$ 4	$ 17
Merck	4	11	4	12
Vertex	9	2	18	4
Other	1	—	2	—
Total collaboration revenue	$ 18	$ 29	$ 28	$ 33

The following table presents changes in the balances of our receivables and contract liabilities related to our strategic collaboration agreements during the six months ended June 30, 2021 (in millions):

	December 31, 2020	Additions	Deductions	June 30, 2021
Contract Assets:				
Accounts receivable	$ 6	$ 17	$ (16)	$ 7
Contract Liabilities:				
Deferred revenue	$ 240	$ 18	$ (28)	$ 230

As of June 30, 2021, the aggregated amount of the transaction price allocated to performance obligations under our collaboration agreements that are unsatisfied or partially unsatisfied was $321 million.

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 June 30, 2021 and December 31, 2020 (in millions):

	June 30, 2021						
	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value	Cash and Cash Equivalents	Current Marketable Securities	Non-Current Marketable Securities
Cash and cash equivalents	$ 5,603	$ —	$ —	$ 5,603	$ 5,603	$ —	$ —
Available-for-sale:							
Certificates of deposit	50	—	—	50	—	50	—
U.S. treasury bills	87	—	—	87	—	87	—
U.S. treasury notes	4,349	—	(3)	4,346	—	1,411	2,935
Corporate debt securities	2,113	1	(3)	2,111	—	839	1,272
	$ 12,202	$ 1	$ (6)	$ 12,197	$ 5,603	$ 2,387	$ 4,207

	December 31, 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	$ 2,624	$ —	$ —	$ 2,624	$ 2,624	$ —	$ —
Available-for-sale:							
Certificates of deposit	239	—	—	239	—	215	24
U.S. treasury bills	492	—	—	492	—	492	—
U.S. treasury notes	87	—	—	87	—	38	49
Corporate debt securities	1,801	4	—	1,805	—	1,239	566
	$ 5,243	$ 4	$ —	$ 5,247	$ 2,624	$ 1,984	$ 639

The amortized cost and estimated fair value of marketable securities by contractual maturity at June 30, 2021 and December 31, 2020 were as follows (in millions):

	June 30, 2021	
	Amortized Cost	Estimated Fair Value
Due in one year or less	$ 2,386	$ 2,387
Due after one year through five years	4,213	4,207
Total	$ 6,599	$ 6,594

	December 31, 2020	
	Amortized Cost	Estimated Fair Value
Due in one year or less	$ 1,981	$ 1,984
Due after one year through five years	638	639
Total	$ 2,619	$ 2,623

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, 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 impairment charges related to available-for-sale securities for the three and six months ended June 30, 2021 and 2020. We did not recognize any credit-related allowance to available-for-sale securities as of June 30, 2021 and December 31, 2020.

As of June 30, 2021 and December 31, 2020, we did not have material gross unrealized losses. We neither intend to sell these investments, nor do we believe that we are more-likely-than-not to conclude 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.

Assets and Liabilities Measured at Fair Value on a Recurring Basis

The following fair value hierarchy is used to classify assets and liabilities based on the observable inputs and unobservable inputs used to value the assets and liabilities:

- Level 1: Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities;
- Level 2: Quoted prices for similar assets and liabilities in active markets, quoted prices in markets that are not active, or inputs which are observable, either directly or indirectly, for substantially the full term of the asset or liability; or
- Level 3: Prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable (i.e., supported by little or no market activity).

The following tables summarize our financial assets and liabilities measured at fair value on a recurring basis as of June 30, 2021 and December 31, 2020 (in millions):

	Fair value at June 30, 2021	Fair Value Measurement Using	
		Level 1	Level 2
Assets:			
Money market funds	$ 3,838	$ 3,838	$ —
Certificates of deposit	50	—	50
U.S. treasury bills	87	—	87
U.S. treasury notes	4,346	—	4,346
Corporate debt securities	2,111	—	2,111
Derivative instruments (Note 7)	30	—	30
Total	$ 10,462	$ 3,838	$ 6,624
Liabilities:			
Derivative instruments (Note 7)	$ 2	$ —	$ 2

	Fair value at December 31, 2020	Fair Value Measurement Using	
		Level 1	Level 2
Assets:			
Money market funds	$ 660	$ 660	$ —
Certificates of deposit	239	—	239
U.S. treasury bills	492	—	492
U.S. treasury notes	87	—	87
Corporate debt securities	1,805	—	1,805
Total	$ 3,283	$ 660	$ 2,623

As of June 30, 2021 and December 31, 2020, we did not have non-financial assets or liabilities measured at fair value on a recurring basis and did not have any Level 3 financial assets or financial liabilities.

7. Derivative Financial Instruments

We transact business in various foreign currencies and have international sales and expenses denominated in foreign currencies. Therefore, we are exposed to certain risks arising from both our business operations and economic conditions. Our risk management strategy includes the use of derivative financial instruments to hedge: (1) forecasted product sales that are denominated in foreign currencies and (2) foreign currency exchange rate fluctuations on monetary assets or liabilities denominated in foreign currencies. We do not enter into derivative financial contracts for speculative or trading purposes. We do not believe that we are exposed to more than a nominal amount of credit risk in our foreign currency hedges, as counterparties are large, global and well-capitalized financial institutions. We classify cash flows from our derivative transactions as cash flows from operating activities in our condensed consolidated statements of cash flows.

Cash Flow Hedges

We mitigate the foreign exchange risk arising from the fluctuations in foreign currency denominated product sales in Euro through a foreign currency cash flow hedging program, using forward contracts and foreign currency options that do not exceed 15 months in duration. We hedge these cash flow exposures to reduce the risk that our earnings and cash flows will be adversely affected by changes in exchange rates. To receive hedge accounting treatment, all hedging relationships are formally documented at the inception of the hedge, and the hedges must be highly effective in offsetting changes to future cash flows on hedged transactions. The derivative assets or liabilities associated with our hedging activities are recorded at fair value in other current assets or other current liabilities, respectively, in our condensed consolidated balance sheets. The gains or losses resulting from changes in the fair value of these hedges are initially recorded as a component of accumulated other comprehensive income (AOCI) in stockholders' equity and subsequently reclassified to product sales in the period during which the hedged transaction affects earnings. In the event the underlying forecasted transaction does not occur, or it becomes probable that it will not occur, within the defined hedge period, we reclassify the gains or losses on the related cash flow hedge from AOCI to product sales. We evaluate hedge effectiveness at the inception of the hedge prospectively, and on an on-going basis both retrospectively and prospectively. If we do not elect hedge accounting, or the contract does not qualify for hedge accounting treatment, the changes in fair value from period to period are recorded in the same income statement line item as the hedged item. As of June 30, 2021, we had net deferred gains of $27 million on our foreign currency forward contracts included in AOCI that are expected to be recognized into product sales within the next 12 months.

Balance Sheet Hedges

We enter into foreign currency forward contracts to hedge fluctuations associated with foreign currency denominated monetary assets and liabilities, primarily accounts receivable in Euro and lease liabilities in Swiss Franc, that are not designated for hedge accounting treatment. Therefore, these forward contracts are accounted for as derivatives whereby the fair value of the contracts are reported as other current assets or other current liabilities in our condensed consolidated balance sheets, and gains and losses resulting from changes in the fair value are recorded as a component of other expense, net, in our condensed consolidated statements of operations. The gains and losses on these foreign currency forward contracts generally offset the gains and losses in the underlying foreign currency denominated assets and liabilities, which are also recorded to other expense, net, in our condensed consolidated statements of operations.

Total gross notional amount and fair value of our foreign currency derivatives were as follows (in millions):

	June 30, 2021		
		Fair Value	
	Notional Amount	Asset [1]	Liability [2]
Derivatives designated as cash flow hedging instruments:			
Foreign currency forward contracts	$ 981	$ 27	$ —
Derivatives not designated as hedging instruments:			
Foreign currency forward contracts	308	3	2
Total derivatives	$ 1,289	$ 30	$ 2

	December 31, 2020		
		Fair Value	
	Notional Amount	Asset [1]	Liability [2]
Derivatives not designated as hedging instruments:			
Foreign currency forward contracts	$ 368	$ —	$ —
Total derivatives	$ 368	$ —	$ —

[1] As presented in the condensed consolidated balance sheets within other current assets.
[2] As presented in the condensed consolidated balance sheets within other current liabilities.

Gains (losses) on our foreign currency derivatives, net of tax, recognized in our condensed consolidated statements of comprehensive income (loss) for the three and six months ended June 30, 2021 were as follows (in millions):

	Three Months Ended June 30, 2021	Six Months Ended June 30, 2021
Derivatives in cash flow hedging relationships:		
Foreign currency forward contracts	$ 21	$ 21

The effect of our foreign currency derivatives in our condensed consolidated statements of operations for the three and six months ended June 30, 2021 was as follows (in millions):

	Statement of Operations Classification	Three Months Ended June 30, 2021	Six Months Ended June 30, 2021
Derivatives not designated as hedging instruments:			
Foreign currency forward contracts			
Net realized and unrealized loss	Other expense, net	$ (54)	$ (19)

We had immaterial gains reclassified from AOCI to product sales during the three and six months ended June 30, 2021. There were no hedging activities for the three and six months ended June 30, 2020.

8. Inventory

Inventory as of June 30, 2021 and December 31, 2020 consists of the following (in millions):

	June 30, 2021	December 31, 2020
Raw materials	$ 378	$ 37
Work in progress	224	9
Finished goods	41	1
Total inventory	$ 643	$ 47

9. Property and Equipment, Net

Property and equipment, net, as of June 30, 2021 and December 31, 2020 consists of the following (in millions):

	June 30, 2021	December 31, 2020
Laboratory equipment	$ 142	$ 121
Leasehold improvements	199	180
Furniture, fixtures and other	6	5
Computer equipment and software	14	13
Internally developed software	9	7
Right-of-use asset, financing (Note 11)	545	56
Construction in progress	83	35
	998	417
Less: Accumulated depreciation	(204)	(120)
Property and equipment, net	$ 794	$ 297

Depreciation and amortization expense for the three months ended June 30, 2021 and 2020 was $69 million and $8 million, respectively. Depreciation and amortization expense for the six months ended June 30, 2021 and 2020 was $84 million and $15 million, respectively.

10. Other Balance Sheet Components

Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets, as of June 30, 2021 and December 31, 2020 consists of the following (in millions):

	June 30, 2021	December 31, 2020
Down payments to manufacturing vendors	$ 138	$ 217
Other prepaid expenses	59	7
Value added tax receivable	51	7
Derivative assets	30	—
Other current assets	38	21
Prepaid expenses and other current assets	$ 316	$ 252

Accrued Liabilities

Accrued liabilities, as of June 30, 2021 and December 31, 2020 consists of the following (in millions):

	June 30, 2021	December 31, 2020
Clinical trials	$ 108	$ 98
Raw materials	184	78
Royalties	146	—
Development operations	102	29
Manufacturing	158	53
Other external goods and services	49	92
Compensation-related	62	95
Other	39	25
Accrued liabilities	$ 848	$ 470

Other Current Liabilities

Other current liabilities, as of June 30, 2021 and December 31, 2020 consists of the following (in millions):

	June 30, 2021	December 31, 2020
Lease liabilities - financing (Note 11)	$ 159	$ 24
Lease liabilities - operating (Note 11)	11	6
Income taxes payable	377	—
Other	66	4
Other current liabilities	$ 613	$ 34

Deferred Revenue

The following table summarizes the activities in deferred revenue for the six months ended June 30, 2021 (in millions):

	December 31, 2020	Additions	Deductions	June 30, 2021
Product sales	$ 3,799	$ 6,145	$ (2,705)	$ 7,239
Grant revenue	5	10	(7)	8
Collaboration revenue	240	18	(28)	230
Total deferred revenue	$ 4,044	$ 6,173	$ (2,740)	$ 7,477

11. Leases

We have entered into various long-term non-cancelable lease arrangements for our facilities and equipment expiring at various times through 2035. 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, located in Norwood. We also leased other office spaces globally for our business operations.

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 261,000 square feet. Our Cambridge facility leases have expiry ranges from 2022 to 2029.

Finance Leases

Moderna Technology Center

We have an industrial technology center in Norwood, Massachusetts, Moderna Technology Center (MTC), which comprises three buildings, MTC South, MTC North, and MTC East.

In August 2016, we entered into a lease agreement for approximately 200,000 square feet of office, laboratory, and light manufacturing space (MTC South). 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.

In February 2019, we entered into a lease agreement for office and laboratory space of approximately 200,000 square feet (MTC North). 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. 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 million to be paid back over the term of the lease with interest and extend the term of the lease to 2035.

In April 2021, we entered into a lease agreement for a 240,000 square foot building located on the same campus for expansion of our commercial and clinical activities (MTC East). The lease will expire in February 2034. We have the option to extend the term for two extension periods of five years each at market-based rents.

Embedded Leases

We have entered into multiple contract manufacturing service agreements with third parties which contain embedded leases within the scope of ASC 842. As of June 30, 2021 and December 31, 2020, we had lease liabilities of $251 million and $24 million, respectively, related to the embedded leases. As of June 30, 2021 and December 31, 2020, we had right-of-use assets of $296 million and zero, as certain embedded leases dedicated to our COVID-19 vaccine program were deemed to have no alternative use prior to the EUA from the FDA in December 2020.

Operating and financing lease right-of-use assets and lease liabilities as of June 30, 2021 and December 31, 2020 were as follows (in millions):

	June 30, 2021	December 31, 2020
Assets:		
Right-of-use assets, operating, net [1] [2]	$ 104	$ 90
Right-of-use assets, financing, net [3] [4]	475	55
Total	$ 579	$ 145
Liabilities:		
Current:		
Operating lease liabilities [5]	$ 11	$ 6
Financing lease liabilities [5]	159	24
Total current lease liabilities	170	30
Non-current:		
Operating lease liabilities, non-current	105	97
Financing lease liabilities, non-current	328	110
Total non-current lease liabilities	$ 433	$ 207
Total	$ 603	$ 237

[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 South, MTC North, and MTC East leases as well as assets related to contract manufacturing service agreements.
[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.

Future minimum lease payments under our non-cancelable lease agreements at June 30, 2021, are as follows (in millions):

Fiscal Year	Operating Leases [1]	Financing Leases [1]
2021 (remainder of the year)	$ 9	$ 100
2022	23	174
2023	23	19
2024	16	19
2025	17	19
Thereafter	94	600
Total minimum lease payments	182	931
Less amounts representing interest or imputed interest	(66)	(444) [2]
Present value of lease liabilities	$ 116	$ 487

[1] Includes optional extensions in the MTC South, MTC North, and MTC East lease terms which represent a total of $445 million undiscounted future lease payments.

[2] MTC South interest is based on an imputed interest rate of 17.2%. MTC North, MTC East, and the embedded lease interest is based upon incremental borrowing rates of 8.2%, 3.7%, and 0.6%, respectively.

12. 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 Personalized Cancer Vaccine (PCV) Agreement and PCV/SAV Agreement (which also relates to shared neoantigen mRNA cancer vaccine) 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 million for both periods as of June 30, 2021 and December 31, 2020. Please refer to our 2020 Form 10-K Note 5 to our consolidated financial statements.

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 and six months ended June 30, 2021 and the year ended December 31, 2020, 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

We enter into agreements in the normal course of business with vendors and contract manufacturing organizations (CMOs) for raw materials and manufacturing services and with vendors for preclinical research studies, clinical trials and other goods or services. As of June 30, 2021, we had $1.5 billion of non-cancelable purchase commitments related to raw materials and manufacturing agreements, which are expected to be paid through 2022. As of June 30, 2021, we had $49 million of non-cancelable purchase commitments related to clinical services and other goods and services which are expected to be paid through 2024. These amounts represent our minimum contractual obligations, including termination fees.

In addition to purchase commitments, we have agreements with third parties for various services, including services related to clinical operations and support and contract manufacturing, for which we are not contractually able to terminate for convenience and avoid any and all future obligations to the vendors. Certain agreements provide for termination rights subject to termination fees or wind down costs. Under such agreements, we are contractually obligated to make certain payments to vendors, mainly, to reimburse them for their unrecoverable outlays incurred prior to cancellation. At June 30, 2021 and December 31, 2020, we had cancelable open purchase orders of $1.3 billion and $897 million, respectively, in total under such agreements for our significant clinical operations and support and contract manufacturing. These amounts represent only our estimate of those items for which we had a contractual commitment to pay at June 30, 2021 and December 31, 2020, 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.

Licenses to Patented Technology

On June 26, 2017, we entered into sublicense agreements with Cellscript, LLC and its affiliate, mRNA RiboTherapeutics, Inc. to sublicense certain patent rights. Pursuant to each agreement, we are required to pay certain license fees, annual maintenance fees, minimum royalties on future net sales and milestone payments contingent on achievement of certain development, regulatory and commercial milestones for specified products, on a product-by-product basis. Commercial milestone payments, up to $24 million, and royalties based on annual net sales of licensed products for therapeutic and prophylactic products are accounted for as additional expense of the related product sales in the period in which the corresponding sales occur. For the three and six months ended June 30, 2021, we recognized $148 million and $232 million, respectively, of royalty expenses associated with our product sales, which was recorded to cost of sales in our condensed consolidated statements of operations. We did not recognize any such royalties in the first half of 2020 as we did not have product sales during the period.

Additionally, we have other in-license agreements with third parties which require us to make future development, regulatory and commercial milestone payments for specified products associated with the agreements. The achievement of these milestones was not deemed probable as of June 30, 2021.

13. Stock-Based Compensation

As of June 30, 2021, we had a total of 60 million shares reserved for future issuance under our Equity Plans, of which 33 million shares were reserved for equity awards previously granted, and 27 million shares were available for future grants under the 2018 Equity Plan.

Options

The following table summarizes our option activity during the six months ended June 30, 2021:

	Number of Options (in millions)	Weighted-Average Exercise Price per Share	Weighted-Average Grant Date Fair Value per Share	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value[(1)] (in millions)
Outstanding at December 31, 2020	34.06	$ 17.14	$ 9.12	6.7 years	$ 2,976
Granted	1.13	173.82	76.63		
Exercised	(3.86)	15.31	8.60		
Canceled/forfeited	(0.45)	27.47	14.33		
Outstanding at June 30, 2021	30.88	22.98	11.59	6.3 years	6,547
Exercisable at June 30, 2021	17.22	12.16	6.30	5.1 years	3,837
Expected to vest at June 30, 2021	13.66	36.62	18.26	7.8 years	2,710

[(1)]Aggregate intrinsic value is calculated as the difference between the exercise price of the underlying options and the fair value of common stock for those options in the money as of June 30, 2021.

The total intrinsic value of options exercised was $575 million for the six months ended June 30, 2021. 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 $59 million for the six months ended June 30, 2021.

Restricted Common Stock Units (RSUs) and Performance Stock Units (PSUs)

The following table summarizes our RSU and PSU activity during the six months ended June 30, 2021:

	Units (in millions)	Weighted-Average Fair Value per Unit
Outstanding, non-vested at December 31, 2020	2.19	$ 30.85
Issued	0.55	170.03
Vested	(0.35)	25.63
Canceled/forfeited	(0.07)	37.99
Outstanding, non-vested at June 30, 2021	2.32	64.40

The total fair value of restricted stock units vested during the six months ended June 30, 2021 was $9 million. The total intrinsic value of restricted stock units vested during the six months ended June 30, 2021 was $54 million.

During the first quarter of 2021, we granted PSUs to certain senior executives with vesting that is contingent upon the achievement of specified preestablished goals over the performance period, generally three years. The actual number of common shares ultimately issued is calculated by multiplying the number of PSUs by a payout percentage ranging from 0% to 200%. The estimated fair value of PSUs is based on the grant date fair value.

2018 Employee Stock Purchase Plan (ESPP)

We sold an immaterial number of shares under the ESPP during the six months ended June 30, 2021. As of June 30, 2021, 4 million shares were available for future issuance under the ESPP.

The following table presents the components and classification of stock-based compensation expense for the three and six months ended June 30, 2021 and 2020 as follows (in millions):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Options	$ 24	$ 21	$ 46	$ 39
RSUs and PSUs	10	3	17	5
ESPP	1	1	2	1
Total	$ 35	$ 25	$ 65	$ 45
Cost of sales	$ 8	$ —	$ 12	$ —
Research and development	15	15	29	27
Selling, general and administrative	12	10	24	18
Total	$ 35	$ 25	$ 65	$ 45

As of June 30, 2021, there was $336 million of total unrecognized compensation cost related to unvested stock-based compensation with respect to options, RSUs and PSUs granted. That cost is expected to be recognized over a weighted-average period of 3.0 years at June 30, 2021.

14. Income Taxes

We are subject to U.S. federal, state, and foreign income taxes. For the three and six months ended June 30, 2021, we recorded provisions for income taxes of $283 million and $322 million, respectively, compared to an insignificant amount for the same periods in 2020. Our effective tax rate for the three and six months ended June 30, 2021 was 9% and 7%, respectively, and was lower than the U.S. statutory rate primarily due to the benefit related to the release of the valuation allowance on the majority of our tax attributes, the benefit of the foreign derived intangible income deduction and other deferred tax assets, as well as a discrete item for excess tax benefits related to stock-based compensation. Our effective tax rate for the three and six months ended June 30, 2020 was lower than the U.S. statutory rate primarily due to the valuation allowance.

We recognize deferred tax assets and liabilities for the expected future tax consequences of temporary differences between the financial reporting and tax bases of assets and liabilities. These differences are measured using the enacted statutory tax rates that are expected to be in effect for the years in which differences are expected to reverse. On a periodic basis, we reassess any valuation allowances that we maintain on our deferred tax assets, weighing positive and negative evidence to assess the recoverability of the deferred tax assets. In the first quarter of 2021, we reassessed the valuation allowance noting the increase in positive evidence, including significant revenue growth, expectations regarding future profitability, and successful supply chain and manufacturing capabilities to meet global product demand. After assessing both the positive evidence and negative evidence, we determined it was more likely than not that we will realize the majority of our deferred tax assets. Therefore, we determined we should reverse the majority of our valuation allowance through the annual effective tax rate (AETR) with respect to amounts we expect to realize through current year income. In addition, for the three and six months ended June 30, 2021, we have recorded a discrete benefit of $49 million related to the release of the valuation allowance on deferred tax assets that we expect to utilize in future years. We maintain a valuation allowance on certain state tax attributes that we expect will expire prior to the utilization.

In March 2020, the Coronavirus Aid, Relief and Economic Security Act (CARES Act) was signed into law. The CARES Act includes provisions relating to several aspects of corporate income taxes. We do not currently expect the CARES Act to have a significant impact on our provision for income taxes.

We have reviewed the tax positions taken, or to be taken, in our tax returns for all tax years currently open to examination by a taxing authority. Unrecognized tax benefits represent the aggregate tax effect of differences between tax return positions and the benefits recognized in the financial statements. As of June 30, 2021 and December 31, 2020, we had an immaterial amount of gross unrecognized tax benefits, which would affect our tax rate if recognized. We do not expect that our unrecognized tax benefits will materially increase within the next twelve months. We accrue interest and penalties related to unrecognized tax benefits as a component of our provision for income taxes. We did not recognize any material interest or penalties related to uncertain tax positions during the three and six months ended June 30, 2021 and 2020.

We file U.S. federal income tax returns and income tax returns in various state, local and foreign jurisdictions. We are not currently subject to any tax assessment from an income tax examination in the United States or any other major taxing jurisdiction since inception.

15. Earnings (Loss) per Share

The computation of basic earnings (loss) per share (EPS) is based on the weighted-average number of our common shares outstanding. The computation of diluted EPS is based on the weighted-average number of our common shares outstanding and potential dilutive common shares outstanding during the period as determined by using the treasury stock method.

Basic and diluted EPS for the three and six months ended June 30, 2021 and 2020 were calculated as follows (in millions, except per share data):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Numerator:				
Net income (loss)	$ 2,780	$ (117)	$ 4,001	$ (241)
Denominator:				
Basic weighted-average common shares outstanding	402	381	401	367
Effect of dilutive securities	29	—	29	—
Diluted weighted-average common shares outstanding	431	381	430	367
Basic EPS	$ 6.93	$ (0.31)	$ 9.98	$ (0.66)
Diluted EPS	$ 6.46	$ (0.31)	$ 9.30	$ (0.66)

The following common stock equivalents, presented based on amounts outstanding as of June 30, 2020 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 (in millions):

	June 30, 2020
Stock options	40
Restricted common stock units	2
	42

16. Subsequent Events

Subsequent to June 30, 2021, we have entered into additional supply agreements with customers to provide up to 262 million doses of our COVID-19 vaccine and our updated variant booster vaccine candidate based on the initial confirmed volume, subject to modifications.

On August 2, 2021, our Board of Directors authorized a Share Repurchase Program of our common stock, which expires on August 2, 2023. Pursuant to the Share Repurchase Program, we may repurchase up to $1.0 billion of our outstanding common stock. The timing and actual number of shares repurchased depend on a variety of factors, including price, general business and market conditions, and other investment opportunities, and shares may be repurchased through open market purchases through the use of trading plans intended to qualify under Rule 10b5-1 under the Exchange Act.

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, 2020, which was filed with the SEC on February 26, 2021 (the "2020 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;
- systemic secreted and cell surface therapeutics;
- cancer vaccines;
- intratumoral immuno-oncology;
- localized regenerative therapeutics; and
- systemic intracellular therapeutics.

We have designated our prophylactic vaccines and systemic secreted and cell surface therapeutics modalities as our "core modalities". 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. Our exploratory modalities continue to be a critical part of advancing our strategy to maximize the application of our potential mRNA medicines.

Business Highlights

Moderna COVID-19 Vaccine

On December 18, 2020, the U.S. Food and Drug Administration (FDA) authorized the emergency use of the Moderna COVID-19 Vaccine in individuals 18 years of age or older. We have also received authorization for our COVID-19 vaccine from health agencies in more than 50 countries and from the World Health Organization. Additional authorizations are currently under review in other countries. In addition, we have received authorization for our COVID-19 vaccine for use in adolescents in the European Union and Japan and have pending applications for authorization to administer the vaccine to adolescents with regulatory agencies in the United States and other countries. On June 1, 2021, we initiated the rolling submission process with the U.S. FDA for a Biologics License Application for our COVID-19 vaccine and we currently anticipate completing our submission in August 2021.

We have entered into supply agreements with the U.S. Government, several other governments outside the United States and with UNICEF (on behalf of the COVAX Facility) for the supply of our COVID-19 vaccine. The agreements are generally subject to receipt of authorization or approval for the use and distribution of the vaccine from the relevant regulatory authority in each jurisdiction. Under these agreements, we are entitled to upfront deposits for our COVID-19 vaccine supply, initially recorded as deferred revenue. As of June 30, 2021, we had approximately $7.2 billion in deferred revenue in connection with the supply agreements with the U.S. Government and other customers, which will be recognized as revenue when revenue recognition criteria have been met.

For the second quarter of 2021, we delivered approximately 126 million doses of our COVID-19 vaccine to the U.S. government and approximately 73 million doses to other governments, and recognized $4.2 billion in product sales. For the first quarter of 2021, we delivered approximately 88 million doses of our COVID-19 vaccine to the U.S. government and approximately 14 million doses to other governments, and recognized $1.7 billion in product sales.

In the second quarter of 2021, we announced additional investments to facilitate the increased supply of our COVID-19 vaccine from our own and partnered manufacturing facilities, and an expansion of the Moderna Technology Center (MTC) in Norwood, Massachusetts, to more than double our facility space to help transform it from a production and lab space to an industrial technology center. As a result of these investments, we expect that we will supply between 800 million and 1 billion doses of our COVID-19 vaccine in 2021, at the 100 µg dose. We anticipate these investments will also increase our global 2022 capacity for the vaccine to up to 3 billion doses, in the event that our 2022 production is dedicated to 50 µg booster doses. If our 2022 production is dedicated to 100 µg doses, we expect our total potential capacity to be approximately 2 billion doses. The ultimate dosage for our 2022 supply is subject to ongoing internal review, and is also subject to further regulatory approval and authorization, among other factors. These investments are expected to facilitate a doubling of drug substance manufacturing from Lonza's Switzerland-based facility, a more than doubling of formulation, fill and finish and drug substance manufacturing at Rovi's Spain-based facility, as well as a 50% increase of drug substance at Moderna's facilities in the U.S. When completed, the investments are expected to also result in an increase in safety stock of raw materials and finished product used to deliver committed volumes. These forecasted increases to our supply are subject in part to performance by our manufacturing partners, which will require ramping-up capabilities at their own facilities and the hiring of qualified manufacturing personnel.

Moderna COVID-19 Vaccine Clinical Studies

The final analysis of adjudicated cases from the Phase 3 clinical trial for mRNA-1273, which we refer to as the COVE Study, demonstrated efficacy of 93% through six months after the second dose of the vaccine. The final analysis also demonstrated greater than 98% efficacy against severe cases of COVID-19 and 100% efficacy against death caused by COVID-19 in the per protocol cohort. The final analysis also demonstrated consistency in our subgroup analysis, including analyses by gender, by race and by preexisting medical conditions. The safety profile for mRNA-1273 continues to be consistent with the Phase 3 data over the longer period of safety follow up and across population subgroups.

The Phase 2/3 TeenCOVE study of mRNA-1273 in adolescents ages 12-17 years has completed enrollment in the U.S. An initial analysis of 3,732 participants randomized 2:1 in the TeenCOVE study showed a vaccine efficacy rate of 93% in seronegative participants who received at least one injection (modified intent-to-treat cohort) in a secondary analysis. The median duration for follow-up in this analysis was 53 days following the second dose. mRNA-1273 was generally well tolerated. The majority of adverse events were mild or moderate in severity. No serious safety concerns have been identified to date. The most common solicited local adverse event was injection site pain. The most common solicited systemic adverse events after the second dose of mRNA-1273 were headache, fatigue, myalgia and chills. The Conditional Marketing Authorization (CMA) for our COVID-19 vaccine in the European Union has been expanded to include adolescents 12 years of age and older. In addition, the Japanese Ministry of Health, Labor and Welfare also approved our COVID-19 vaccine for ages 12 to 17. We have filed for an EUA for adolescents with the U.S. FDA as well as with additional regulatory agencies around the world.

The Phase 2/3 KidCOVE study of mRNA-1273 in the pediatric population ages 6 months-11 years is currently enrolling. We expect to enroll 12,000 healthy pediatric participants in the U.S. and Canada into this two-part, dose escalation study. In Part 1, each participant ages 2 years to less than 12 years may receive one of two dose levels (50 µg or 100 µg). Also in Part 1, each participant ages six months to less than 2 years may receive one of three dose levels (25 µg, 50 µg and 100 µg). An interim analysis will be conducted to determine which dose will be used in Part 2, the placebo-controlled expansion portion of the study.

Variant-Specific Booster Candidates

On February 24, we announced that we had completed manufacturing of clinical trial material for our variant-specific vaccine candidate, mRNA-1273.351, against the SARS-CoV-2 variant known as the Beta variant (or B.1.351, first identified in the Republic of South Africa) and that this vaccine had been shipped to the National Institutes of Health (NIH) for a Phase 1 clinical trial to be led and funded by the NIH's National Institute of Allergy and Infectious Diseases. We are also developing a multivalent booster candidate, mRNA-1273.211, which combines mRNA-1273 (Moderna's authorized vaccine against ancestral strains) and the Beta variant in a single vaccine.

Data from our Phase 2 study showed that a single 50 µg dose of mRNA-1273, mRNA-1273.351 or mRNA-1273.211 given as a booster to previously vaccinated individuals (n=20 per group) increased neutralizing antibody titer responses against SARS-CoV-2 and important variants of concern, including the Gamma variant (or P.1, first identified in Brazil), the Beta variant, and the Delta variant (B.1.617.2). Neutralizing antibody levels following the boost approached those observed after primary vaccination with two doses of 100 µg of mRNA-1273. These data have been submitted to a peer-reviewed journal for publication. Safety and tolerability profiles following third dose booster injections of 50 µg of mRNA-1273, mRNA-1273.351 or mRNA-1273.211 were generally comparable to those observed after the second dose of mRNA-1273 in the previously reported Phase 2 and Phase 3 studies. Our Phase 2 study to evaluate three approaches to boosting is ongoing. We are also in the process of developing a booster tailored to the Delta variant (mRNA-1273.617), and anticipate developing a multivalent booster—referred to as mRNA-1273.213—that combines mRNA-1273.617 with another COVID-19 candidate.

Our strategy on the dosing for boosters will be informed by ongoing clinical trials that assess mRNA-1273 at the 100 µg dose against the results seen at the 50 µg dose, before pursuing an approach with regulatory authorities.

Key Updates for our Other Development Candidates

- **CMV vaccine (mRNA-1647):** Our vaccine against cytomegalovirus, or CMV (mRNA-1647) is a vaccine combining six mRNAs in a single vial, which encode for two antigens located on the surface of CMV: five mRNAs encoding the subunits that form the membrane-bound pentamer complex and one mRNA encoding the full-length membrane-bound glycoprotein B (gB). Both the pentamer and gB are essential for CMV to infect barrier epithelial surfaces and gain access to the body. mRNA-1647 is designed to produce an immune response against both the pentamer and gB for the prevention of CMV infection.

  Based on the interim analysis of the Phase 2 study, which we announced in April 2021, the 100 µg dose has been chosen for the Phase 3 pivotal study for mRNA-1647, which will evaluate the prevention of primary CMV infection in seronegative women ages 16-40 years. We plan to enroll approximately 8,000 participants from approximately 150 sites across the U.S., Europe and Asia-Pacific into the Phase 3 study, which has begun site initiation and is expected to start in the near-term. Moderna owns worldwide commercial rights for mRNA-1647.

- **Respiratory syncytial virus (RSV) vaccine (mRNA-1345):** mRNA-1345 is a vaccine against RSV encoding for a prefusion F glycoprotein, which elicits a superior neutralizing antibody response compared to the postfusion state. The Phase 1 study of mRNA-1345 to evaluate the tolerability, reactogenicity and immunogenicity of mRNA-1345 in younger adults, older adults, women of child bearing age and children is ongoing. All younger adult (ages 18-49 years) and older adult (ages 65-79 years) cohorts are fully enrolled. Dosing in the older adult cohort (ages 65-79 years) is ongoing. The age range of toddlers in this de-escalation Phase 1 study is 12-59 months and the pediatric cohort is ongoing, as are the cohorts of women of child-bearing potential. The U.S. FDA has granted Fast Track designation for mRNA-1345 in adults older than 60 years of age.

  We also intend to evaluate the potential of combinations of mRNA-1345 with our vaccines against other respiratory pathogens in children and separately in older adults. There is no approved vaccine for RSV. Moderna owns worldwide commercial rights to mRNA-1345.

- **Seasonal influenza (flu) (mRNA-1010, mRNA-10202 and mRNA-1030):** In January 2021, we announced three development candidates for a seasonal influenza vaccine (mRNA-1010, mRNA-1020 and mRNA-1030). In July 2021, the first participants were dosed in the Phase 1/2 study of mRNA-1010, our first generation flu program. mRNA-1010 is a

quadrivalent seasonal influenza vaccine candidate targeting WHO recommendations including A H1N1, H3N2 and influenza B Yamagata and Victoria lineages. Our vision is to develop a respiratory vaccine for the adult and elderly populations combining seasonal flu, COVID-19 variant booster and RSV. Moderna owns worldwide commercial rights to mRNA-1010.

- **Zika vaccine (mRNA-1893):** mRNA-1893 is a vaccine against ZIKV. After administration of the vaccine, the mRNA is translated as a polyprotein and processed inside the cell to make a virus-like particle, or VLP. This process mimics the response of the cell after natural infection. This program is funded by BARDA. In 2020, we announced positive Phase 1 data showing that mRNA-1893 was well-tolerated at all dose levels, and safety and tolerability did not appear to be influenced by the serostatus of the participants at baseline. All dose levels of mRNA-1893 induced a strong neutralizing ZIKV-specific antibody response in baseline flavivirus seronegative participants. GMTs post-dose two were comparable to those in a small panel of Zika convalescent sera collected during the epidemic. In participants with pre-existing flavivirus antibodies, neutralizing antibody titers were boosted with a single dose of the vaccine as shown by the GMTs and the seroconversion rates. We have started a Phase 2 study that is expected to enroll approximately 800 participants in the United States and Puerto Rico. There is no approved vaccine for Zika.

- **Human immunodeficiency virus (HIV) (mRNA-1644 and mRNA-1574):** In January 2021, we announced two vaccine programs against HIV. mRNA-1644 is a novel approach to HIV vaccine strategy in humans designed to elicit broadly neutralizing HIV-1 antibodies (bNAbs) and is being developed in collaboration with the International AIDS Vaccine Initiative (IAVI) and the Gates Foundation. A Phase 1 study for mRNA-1644 will use iterative human testing to validate the approach and antigens and multiple novel antigens will be used for germline-targeting and immuno-focusing. A second approach, mRNA-1574, is being evaluated in collaboration with the National Institutes of Health (NIH) and includes multiple native-like trimer antigens.

- **Propionic acidemia (PA) (mRNA-3927):** Enrollment for the Phase 1/2 clinical trial for mRNA-3927, our therapy for the treatment of propionic acidemia, or PA, is ongoing. The Phase 1/2 study is designed to evaluate the safety and tolerability of mRNA-3927 in patients with PA. PA, is a rare, life-threatening, inherited metabolic disorder due to a defect in the mitochondrial enzyme propionyl-CoA carboxylase, or PCC. It primarily affects the pediatric population. There is no approved therapy for PA, including no approved enzyme replacement therapy. We have received Rare Pediatric Disease Designation and Orphan Drug Designation from the FDA and Orphan Drug Designation from the European Commission for the PA program. The FDA has also granted Fast Track designation to mRNA-3927. This is the first development candidate to enter the clinic in our intracellular therapeutics modality.

- **Methylmalonic acidemia (MMA) (mRNA-3705):** Site start-up activities ongoing for the Phase 1/2 study. The Phase 1/2 study is designed to evaluate the safety and tolerability of mRNA-3705 in patients with MMA. MMA is a rare, life-threatening, inherited metabolic disorder that is primarily caused by a defect in the mitochondrial enzyme methylmalonyl-coenzyme A mutase, or MUT. It primarily affects the pediatric population. There is no approved therapy that addresses the underlying disorder, including no approved enzyme replacement therapy, due to the complexity of the protein and its mitochondrial localization.

- **IL-2 Mutein (mRNA-6231):** mRNA-6231 is an mRNA-encoded IL-2 modified for the expansion of regulatory T cells. A Phase 1 study in healthy volunteers has dosed its first participants. It is also our first subcutaneously administered therapeutic program.

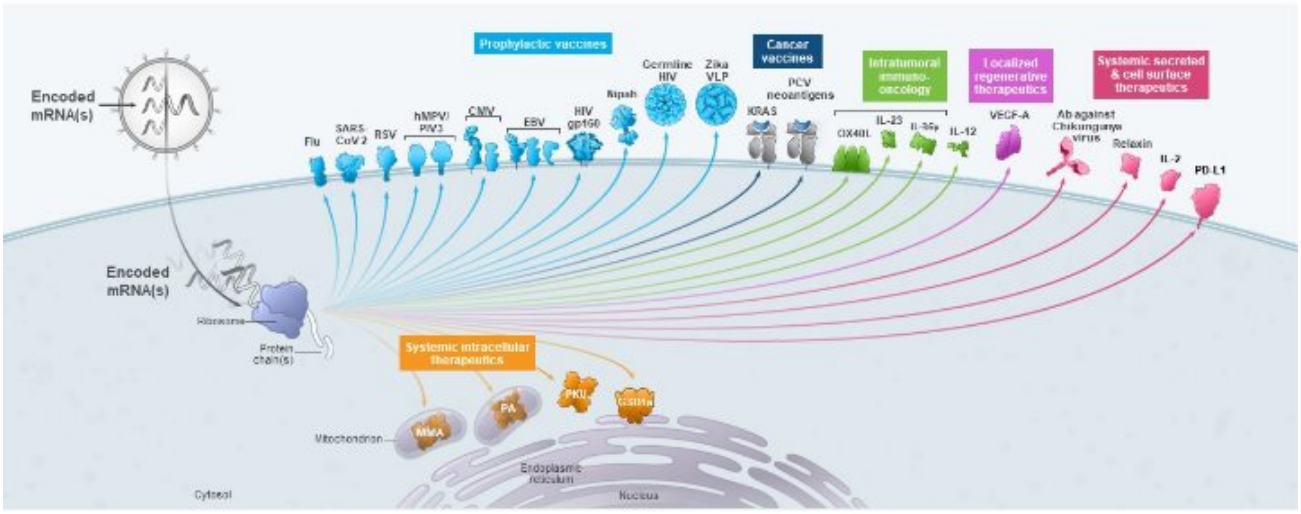
- **Intratumoral Immuno-Oncology:** We have decided to discontinue the development of our OX40L program (mRNA-2416), which was in a Phase 2 study in ovarian patients. We are continuing development of Triplet (mRNA-2752) which includes OX40L and two proinflammatory cytokines, IL-23, and IL-36γ, encapsulated in our proprietary LNP. The Phase 1 is ongoing and new expansion cohorts are currently enrolling and dosing patients.

Our Pipeline

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

Abbreviations: EBV, Epstein-Barr virus; PD-L1, programmed death-ligand-1; PKU, phenylketonuria; GSD1a, Glycogen storage disease type 1a; H7N9, H7N9 influenza vaccine; hMPV/PIV3, human metapneumovirus (hMPV)/parainfluenza virus type 3 (PIV3) vaccine; IL-2, Interleukin 2: IL-12, interleukin 12; IL-23, interleukin 23; IL-36γ, interleu; OX40L, wildtype OX40 ligand; VEGF-A, vascular endothelial growth factor A.

The breadth of biology addressable using mRNA technology is reflected in our current development pipeline of 23 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 ten programs, six of which have entered into clinical trials and demonstrated desired pharmacology, in the form of immunogenicity, in positive Phase 1 clinical trials: H7N9 vaccine (mRNA-1851), RSV vaccine (mRNA-1777), human metapneumovirus (hMPV)/parainfluenza virus type 3 (PIV3) vaccine (mRNA-1653), Zika vaccine (mRNA-1893), CMV vaccine (mRNA-1647), COVID-19 vaccine (mRNA-1273). We have ongoing Phase 1 trials for our RSV vaccine (mRNA-1345), flu vaccine (mRNA-1010) and hMPV/PIV3 vaccine (mRNA-1653). We have an ongoing Phase 2 study for our Zika vaccine (mRNA-1893) and CMV vaccine

(mRNA-1647). Our CMV vaccine is also expected to start a Phase 3 trial in the near-term. Our COVID-19 vaccine (mRNA-1273) is described in detail above. Our three preclinical programs within our prophylactic vaccines modality are for Epstein-Barr virus (mRNA-1189), Nipah virus (mRNA-1215) and HIV (mRNA-1644 and mRNA-1574). Two other vaccines being developed as part of public health programs—H10N8 vaccine (mRNA-1440) and Chikungunya vaccine (mRNA-1388)—also produced positive Phase 1 clinical trial results, but are not being further developed without government or other funding.

- **Systemic secreted and cell surface 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 (mRNA-0184) for cardiac disorders, 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. Our IL-2 program (mRNA-6231) is currently in a Phase 1 study, and is our first first autoimmune therapeutic candidate to enter the clinic. The remaining programs for Relaxin (mRNA-0184) and PD-L1 (mRNA-6981) are 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. 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 two programs in this modality. Our first program, OX40L/IL-23/IL-36γ (Triplet) (mRNA-2752), is currently in a Phase 1 study that is designed as an open-label, multicenter study of intratumoral injections of Triplet (mRNA-2752) alone or in combination with durvalumab (anti-PD-L1) with sites in the United States and Israel. Our second program, IL-12 (MEDI1191), is being developed in collaboration with AstraZeneca. AstraZeneca is currently enrolling an open-label multicenter Phase 1 clinical trial of intratumoral injections of MEDI1191 alone and in combination with the checkpoint inhibitor, durvalumab.

- **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. 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 ongoing Phase 1 clinical trial for PA (mRNA-3927). MMA (mRNA-3705), PKU (mRNA-3283) and GSD1a (mRNA-3745) are currently in preclinical development.

Financial Operations Overview

Revenue

The following table summarizes revenue for each period presented (in millions):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Revenue:				
Product sales	$ 4,197	$ —	$ 5,930	$ —
Grant revenue	139	38	333	42
Collaboration revenue	18	29	28	33
Total revenue	$ 4,354	$ 67	$ 6,291	$ 75

We began to record product sales for our COVID-19 vaccine subsequent to its authorization for emergency use by the FDA and Health Canada in December 2020. For the three months ended June 30, 2021, we recognized $4.2 billion of product sales from our COVID-19 vaccine, of which $2.1 billion was generated in the United States and $2.1 billion was generated from the rest of the world. For the six months ended June 30, 2021, we recognized $5.9 billion of product sales from our COVID-19 vaccine, of which $3.4 billion was generated in the United States and $2.5 billion was generated from the rest of the world.

Other than product sales, 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.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Grant revenue:				
BARDA [1]	$ 134	$ 37	$ 326	$ 40
Other	5	1	7	2
Total grant revenue	$ 139	$ 38	$ 333	$ 42

[1] For the three months ended June 30, 2021, $132 million of BARDA grant revenue was related to our mRNA-1273 program and $2 million was related to our Zika vaccine program. For the six months ended June 30, 2021, $322 million of BARDA grant revenue was related to our mRNA-1273 program and $4 million was related to our Zika vaccine program.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Collaboration revenue:				
AstraZeneca	$ 4	$ 16	$ 4	$ 17
Merck	4	11	4	12
Vertex	9	2	18	4
Other	1	—	2	—
Total collaboration revenue	$ 18	$ 29	$ 28	$ 33

We expect our product sales to significantly increase in 2021 compared to 2020. As of June 30, 2021, we had signed supply agreements of approximately $19.2 billion for the future supply of our COVID-19 vaccine through 2022 and had deferred revenue of $7.2 billion associated with customer deposits received or billable under these agreements. Additional supply agreements have been agreed upon since June 30, 2021, and others are under discussion for 2021 and 2022 deliveries. In addition, we expect to continue to receive funding from our contract with BARDA. As of June 30, 2021, the remaining available funding, net of revenue, earned under our agreement with BARDA for the development of our mRNA-1273 vaccine was $421 million. To the extent that existing or potential future products generate revenue, our revenue may vary due to many uncertainties in the independent development of our mRNA medicines and pursuant to our strategic alliances and other factors.

Cost of sales

Cost of sales includes raw materials, personnel and facility and other costs associated with manufacturing our commercial product. These costs include production materials, production costs at our manufacturing facilities, third-party manufacturing costs, and final formulation and packaging costs. Cost of sales also includes shipping costs and royalties payable to third parties based on sales of our products.

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;
- 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 (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 and clinical trials, including both internal manufacturing and third-party contract manufacturing organizations (CMOs);
- expenses incurred for the procurement of materials, laboratory supplies, and non-capital equipment used in the research and development process; and
- facilities, depreciation, and amortization, and other direct and allocated expenses incurred as a result of research and development activities.

We use our employee and infrastructure resources for the advancement of our platform, and for discovering and developing programs. Due to the number of ongoing programs and our ability to use resources across several projects, indirect or shared operating costs incurred for our research and development programs are generally not recorded or maintained on a program- or modality-specific basis. The following table reflects our research and development expenses, including direct program-specific expenses summarized by modality and indirect or shared operating costs summarized under other research and development expenses during the three and six months ended June 30, 2021 and 2020 (in millions):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Program expenses by modality:				
Prophylactic vaccines	$ 241	$ 36	$ 489	$ 45
Cancer vaccines	7	12	24	16
Intratumoral immuno-oncology	7	1	13	3
Systemic secreted and cell surface therapeutics	1	—	2	1
Systemic intracellular therapeutics	6	6	11	13
Total program-specific expenses by modality [1]	262	55	539	78
Other research and development expenses:				
Discovery programs	15	11	28	21
Platform research	27	18	52	40
Technical development and unallocated manufacturing expenses	53	29	86	58
Shared discovery and development expenses	49	24	88	43
Stock-based compensation	15	15	29	27
Total research and development expenses	$ 421	$ 152	$ 822	$ 267

[1] Includes a total of 30 and 23 development candidates at June 30, 2021 and 2020, 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 inventory, mRNA supply and consumables. Costs to acquire and manufacture 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 preclinical and clinical development of our product candidates, 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.

As we continue to progress mRNA-1273 through the development process toward a Biologics License Application approval, indication expansion of mRNA-1273 and variant-specific vaccine candidates during the current pandemic, we expect to continue to incur significant additional expenses. At this time, the magnitude of these potential expenditures is not known. In connection with the BARDA agreement to accelerate development of mRNA-1273, significant grant revenue and expenses are expected in 2021. BARDA's funding is expected to offset those expenses that are covered under the BARDA agreement, subject to our obtaining reimbursement from BARDA. As of June 30, 2021, the remaining available funding, net of revenue, earned was $421 million.

Changes 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, such as our CMV vaccine (mRNA-1647) and our COVID-19 vaccine, 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 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.

Selling, general and administrative expenses

We started to incur sales and marketing expenses in the fourth quarter of 2020 to prepare for commercial operations in connection with the sale of our COVID-19 vaccine. Selling, 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, sales and marketing, 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 selling, general and administrative expenses will increase as we continue to expand the number of programs in development and to establish our 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 our COVID-19 vaccine. If we obtain regulatory approval for 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 selling, general and administrative expenses.

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, foreign currency transaction and remeasurement gains (losses), gains (losses) on foreign currency balance sheet hedges, 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, and certain contract manufacturing service agreements.

We expect to continue to incur significant expenses as we continue our research and development and commercialization 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 commercialize any approved mRNA medicines. If we fail to sustain profitability on a continuing basis, we may incur losses in the future.

Critical accounting policies and significant judgments and estimates

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

There have been no material changes in our critical accounting policies and estimates in the preparation of our condensed consolidated financial statements during the three months ended June 30, 2021 compared to those disclosed in our 2020 Form 10-K.

Recently issued accounting pronouncements

We have reviewed all recently issued standards and have determined that 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 table summarizes our condensed consolidated statements of operations for each period presented (in millions):

	Three Months Ended June 30,		Change 2021 vs. 2020	
	2021	2020	$	%
Revenue:				
Product revenue	$ 4,197	$ —	$ 4,197	100%
Grant revenue	139	38	101	266%
Collaboration revenue	18	29	(11)	(38)%
Total revenue	4,354	67	4,287	6,399%
Operating Expenses:				
Cost of sales	750	—	750	100%
Research and development	421	152	269	177%
Selling, general and administrative	121	37	84	227%
Total operating expenses	1,292	189	1,103	584%
Income (loss) from operations	3,062	(122)	3,184	2,610%
Interest income	3	7	(4)	(57)%
Other expense, net	(2)	(2)	—	—%
Income (loss) before income taxes	3,063	(117)	3,180	2,718%
Provision for income taxes	283	—	283	100%
Net income (loss)	$ 2,780	$ (117)	$ 2,897	2,476%

	Six Months Ended June 30,		Change 2021 vs. 2020	
	2021	2020	$	%
Revenue:				
Product revenue	$ 5,930	$ —	$ 5,930	100%
Grant revenue	333	42	291	693%
Collaboration revenue	28	33	(5)	(15)%
Total revenue	6,291	75	6,216	8,288%
Operating Expenses:				
Cost of sales	943	—	943	100%
Research and development	822	267	555	208%
Selling, general and administrative	198	61	137	225%
Total operating expenses	1,963	328	1,635	498%
Income (loss) from operations	4,328	(253)	4,581	1,811%
Interest income	7	15	(8)	(53)%
Other expense, net	(12)	(3)	(9)	300%
Income (loss) before income taxes	4,323	(241)	4,564	1,894%
Provision for income taxes	322	—	322	100%
Net income (loss)	$ 4,001	$ (241)	$ 4,242	1,760%

Revenue

Total revenue increased by $4.3 billion for the three months ended June 30, 2021, compared to the same period in 2020, due to increases in product sales and grant revenue. Product revenue was $4.2 billion for the three months ended June 30, 2021 from sales of our COVID-19 vaccine. For the three months ended June 30, 2021, we delivered approximately 126 million doses to the U.S. government and approximately 73 million doses to other governments of our COVID-19 vaccine. We did not have product sales until December 2020. Grant revenue increased by $101 million for the three months ended June 30, 2021, compared to the same period in 2020, mainly driven by an increase in revenue from BARDA related to our mRNA-1273 vaccine development.

Total revenue increased by $6.2 billion, for the six months ended June 30, 2021, compared to the same period in 2020, due to increases in product sales and grant revenue. Product revenue was $5.9 billion for the six months ended June 30, 2021 from sales of

our COVID-19 vaccine. For the six months ended June 30, 2021, we delivered approximately 215 million doses to the U.S. government and approximately 87 million doses to other governments. We did not have product sales until December 2020. Grant revenue increased by $291 million for the six months ended June 30, 2021, compared to the same period in 2020, primarily driven by an increase in revenue from BARDA related to our mRNA-1273 vaccine development.

Operating expenses

Cost of sales

We began capitalizing our COVID-19 vaccine inventory costs in December 2020, in connection with an EUA from the FDA, and based upon our expectation that these costs would be recoverable through commercialization of our COVID-19 vaccine. Prior to the capitalization of our COVID-19 vaccine inventory costs, such costs were recorded as research and development expenses in the period incurred. We expensed $242 million of pre-launch inventory costs in 2020. Our cost of sales was $750 million, or 18%, of our product sales, for the three months ended June 30, 2021, including third-party royalties of $148 million. Our cost of sales was $943 million, or 16%, of our product sales, for the six months ended June 30, 2021, including third-party royalties of $232 million. A portion of the inventory costs associated with our product sales for the six months ended June 30, 2021 was expensed previously. At the end of the first quarter of 2021, we had substantially utilized our zero-cost COVID-19 vaccine inventory. If inventory sold for the six months ended June 30, 2021 was valued at cost, our cost of sales for the period would have been $1.1 billion, or 19%, of our product sales. We expect that our cost of sales as a percentage of product sales will remain at a similar level for the second half of 2021.

Research and development expenses

Research and development expenses increased by $269 million, or 177%, for the three months ended June 30, 2021, compared to the same period in 2020. The increase was primarily attributable to an increase in clinical trial expenses of $217 million, and an increase in personnel, technology and facility-related costs of $24 million.

Research and development expenses increased by $555 million, or 208%, for the six months ended June 30, 2021, compared to the same period in 2020. The increase was primarily attributable to an increase in clinical trial expenses of $436 million, an increase in personnel-related costs of $37 million, an increase in manufacturing expenses related to our clinical trials of $30 million, and an increase in consulting and outside services of $29 million.

These increases for both the three and six month periods in 2021 were largely driven by increased mRNA-1273 clinical development and headcount.

Selling, general and administrative expenses

Selling, general and administrative expenses increased by $84 million, or 227%, for the three months ended June 30, 2021, compared to the same period in 2020. The increase was mainly due to an increase in consulting and outside services of $33 million, an increase in personnel-related costs of $20 million, and an increase in marketing expenses of $15 million.

Selling, general and administrative expenses increased by $137 million, or 225%, for the six months ended June 30, 2021, compared to the same period in 2020. The increase was mainly due to an increase in consulting and outside services of $50 million, an increase in marketing, legal and licensing expenses of $32 million, and an increase in personnel-related costs of $31 million.

These increases for both the three and six month periods in 2021 were primarily driven by our COVID-19 vaccine commercialization-related activities and increased headcount.

Interest income

Interest income decreased by $4 million, or 57%, for the three months ended June 30, 2021, compared to the same period in 2020. Interest income decreased by $8 million, or 53%, for the six months ended June 30, 2021, compared to the same period in 2020. The decreases in interest income from our investments in marketable securities for both the three and six month periods in 2021 were mainly driven by an overall lower interest rate environment, partially offset by increased investment balances.

Other expense, net

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

	Three Months Ended June 30,		Change 2021 vs. 2020	
	2021	2020	$	%
Gain on investments	$ 2	$ 1	$ 1	100%
Interest expense	(5)	$ (3)	(2)	67%
Other income, net	1	—	1	100%
Total other expense, net	$ (2)	$ (2)	$ —	—%

	Six Months Ended June 30,		Change 2021 vs. 2020	
	2021	2020	$	%
Gain on investments	$ 2	$ 1	$ 1	100%
Interest expense	(8)	$ (4)	(4)	100%
Other expense, net	(6)	—	(6)	100%
Total other expense, net	$ (12)	$ (3)	$ (9)	300%

Total other expense, net remained flat for the three months ended June 30, 2021, compared to the same period in 2020. Total other expense, net increased by $9 million, or 300%, for the six months ended June 30, 2021, compared to the same period in 2020. The increase in other expense, net for the six-month period in 2021 was primarily due to losses on foreign currency transactions and remeasurements, partially offset by our balance sheet hedge activities. Our interest expense is primarily related to our finance leases.

Income taxes

Our provision for income taxes for the three and six months ended June 30, 2021 was $283 million and $322 million, respectively, as compared to an insignificant amount for the same periods in 2020. Our effective tax rate for the three and six months ended June 30, 2021 was lower than the U.S. statutory rate primarily due to the benefit related to the release of the valuation allowance on the majority of our tax attributes, the benefit of the foreign derived intangible income deduction and other deferred tax assets, as well as a discrete item for excess tax benefits related to stock-based compensation. Our effective tax rate for the three and six months ended months ended June 30, 2020 was lower than the U.S. statutory rate primarily due to the valuation allowance.

On a periodic basis, we reassess any valuation allowances that we maintain on our deferred tax assets, weighing positive and negative evidence to assess the recoverability of the deferred tax assets. In the first quarter of 2021, we reassessed the valuation allowance noting the increase in positive evidence, including significant revenue growth, expectations regarding future profitability, and successful supply chain and manufacturing capabilities to meet global product demand. After assessing both the positive evidence and negative evidence, we determined it was more likely than not that we will realize the majority of our deferred tax assets. Therefore, in the first quarter of 2021, we released our valuation allowance on the majority of our federal and state net operating losses and other deferred tax assets through the annual effective tax rate (AETR) as income is earned, resulting in a reduction in the AETR. In addition, we have recorded a discrete benefit of $49 million related to the deferred tax assets that we expect to utilize in future years. As of June 30, 2021, we continue to maintain a valuation allowance on certain state tax attributes.

Liquidity and capital resources

As of June 30, 2021, we had cash, cash equivalents and investments of $12.2 billion. Cash, cash equivalents and investments are invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation. Investments, consisting primarily of government and corporate debt securities, are stated at fair value. As of June 30, 2021, we had current and non-current investments of approximately $2.4 billion and $4.2 billion, respectively.

We historically funded our operations primarily from the sale of equity instruments and from proceeds from certain strategic alliance arrangements and grant agreements. Starting in August 2020, we have entered into supply agreements with the U.S. Government and several governments outside the United States for the supply of our COVID-19 vaccine and receive upfront deposits. As of June 30, 2021, we had $7.2 billion in deferred revenue related to customer deposits received or billable. In addition, as of June 30, 2021, BARDA has committed to fund up to $1.3 billion for the clinical development and advancement of mRNA-1273 to FDA licensure and the scale-up of manufacturing processes of our COVID-19 vaccine. As of June 30, 2021, the remaining available funding from BARDA, net of revenue earned was $421 million.

We continue to work toward the large-scale technical development, manufacturing scale-up in several countries and larger scale deployment of our COVID-19 vaccine. To support the scale-up, we have expended and will need to continue to expend significant resources and capital.

Cash flow

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

	Six Months Ended June 30,	
	2021	2020
Net cash provided by (used in):		
Operating activities	$ 7,034	$ (130)
Investing activities	(4,058)	(303)
Financing activities	2	1,959
Net increase in cash, cash equivalents and restricted cash	$ 2,978	$ 1,526

Operating activities

We derive cash flows from operations primarily from cash collected from customer deposits and accounts receivable related to our COVID-19 vaccine supply agreements as well as certain government-sponsored and private organizations and strategic alliances. Our cash flows from operating activities are significantly affected by our use of cash for operating expenses and working capital to support the business. Prior to 2020, we historically experienced negative cash flows from operating activities as we have invested in mRNA technologies, development pipeline, digital infrastructure, manufacturing technology and infrastructure.

Net cash provided by operating activities for the six months ended June 30, 2021 was $7.0 billion and consisted of net income of $4.0 billion and non-cash adjustments of $90 million, plus a net change in assets and liabilities of $2.9 billion. Non-cash items included depreciation and amortization of $84 million, deferred income taxes of $72 million, stock-based compensation of $65 million, and amortization of investment premium and discount of $13 million. The net change in assets and liabilities was mainly due to an increase in deferred revenue of $3.4 billion, an increase in other liabilities of $440 million, an increase in accrued liabilities of $367 million and an increase in accounts payable of $44 million, partially offset by an increase in accounts receivable of $629 million, an increase in inventory of $596 million, and an increase in prepaid expenses and other assets of $110 million.

Net cash used in operating activities for the six months ended June 30, 2020 was $130 million and consisted of net loss of $241 million and non-cash adjustments of $62 million, plus a net change in assets and liabilities of $49 million. Non-cash items primarily included stock-based compensation of $45 million and depreciation and amortization of $15 million. The net change in assets and liabilities was due to an increase in deferred revenue of $51 million, an increase in accrued liabilities of $20 million, an increase in operating lease liabilities of $14 million, an increase in accounts payable of $12 million and an increase in other liabilities of $4 million, partially offset by an increase in accounts receivable of $28 million, an increase in right-of-use assets related to operating leases of $12 million, and an increase in prepaid expenses and other assets of $12 million.

Investing activities

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

Net cash used in investing activities for the six months ended June 30, 2021 was $4.1 billion, which included purchases of marketable securities of $6.6 billion and purchases of property and equipment of $65 million, partially offset by proceeds from sales of marketable securities of $1.7 billion and proceeds from maturities of marketable securities of $860 million.

Net cash used in investing activities for the six months ended June 30, 2020 was $303 million, which included purchases of marketable securities of $903 million and purchases of property and equipment of $25 million, partially offset by proceeds from maturities of marketable securities of $517 million and proceeds from sales of marketable securities of $108 million.

Financing activities

We generated cash from financing activities of $2 million for the six months ended June 30, 2021, primarily from net proceeds from the issuance of common stock in connection with the exercise of stock options and employee stock purchases under our equity plans of $64 million, partially offset by changes in financing lease liabilities of $62 million.

We generated cash from financing activities of $2.0 billion for the six months ended June 30, 2020, primarily from net proceeds from equity offerings of $1.9 billion and net proceeds from the issuance of common stock in connection with the exercise of stock options under our equity plans of $106 million.

Operation and funding requirements

From our inception to the end of 2020, we incurred significant losses and negative cash flows from operations due to our significant research and development expenses. We generated net income in the first half of 2021 in connection with our product sales. We have retained earnings of $1.8 billion as of June 30, 2021. We expect our expenses to increase in connection with our ongoing activities, particularly 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, including our arrangements with our international supply and manufacturing partners. Our ongoing work on mRNA-1273, including development of any new generations of boosters and vaccines against variants of SARS-CoV-2, will require significant cash outflows during 2021, most of which may not be reimbursed or otherwise paid for by our partners or collaborators.

We believe that our cash, cash equivalents, and investments as of June 30, 2021, together with cash expected to be generated from operations, will be sufficient to enable us to fund our projected operations, capital expenditures and stock repurchases through at least the next 12 months from the issuance of these financial statements. 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 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.

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

Contractual Obligations

As of June 30, 2021, other than disclosed at Note 11 and Note 12 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 2020 Form 10-K.

Off balance sheet arrangements

As of June 30, 2021, 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

As of June 30, 2021 and December 31, 2020, we had cash, cash equivalents, and investments in marketable securities of $12.2 billion and $5.2 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), which are classified as available-for-sale securities. 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 one percentage point from levels at June 30, 2021, the net fair value of our marketable securities would decrease by approximately $98 million.

Foreign Currency Risk

Our revenue generating activities and operations have been primarily denominated in U.S. dollars. 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. To help manage the exposure to foreign currency exchange rate fluctuations, we have implemented cash flow hedging and balance sheet hedging programs.

Cash Flow Hedging Activities

We hedge foreign currency product sales denominated in Euros, including the use of foreign exchange forward contracts or purchased options. We hedge our cash flow exposures to reduce the risk that our earnings and cash flows will be adversely affected by changes in exchange rates. These transactions are designated and qualify as cash flow hedges. Our foreign exchange contracts at June 30, 2021, carried at fair value, had maturities of up to six months.

Balance Sheet Hedging Activities

We use foreign currency forward contracts to mitigate foreign currency exchange risk associated with foreign currency-denominated monetary assets and liabilities. These contracts reduce the impact of currency exchange rate movements on our assets and liabilities. As of June 30, 2021, our outstanding balance sheet hedging derivatives, carried at fair value, had maturities of less than three months.

We enter into these foreign exchange contracts to hedge forecasted revenue in the normal course of business and accordingly, they are not speculative in nature. We believe the counterparties to our foreign currency forward contracts are creditworthy multinational commercial banks. While we believe the risk of counterparty nonperformance is not material, a sustained decline in the financial stability of financial institutions as a result of disruption in the financial markets could affect our ability to secure creditworthy counterparties for our foreign currency hedging programs.

Notwithstanding our efforts to mitigate some foreign currency exchange risks, there can be no assurance that our hedging activities will adequately protect us against the risks associated with foreign currency fluctuations. As of June 30, 2021, a hypothetical adverse movement of 10 percent in foreign currency exchange rates compared to the U.S. dollars across all maturities would have resulted in potential declines in the fair value on our foreign currency forward contracts used in cash flow hedging of approximately $95 million. As of June 30, 2021, a hypothetical adverse movement of 10 percent in foreign currency exchange rates compared to the U.S. dollars across all maturities would have resulted in potential declines in the fair value on our foreign currency forward contracts used in balance sheet hedging of approximately $6 million. We expect that any increase or decrease in the fair value of the balance sheet hedging portfolio would be substantially offset by increases or decreases in the underlying exposures being hedged.

Item 4. Controls and Procedures

Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2021. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, or the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of June 30, 2021, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the three months ended June 30, 2021, 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

Investing in our common stock involves a high degree of risk. Information regarding risk and uncertainties related to our business appears in Part I, Item 1A. "Risk Factors" of our Annual Report on Form 10-K for the year ended December 31, 2020, which was filed with the Securities and Exchange Commission, or the SEC, on February 26, 2021. There have been no material changes from the risk factors previously disclosed in the Annual Report on Form 10-K. 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 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.

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*†	Amendment Nos. P00004, P00005, P00006, P00007, P00008, P00009, P00010, P00011 and P00012 to Award Contract No. W911QY20C0100, by and between Moderna US Inc. and the Army Contracting Command of the U.S. Department of Defense, dated June 15, 2021
10.2*†	Amendment Nos. 8 and 9 to Agreement No. HHSO100201600029C, by and between ModernaTX, Inc. and the Biomedical Advanced Research and Development Authority, dated as of April 16, 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 - The instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL 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

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

\+ 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.

SIGNATURES

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

MODERNA, INC.

Date:
August 5, 2021

By: /s/ Stéphane Bancel

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

Date:
August 5, 2021

By: /s/ David W. Meline

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

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 29

2. AMENDMENT/MODIFICATION NO.: **P00004**

3. EFFECTIVE DATE: **11-Feb-2021**

4. REQUISITION/PURCHASE REQ. NO.: **SEE SCHEDULE**

5. PROJECT NO.(If applicable):

6. ISSUED BY | CODE **W911QY**
W6QK ACC-APG NATICK DIVISION
BLDG 1 GENERAL GREENE AVENUE
NATICK MA 01760-5011

7. ADMINISTERED BY (If other than item 6) | CODE **S2206A**
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)
MODERNA US, INC.
[***]
200 TECHNOLOGY SQ
CAMBRIDGE MA 02139-3578

CODE **8PTM0** FACILITY CODE

9A. AMENDMENT OF SOLICITATION NO.

9B. DATED (SEE ITEM 11)

X 10A. MOD. OF CONTRACT/ORDER NO. **W911QY20C0100**

X 10B. DATED (SEE ITEM 13) **09-Aug-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 Offer is extended, is not extended.

Offer mist 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)

See Schedule

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:
See Block 14 Continuation Page

D. OTHER (Specify type of modification and authority)

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.)
Modification Control Number: **[***]**

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 foil force and effect.

15A. NAME AND TITLE OF SIGNER (Type or print)
Stephane Bancel, CEO

15B. CONTRACTOR/OFFEROR
/s/ Stephane Bancel
(Signature of person authorized to sign)

15C. DATE SIGNED

16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)
[***]
TEL: [***] EMAIL: [***]

16B. UNITED STATES OF AMERICA
BY
(Signature of Contracting Officer)

16C. DATE SIGNED
11 Feb 2021

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:

OBLIGATION AMOUNT: $1,650,000,000

a. The purpose of this modification (P00004) is to:
   - Exercise, fund Option 2 CLINs 2001AA, 2001AB, 2001AC for a total of $1,650,000,000 (Authority FAR 52.217-7)
   - Add clauses H. 16 & H. 17, and revise the delivery schedule for the Base period, Option 1, and Option 2 LAW the table contained within H. 16 (Authority FAR 43.103(a)(3), Mutual Agreement of the Parties)
   - Revise the table in Section G back to previous amounts, due to an administrative error on modification no. P00003, where the amounts were revised (Authority FAR 52.232-16)
   - Update Contract Data Requirement List (CDRL) no.'s A003, A008, A009, A011, A014, A021, and the corresponding information to the CDRLs in Section C, Statement of Work. (Authority FAR 43.103(a)(3), Mutual Agreement of the Parties)

b. This modification was requested by the program office to meet the Government's mission requirements.
c. The total contract value and total funded amount has increased by $1,650,000,000 from $3,191,598,000 to $4,841,598,000.

All other terms and conditions remain unchanged. Please see below for details.

SECTION A - SOLICITATION/CONTRACT FORM

The total cost of this contract was increased by $1,650,000,000.00 from $3,191,598,000.00 to $4,841,598,000.00.

SECTION B - SUPPLIES OR SERVICES AND PRICES

CLIN 0001

The CLIN extended description has changed from:

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

To:

The contractor shall produce and deliver 100M doses of the SARS-CoV-2 mRNA-1273 Vaccine filled drug product (FDP) IAW clause H.16 Delivery Schedule, Section C Statement of Work (SOW), and CDRLs (Exhibit A) on this contract.

CLIN 1001

The CLIN extended description has changed from:

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.

To:

The contractor shall produce and deliver 100M doses of the SARS-CoV-2 mRNA-1273 Vaccine filled drug product (FDP) IAW clause H.16 Delivery Schedule, Section C Statement of Work (SOW), and CDRLs (Exhibit A) on this contract.

CLIN 2001

The CLIN extended description has changed from:

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.

To:

The contractor shall produce and deliver 100M doses of the SARS-CoV-2 mRNA-1273 Vaccine filled drug product (FDP) IAW clause H.16 Delivery Schedule, Section C Statement of Work (SOW), and CDRLs (Exhibit A) on this contract.

The option status has changed from Option to Option Exercised.

SUBCLIN 2001AA

The option status has changed from Option to Option Exercised.

SUBCLIN 2001 AB

The option status has changed from Option to Option Exercised.

SUBCLIN 2001AC

The option status has changed from Option to Option Exercised.

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 [***], with overlapping options for a total of [***] 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/Title21/21cfiv4_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 [***]. (Based on FDP stability data that supports a [***] 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 [***]. 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 [***] 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 biologies 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 [***]. (Based on FDP stability data that supports a [***] 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 produetto the designated distribution site via a qualified distribution vendor in accordance with Section F and paragraph C.7 below. [***].

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 biologies 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 [***]. (Based on FDP stability data that supports a [***] 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. [***].

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 biologies 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 [***]. (Based on FDP stability data that supports a [***] 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. [***].

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 [***]. (Based on FDP stability data that supports a [***] 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. [***].

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 AO 15. 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 biologies 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, ~~Built tnRNA,~~ 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 [***].

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 (SCRP). The contractor shall provide, in accordance with CDRL A010 and CDRL Attachment 0001, a comprehensive SCRP 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 [***].

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 [***].

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 [***] 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 AOI 8.

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 [***] 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 [***] 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 CO VID-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 AO 19, 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 [***], 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 [***] 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 [***].

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 [***] 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 E - INSPECTION AND ACCEPTANCE

The following have been modified:

E.1 Inspection:

Vaccine CLINs:
Quality inspection of Filled Drug Product (FDP) shall occur when the Contractor performs release testing to confirm that products complies with Contractor's release specifications and criteria. Contractor will submit the Certificate of Analysis for quality inspection of all drug product lots in BARDA Data Infrastructure (BDI) system. 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).

The Government shall inspect each shipment of product delivered to it hereunder for visible damage and quantity [***] of final 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 final delivery, the Government shall promptly notify Contractor in writing [***]. A BDI extract of the inspection documentation shall also be submitted in Wide Area Workflow (WAWF) as supporting documentation for invoice submittals.

Storage CLIN:
In the event the USG requires storage of the FDP to a Vendor Managed Inventory (VMI) location, quantity inspection shall be conducted by submission of shipping or other documentation into WAWF confirming quantity to VMI location. Physical inspection of the FDP shall be conducted upon receipt of product to USG CDC location.

Data CLIN:
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 [***]. Acceptance [***]. 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 of vaccines under this agreement will be performed by the COTR in the BDI system, which constitutes government acceptance [***]. Documentation of acceptance shall be submitted in accordance with WAWF instructions.

(c) Acceptance of storage services under VMI CLIN No. 0002 shall occur upon [***]. Acceptance of Data CLIN No. 0004 shall occur in WAWF by the KO.

(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

The following Delivery Schedule item for SUBCLIN 1001 AB has been changed from:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
[***]	[***]	[***] FOB: Destination	[***]

To:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
[***]	[***]	[***] FOB: Destination	[***]

The following Delivery Schedule item for SUBCLIN 1001 AC has been changed from:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
[***]	[***]	[***] FOB: Destination	[***]

To:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
[***]	[***]	[***] FOB: Destination	[***]

The following Delivery Schedule item for SUBCLIN 2001AA has been changed from:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
[***]	[***]	[***] FOB: Destination	[***]

To:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
[***]	[***]	[***] FOB: Destination	[***]

The following Delivery Schedule item for SUBCLIN 2001AB has been changed from:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
[***]	[***]	[***] FOB: Destination	[***]

To:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
[***]	[***]	[***] FOB: Destination	[***]

The following Delivery Schedule item for SUBCLIN 2001AC has been changed from:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
[***]	[***]	[***] FOB: Destination	[***]

To:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
[***]	[***]	[***] FOB: Destination	[***]

The following have been modified:

F.1 The contractor shall ship mRNA-1273 vaccines to the designated locations listed below. The contractor shall be responsible for secure shipment of all vaccine product whether acceptance is conducted [***].

Delivery Locations:

Location 1

[***]

Location 2

[***]

SECTION G - CONTRACT ADMINISTRATION DATA

Accounting and Appropriation

Summary for the Payment Office

As a result of this modification, the total funded amount for this document was increased by $ 1,650,000,000.00 from $3,191,598,000.00 to $4,841,598,000.00.

SUBCLIN 2001AA:

AF: [***] increased by $551,100,000.00 from $0.00 to $551,100,000.00
The contract ACRN AF has been added.
The CIN [***] has been added.
The Cost Code [***] has been added.

SUBCLIN 2001AB:

AG: [***] was increased by $551,100,000.00 from $0.00 to $551,100,000.00
The contract ACRN AG has been added.
The CIN [***] has been added.
The Cost Code [***] has been added.

SUBCLIN 2001AC:

AH: [***] was increased by $547,800,000.00 from $0.00 to $547,800,000.00
The contract ACRN AH has been added.
The CIN [***] has been added.
The Cost Code [***] has been added.

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:

[***]
Bldg. 1, General Greene Avenue
Natick, MA 01760-5011

Contract Specialist:
[***]
Bldg. 1, General Greene Avenue
Natick, MA 01760-5011

G.2 **GOVERNMENT TECHNICAL POINT OF CONTACT**

[***]
Biologist/Project Officer
200 C Street, SW
Washington, DC 20201

G.3 **CONTRACTOR'S CONTRACT ADMINISTRATION**

[***]
Moderna US, 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 dated 4 December 2020.

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 request 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:

(i) 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 2-in-l, 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

Field Name in WAWF	*Data to be entered in WA WF*
Pay Official DoDAAC	HQ0337
Issue By DoDAAC	W911QY
Admin DoDAAC	S2206A
Inspect By DoDAAC	W56XNH
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:

DEARS PGI 204.7108 Payment Instructions Table

https://www.acq.osd.mil1/dpap/dars/pgi/pgi_htm/current/PGI204_71.htm#payment_instructions

SECTION H - **SPECIAL CONTRACT REQUIREMENTS**

The following have been modified:

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), biologies 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(f), 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 [***] of award.

b. [***].

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 Contractors 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 CO VID-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.9 **[***].**

H.10 **[***].**

H.11 **[***].**

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.

H.15 **Base & Option 1 Delivery Acceleration**

In an effort to accelerate production of the mRNA-1273 vaccine, [***] within the Option 1 period via a Modification to the contract. If these manufacturing slots are successfully utilized, [***] above what was projected by Moderna and assumed within the price per dose for the doses of tnRNA-1273 vaccine delivered in the Base Period and Option 1. However, because the Government is funding the additional slots within the Base and Option 1 periods in order to accelerate production, the Government is entitled to an adjustment under the conditions outlined. The Government and Moderna agree to the following:

1. If the Government exercises Option 2 (NLT 15 May):

a [***].

2. If the Government does not exercise Option 2 (NLT 15 May):

a. In the event Moderna timely cancels the manufacturing slots and/or is able to otherwise fully utilize the slots originally reserved for production in the Option 2 period, Moderna agrees to [***] for [***] and [***] for [***]. In no case shall the number of drug product manufacturing slots credited exceed the number of successfully accelerated drug product manufacturing fills under the Base Period and Option 1. It is understood that Moderna will make all good-faith efforts to fill reserved slots or cancel reservations in a timely manner (i.e. within the time period required by the subcontractor).

b. In the event that Moderna is unable to fill those reserved slots (i.e. due to lack of demand) and cancels slots, Moderna shall be entitled to recoup those reservation cancellation costs from the USG. The process is outlined as follows:

1.) Moderna shall submit documentation to the USG of the following:

i.) Cancellation notice to the subcontractor,
ii.) The basis of the cancellation, and
iii.) Cancellation fees incurred.

2.) [***].

H.16 **Delivery Schedule, as revised 11 Feb 2021 via modification P00004**

[***]

Moderna confirms that it will provide the USG with the first 300M doses manufactured within its US-based supply chain [***], with the exception of doses required for clinical studies. [***]. Both parties acknowledge that resulting revisions to future accounting, invoicing, acceptance and delivery of doses subject to the revised label will be implemented via a subsequent modification.

H.17 **Post-Termination Disposition of Undelivered Product**

For the avoidance of doubt, if the USG elects to terminate the exercised CLINs prior to acceptance and delivery in full of the required quantities of mRNA-1273, Moderna will be free to direct any unaccepted/undelivered supplies of mRNA-1273 to customers other than the USG, at its discretion, without further obligation of either party with regard to such unaccepted/undelivered supplies of mRNA-1273. The contract will be bilaterally modified to decrease the quantities by the agreed upon volume.

SECTION I - CONTRACT CLAUSES

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 $300,000,000.00 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 items(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 if 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

Modification P00003 dated 11 Dec 2020 - $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	11 Feb 2021
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	17	4 December 2020
Attachment 0009	HRPAS Moderna Letter	1	3 September 2020

(End of Summary of Changes)

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE | PAGE OF PAGES: 1 23

2. AMENDMENT/MODIFICATION NO.: **P00005**

3. EFFECTIVE DATE: **23-Apr-2021**

4. REQUISITION/PURCHASE REQ. NO.: **SEE SCHEDULE**

5. PROJECT NO.(If applicable):

6. ISSUED BY: CODE **W911QY**

W6QK ACC-APG NATICK DIVISION
BLDG 1 GENERAL GREENE AVENUE
NATICK MA 01760-5011

7. ADMINISTERED BY (If other than item 6): CODE **S2206A**

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)

MODERNA US, INC.
[***]
200 TECHNOLOGY SQ
CAMBRIDGE MA 02139-3578

CODE **8PTM0** FACILITY CODE

9A. AMENDMENT OF SOLICITATION NO.

9B. DATED (SEE ITEM 11)

X 10A. MOD. OF CONTRACT/ORDER NO. **W911QY20C0100**

X 10B. DATED (SEE ITEM 13) **09-Aug-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 Offer is extended, is not extended.

Offer mist 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)

See Schedule

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:

See Block 14 Continuation Page

D. OTHER (Specify type of modification and authority)

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.)
Modification Control Number: **[***]**

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 foil force and effect.

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

Stephen Hoge, President

15B. CONTRACTOR/OFFEROR

/s/ Stephen Hoge

(Signature of person authorized to sign)

15C. DATE SIGNED

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

[***]
TEL: [***] EMAIL: [***]

16B. UNITED STATES OF AMERICA

BY

(Signature of Contracting Officer)

16C. DATE SIGNED

23 April 2021

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:

OBLIGATION AMOUNT: $0.00

a. The purpose of this modification (P00005) is to:

- Revise Section A and Section C to recognize 8.0mL fill volume (1600mcg) [***] along with the 6.3mL fill volume (1260mcg) [***] currently on contract (Authority FAR 43.103(a)(3), Mutual Agreement of the Parties)

- Add H. [***] Invoicing, to Section H (Authority FAR 43.103(a)(3), Mutual Agreement of the Parties)

b. This modification was requested by the program office to meet the Government's mission requirements.

c. The total contract value and total funded amount remain unchanged.

All other terms and conditions remain unchanged. Please see below for details.

SECTION A - SOLICITATION/CONTRACT FORM

The following have been modified:

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 pg) 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 [***]. All doses will be delivered in a multi-dose vial containing either 6.3mL fill volume (1260mcg) [***] (manufactured as described in Moderna's FDA concurrence letter dated 01 April 2021 or 8.0mL fill volume (1600mcg) [***] (as described in Moderna's FDA submission dated (01 April 2021).

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.

C1.1.1 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 [***], with overlapping options for a total of [***] if all options are exercised.

C.1.3 Consistent with the Updated EUA Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) dated 01 April 2021, up to [***] may be extracted from Moderna's newly authorized multidose vials with 8.0mL fdl volume (1600mcg). The Government and Moderna agree that [***] per vial are only attainable using premium low dead volume (LDV) syringes, which are in short supply globally. Utilizing initial ancillary equipment, vaccine administration personnel can reliably extract [***] from these vials; however, the Government has identified needle/syringe combinations that can be used to extract [***].

C.1.3.1 Given the two parties' shared interest in reducing vaccine waste and accelerating the availability of Moderna's SARS-CoV-2 vaccine doses, the Government and Moderna intend that the Moderna vaccines doses be administered with needles and syringes compatible with extraction of [***] when possible. Toward this end, the Government shall maintain a list of syringe and/or needle combinations which will allow extraction of [***] per 8.0mL vial, which list shall be updated jointly by the Government and Moderna as any additional syringe and/or

needle combinations compatible with extraction of [***]/vial are identified. Furthermore, the Government will, to the extent that appropriate needles and syringes are available, assemble and ship kits containing sufficient quantities of syringes and needles compatible with extraction of [***] per vial (Kit Moderna [***]) with Moderna's SARS-CoV-2 vaccine. The Government expects that these kits will be available beginning 01 May 2021 for a significant portion of Moderna's remaining deliveries. If, however, appropriate syringes and needles are not available, the Government will revert to shipping the Kit Moderna [***] with Moderna's SARS-CoV-2 vaccine.

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 [***]. (Based on FDP stability data that supports a [***] 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 [***].

C.3.1.1.4 [***].

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 [***] 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 biologies 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 [***]. (Based on FDP stability data that supports a [***] 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 [***].

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 drags and biologies 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 [***]. (Based on FDP stability data that supports a [***] shelf-life, subject to FDA confirmation of the assigned shelf-life.) Ensure requirements of 21CFR207. Registration of Producers of Drags and Listing of Drags 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 [***].

C.3.3.1.4 Ensuring that the product complies with the Drag 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 biologies 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 [***]. (Based on FDP stability data that supports a [***] 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 [***].

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**.

A.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 [***]. (Based on FDP stability data that supports a [***] 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 [***].

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 biologies 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 14230, 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 (SCRP). The contractor shall provide, in accordance with CDRL A010 and CDRL Attachment 0001, a comprehensive SCRP 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 [***].

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 BARD A 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 [***] 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 AO 17.

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 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 CO VID-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 AO 19. and shall demonstrate how the contractor shall meet and adhere to the security requirements outlined in CDRL Attachment 0002. Titis 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)ZPlan 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 [***], 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 [***] 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 [***]. [***].

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 [***]. 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:
[***]
Bldg. 1, General Greene Avenue
Natick, MA 01760-5011

Contract Specialist:
[***]

Bldg. 1, General Greene Avenue
Natick, MA 01760-5011

G.2 **GOVERNMENT TECHNICAL POINT OF CONTACT**

[***]
Biologist/Project Officer
200 C Street. SW
Washington, DC 20201

G.3 **CONTRACTOR'S CONTRACT ADMINISTRATION**

[***]
Moderna US, 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 I AW 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 dated 4 December 2020.

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.miF.

(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:

(i) 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 2-in-1, 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

Field Name in HA IFF	*Data to be entered in WA WF*
Pay Official DoDAAC	HQ0337
Issue By DoDAAC	W911QY
Admin DoDAAC	S2206A
Inspect By DoDAAC	W56XNH
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.mi1/dpap/dars/pgi/pgihtm/current/PGI204_71.htm#payment_instructions

SECTION H - SPECIAL CONTRACT REQUIREMENTS
The following have been modified:

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 Contractors 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), biologies 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 [***] of award.

b. [***].

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 CO VID-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 Contractors 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 CO VID-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 tins Contract are being developed for both civil and military applications.

H.9 **[***] .**

H.10 **[***].**

H.11 **[***].**

H.12 **Transportation to Final Destination**

During the course of performance under this contract, the Government may require storage of the filled drag 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.

H.15 **Base & Option 1 Delivery Acceleration**

In an effort to accelerate production of the mRNA-1273 vaccine, [***] within the Option 1 period via a Modification to the contract. If these manufacturing slots are successfully utilized, [***] above what was projected by Moderna and assumed within the price per dose for the doses of mRNA-1273 vaccine delivered in the Base Period and Option 1. However, because the Government is funding the additional slots within the Base and Option 1 periods in order to accelerate production, the Government is entitled to an adjustment under the conditions outlined. The Government and Moderna agree to the following:

1. If the Government exercises Option 2 (NLT 15 May):

a. Moderna will reduce the cost of Option 2 by [***] for each successfully accelerated drag product fill under the Base Period [***] and [***] for each successfully accelerated drag product fill under Option 1 [***].

2. If the Government does not exercise Option 2 (NLT 15 May):

a. In the event Moderna timely cancels the manufacturing slots and/or is able to otherwise fully utilize the slots originally reserved for production in the Option 2 period, Moderna agrees to credit the Government [***] for [***] and [***] for [***]. In no case shall the number of drug product manufacturing slots credited exceed the number of successfully accelerated drug product manufacturing fills under the Base Period and Option 1. It is understood that Moderna will make all good-faith efforts to fdl reserved slots or cancel reservations in a timely manner (i.e. within the time period required by the subcontractor).

b. In the event that Moderna is unable to fill those reserved slots (i.e. due to lack of demand) and cancels slots, Moderna shall be entitled to recoup those reservation cancellation costs from the USG. The process is outlined as follows:

1.) Moderna shall submit documentation to the USG of the following:

i.)Cancellation notice to the subcontractor,
ii.) The basis of the cancellation, and
iii.) Cancellation fees incurred.

2.) Moderna shall reduce credits to the USG under paragraph 2a) of this clause. IAW agreed cancellation costs incurred.

3.) Bi-lateral agreement of the final credit shall be included in a modification to the contract. Net credit shall be deducted from final payments under the contract.

H.16 **Delivery Schedule, as revised H Feb 2021 via modification P00004**

[***]

Moderna confirms that it will provide the USG with the first 300M doses manufactured within its US-based supply chain [***], with the exception of doses required for clinical studies. The delivery schedule assumes that Moderna will work to further maximize fill/finish capacity by working with the FDA to increase fill volumes, [***]. Both parties acknowledge that resulting revisions to future accounting, invoicing, acceptance and delivery of doses subject to the revised label will be implemented via a subsequent modification.

H.17 **Post-Termination Disposition of Undelivered Product**

For the avoidance of doubt, if the USG elects to terminate the exercised CLINs prior to acceptance and delivery in full of the required quantities of mRNA-1273, Moderna will be free to direct any unaccepted/undelivered supplies of mRNA-1273 to customers other than the USG, at its discretion, without further obligation of either party with regard to such unaccepted/undelivered supplies of mRNA-1273. The contract will be bilaterally modified to decrease the quantities by the agreed upon volume.

H.18 **[***].**

In order to facilitate projections and invoicing, the Government shall provide or direct a third party (e.g., McKesson) to provide to Moderna (1) actual quantities of Moderna [***] with 8.0mL vials during the reporting period; (2) actual quantities of Moderna [***] with 8.0mL vials during the reporting period; and (3) the number of [***] remaining in inventory and available for upcoming shipments. This information will be provided to Moderna at a frequency of at least twice monthly.

For each 8.0mL fill volume (1600mcg) vial of vaccine shipped with a [***].

Both parties acknowledge that the delivery schedule is based on [***] 8.0mL fill volume (1600mcg) vial delivered. In accordance with the agreed approach for invoicing and counting doses toward Moderna's delivery requirement, [***]. Specifically for purposes of adhering to the scheduled delivery dates set forth in this contract for the Base Period. Option 1 and Option 2, schedule shall be deemed to have been met once doses are released by Moderna and are available for order.

SECTION J - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

The following have been modified:

Document Type	Description	Page #	Date
Exhibit A	CDRLs	15	11 Feb 2021
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	17	4 December 2020
Attachment 0009	HRPAS Moderna Letter	1	3 September 2020

(End of Summary of Changes)

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE

PAGE OF PAGES
1 24

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO.(If applicable)
P00006	**4-Jun-2021**	**SEE SCHEDULE**	

6. ISSUED BY CODE **W911QY**

W6QK ACC-APG NATICK DIVISION
BLDG 1 GENERAL GREENE AVENUE
NATICK MA 01760-5011

7. ADMINISTERED BY (If other than item 6) CODE **S2206A**

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)

MODERNA US, INC.
[***]
200 TECHNOLOGY SQ
CAMBRIDGE MA 02139-3578

CODE **8PTM0** FACILITY CODE

9A. AMENDMENT OF SOLICITATION NO.

9B. DATED (SEE ITEM 11)

X 10A. MOD. OF CONTRACT/ORDER NO. **W911QY20C0100**

X 10B. DATED (SEE ITEM 13) **09-Aug-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 Offer is extended, is not extended.

Offer mist 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)

See Schedule

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).

C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:

X **See Block 14 Continuation Page**

D. OTHER (Specify type of modification and authority)

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.)
Modification Control Number: **[***]**

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 foil force and effect.

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

Stephane Bancel, CEO

15B. CONTRACTOR/OFFEROR
/s/ Stephane Bancel
(Signature of person authorized to sign)

15C. DATE SIGNED

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

[***]
TEL: [***] EMAIL: [***]

16B. UNITED STATES OF AMERICA
BY
(Signature of Contracting Officer)

16C. DATE SIGNED
4 Jun 2021

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:

OBLIGATION AMOUNT: $3,993,662.60

a. The purpose of this modification (P00006) is to:

- Change the Purchasing Office from W911QY (NCD) to W58P05 (JCRD); the new Contracting Officer is [***] and Contract Specialist remains unchanged (Authority FAR 52.243-1)

- Update CLIN 0002 pricing for VMI Storage and obligate funding of $1,355,232.80; revise CLIN structure for 0002 to add 0002AA, 0002AB, 00002AC; void out CLINs 1002, 2002, 3002, 4002 (Authority FAR 52.243-1).

- Add Accelerated Distribution CLINs 0005, 0005AA, 0005AB, 0005AC, and fund in the amount of $2,638,429.80 (Authority FAR 43.103(a)).

- Revise Section E, Inspect and Acceptance (Authority FAR 52.243-1).

- Revise the Acceptor DODAAC from W911QY to W58P05 in FAR Clause 252.232-7006 (Authority FAR 52.243-1)

b. This modification was requested by the program office to meet the Government's mission requirements.

c. The total value of the contract has increased by $3,993,662.60 from $8,141,598,000 to $8,145,591,662.60. The total funded amount has increased by $3,993,662.60 from $4,841,598,000 to $4,845,591,662.60.

All other terms and conditions remain unchanged. Please see below for details.

The following have been modified:

OBLIGATION AMOUNT: $1,650,000,000

a. The purpose of this modification (P00004) is to:

- Exercise, fund Option 2 CLINs 2001AA, 2001AB, 2001AC for a total of $1,650,000,000 (Authority FAR 52.217- 7)

- Add clauses H. 16 & H. 17, and revise the delivery schedule for the Base period, Option 1, and Option 2 IAW the table contained within H. 16 (Authority FAR 43.103(a)(3), Mutual Agreement of the Parties)

- Revise the table in Section G back to previous amounts, due to an administrative error on modification no. P00003, where the amounts were revised (Authority FAR 52.232-16)

- Update Contract Data Requirement List (CDRL) no.'s A003, A008, A009, A011, A014, A021, and the corresponding information to the CDRLs in Section C, Statement of Work, (Authority FAR 43.103(a)(3), Mutual Agreement of the Parties)

b. This modification was requested by the program office to meet the Government's mission requirements.

c. The total contract value and total funded amount has increased by $ 1.650.000.000 from $3.191.598.000 to $4,841,598,000.

All other terms and conditions remain unchanged. Please see below for details.

SECTION A - SOLICITATION/CONTRACT FORM

The total cost of this contract was increased by $3,993,662.60 from $4,841,598,000.00 to $4,845,591,662.60.
The 'administered by' organization has changed from
DEFENSE CONTRACT MANAGEMENT AGENCY
DCMA BOSTON
495 SUMMER STREET
BOSTON MA 02210-2138
to
DEFENSE CONTRACT MANAGEMENT AGENCY
DCMA BOSTON
37 GRENIER STREET, BLDG. 1108
HANSCOM AIR FORCE BASE MA 01731 -1600

SECTION B - SUPPLIES OR SERVICES AND PRICES

CLIN 0002
The pricing detail quantity has increased by 11.00 from 1.00 to 12.00.
The unit price amount has increased by $112,936.07 from $0.00 to $112,936.067.
The unit of issue has changed from Job to Months.
The cost constraint TBN has been deleted.
The total cost of this line item has increased by $1,355,232.80 from $0.00 to $1,355,232.80.

CLIN 1002
The CLIN description has changed from Vendor Managed Inventory to Void - Vendor Managed Inventory.
The CLIN extended description has changed from:

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. [***].

To:

VMI Storage requirements were consolidated into CLIN 0002 via modification P00006. All other VMI Storage CLINs are hereby void.

The pricing detail quantity has decreased by 1.00 from 1.00 to 0.00.
The unit of issue Job has been deleted.
The option status has changed from Option to No Status.
The cost constraint TBN has been deleted.

CLIN 2002
The CLIN description has changed from Vendor Managed Inventory to Void - Vendor Managed Inventory.
The CLIN extended description has changed from:

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. [***].

To:

VMI Storage requirements were consolidated into CLIN 0002 via modification P00006. All other VMI Storage CLINs are hereby void.

The pricing detail quantity has decreased by 1.00 from 1.00 to 0.00.
The unit of issue Job has been deleted.
The option status has changed from Option to No Status.
The cost constraint TBN has been deleted.

CLIN 3001
The CLIN extended description has changed from:

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.

To:

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.

CLIN 3002
The CLIN description has changed from Vendor Managed Inventory to Void - Vendor Managed Inventory.
The CLIN extended description has changed from:

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. [***].

To:

VMI Storage requirements were consolidated into CLIN 0002 via modification P00006. All other VMI Storage CLINs are hereby void.

The pricing detail quantity has decreased by 1.00 from 1.00 to 0.00.
The unit of issue Job has been deleted.
The option status has changed from Option to No Status.
The cost constraint TBN has been deleted.

CLIN 4001
The CLIN extended description has changed from:

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.

To:

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

CLIN 4002
The CLIN description has changed from Vendor Managed Inventory to Void - Vendor Managed Inventory.
The CLIN extended description has changed from:

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. [***].

To:

VMI Storage requirements were consolidated into CLIN 0002 via modification P00006. All other VMI Storage CLINs are hereby void.

The pricing detail quantity has decreased by 1.00 from 1.00 to 0.00.
The unit of issue Job has been deleted.
The option status has changed from Option to No Status.
The cost constraint TBN has been deleted.

CLIN 0005 is added as follows:

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0005	Accelerated Distribution FFP [***] associated with Base, Option 1, and Option 2 periods (300M doses total) to meet fluctuating CDC allocation requirements [***].				$0.00
				NET AMT	$0.00

SUBCLIN 005AA is added as follows:

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
00055AA		1	Job	$879,476.60	$879,476.60
	Base Period FFP [***] FOB: Destination PURCHASE REQUEST NUMBER: [***] PSC CD: 6505				
				NET AMT	$879,476.60
	ACRN AJ CIN: GFEBS001165492700002				$879,476.60

SUBCLIN 0005AB is added as follows:

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0005AB		1	Job	$879,476.60	$879,476.60
	Option 1 Period FFP [***] FOB: Destination PURCHASE REQUEST NUMBER: [***] PSC CD: 6505				
				NET AMT	$879,476.60
	ACRN AJ CIN: GFEBS001165492700003				$879,476.60

SUBCLIN 0005AC is added as follows:

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0005AC		1	Job	$879,476.60	$879,476.60
	[***]. FOB: Destination PURCHASE REQUEST NUMBER: [***] PSC CD: 6505				
				NET AMT	$879,476.60
	ACRN AJ CIN: GFEBS001165492700004				$879,476.60

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 CO VID-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 [***], with overlapping options for a total of [***] if all options are exercised.

C.1.3 Consistent with the Updated EUA Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) dated 01 April 2021, up to [***] may be extracted from Moderna's newly authorized multidose vials with 8.0mL fill volume (1600mcg). The Government and Moderna agree that [***] per vial are only attainable using premium low dead volume (LDV) syringes, which are in short supply globally. Utilizing initial ancillary equipment, vaccine administration personnel can reliably extract [***] from these vials: however, the Government has identified needle/syringe combinations that can be used to extract [***].

C.1.3.1 Given the two parties' shared interest in reducing vaccine waste and accelerating the availability of Moderna's SARS-CoV-2 vaccine doses, the Government and Moderna intend that the Moderna vaccines doses be administered with needles and syringes compatible with extraction of [***] when possible. Toward this end, the Government shall maintain a list of syringe and/or needle combinations which will allow extraction of [***] per 8.0mL vial, which list shall be updated jointly by the Government and Moderna as any additional syringe and/or needle combinations compatible with extraction of [***]/vial are identified. Furthermore, the Government will, to the extent that appropriate needles and syringes are available, assemble and ship kits containing sufficient quantities of syringes and needles compatible with extraction of [***] per vial (Kit Moderna [***]) with Moderna's SARS-CoV-2 vaccine. The Government expects that these kits will be available beginning 01 May 2021 for a significant

portion of Moderna's remaining deliveries. If, however, appropriate syringes and needles are not available, the Government will revert to shipping the Kit Moderna [***] with Moderna's SARS-CoV-2 vaccine.

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=tme&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 [***]. (Based on FDP stability data that supports a [***] 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 [***].

C.3.1.1.4 [***].

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 [***] 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 BARD A 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 biologies 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 [***]. (Based on FDP stability data that supports a [***] 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 [***].

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 biologies 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 [***]. (Based on FDP stability data that supports a [***] 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 [***].

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 AOOL

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 part) in accordance with CDRL A002. The Contractor shall provide the Contracting Officer with a plan for addressing areas of nonconformance, if am 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 biologies 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 [***]. (Based on FDP stability data that supports a [***] 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 [***].

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 [***]. (Based on FDP stability data that supports a [***] 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 [***].

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 biologies 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, 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 (SCRP). The contractor shall provide, in accordance with CDRL A010 and CDRL Attachment 0001, a comprehensive SCRP 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 [***].

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 [***] 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 AO 17.

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 AO 18.

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 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 A02L 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 CO VID-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)ZPlan 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 [***], 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 [***] 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. B ARDA/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 qualify, 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 [***].

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 [***]. 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 E - INSPECTION AND ACCEPTANCE

The following Acceptance/Inspection Schedule was added for CLIN 0005:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
N/A	N/A	N/A	N/A

The following Acceptance/Inspection Schedule was added for SUBCLIN 0005AA:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
Origin	Government	Origin	Government

The following Acceptance/Inspection Schedule was added for SUBCLIN 0005AB:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
Origin	Government	Origin	Government

The following Acceptance/Inspection Schedule was added for SUBCLIN 0005AC:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
Origin	Government	Origin	Government

The following have been modified:

E.1 Inspection:

Vaccine CLINs:

Quality inspection of Filled Drug Product (FDP) shall occur when the Contractor performs release testing to confirm that products complies with Contractor's release specifications and criteria. Contractor will submit the Certificate of Analysis for quality inspection of all drug product lots in BARDA Data Infrastructure (BDI) system. 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).

The Government shall inspect each shipment of product delivered to it hereunder for visible damage and quantity [***] of final 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 final delivery, the Government shall promptly notify Contractor in writing [***]. A BDI extract of the inspection documentation shall also be submitted in Wide Area Workflow (WAWF) as supporting documentation for invoice submittals.

Storage CLIN:

Inspection of storage under this contract will be performed at destination by a duly authorized representative of the Government. Contractor shall submit an invoice into WAWF at the end of each month during the period of performance specified.

Accelerated Distribution CLIN:

Inspection of Accelerated Distribution shall occur at origin when the Contractor completes deliveries for each ordering period: a). Base Period, b). Option 1 Period, and c). Option 2 Period. Contractor shall submit an invoice against the appropriate subCLIN under CLIN 0005 in WAWF, accordingly. Inspection will be conducted by the BARDA Contracting Officer's Technical Representative (COTR) to ensure all vaccines doses have been delivered.

Data CLIN:

Inspection of all reports and Contract Data Requirement List (CDRL) under this contract will be performed at Destination by a duly authorized representative of the Government.

E.2 Acceptance

a. Acceptance [***]. Acceptance [***]. 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 of vaccines under this agreement will be performed by the COTR in the BDI system, which constitutes government acceptance at origin. Documentation of acceptance shall be submitted in accordance with WAWF instructions.

c. Acceptance of storage & accelerated distribution shall occur in WAWF by the KO.

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

The following Delivery Schedule Item has been deleted from CLIN 0002:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
[***]	[***]	N/A FOB: Destination	

The following Delivery Schedule item has been added to CLIN 0002:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
[***]	[***]	[***] FOB: Destination	[***]

The following Delivery' Schedule for SUBCLIN 0005AA has been added:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
[***]	[***]	[***] FOB: Destination	[***]

The following Delivery Schedule for SUBCLIN 0005AB has been added:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
[***]	[***]	[***] FOB: Destination	[***]

The following Delivery Schedule for SUBCLIN 0005AC has been added:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
[***]	[***]	[***] FOB: Destination	[***]

The following Delivery' Schedule for CLIN 1002 has been deleted:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
[***]	[***]	N/A FOB: Destination	

The following Delivery Schedule for CLIN 2002 has been deleted:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
[***]	[***]	N/A FOB: Destination	

The following Delivery Schedule for CLIN 3002 has been deleted:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
[***]	[***]	N/A FOB: Destination	

The following Delivery Schedule for CLIN 4002 has been deleted:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
[***]	[***]	N/A FOB: Destination	

SECTION G - CONTRACT ADMINISTRATION DATA

Accounting and Appropriation

Summary for the Payment Office

As a result of this modification, the total funded amount for this document was increased by $3,993,662.60 from $4,841,598,000.00 to $4,845,591,662.60.

CLIN 0002:

AJ: [***] was increased by $1,355,232.80 from $0.00 to $1,355,232.80
The contract ACRN AJ has been added.
The CIN [***] has been added.

SUBCLIN 0005AA:
Funding on SUBCLIN 0005AA is initiated as follows:

ACRN: AJ

CIN: [***]

Acctng Data: [***]

Increase: $879,476.60

Total: $879,476.60

SUBCLIN 0005AB:
Funding on SUBCLIN 0005AB is initiated as follows:

ACRN: AJ

CIN: [***]

Acctng Data: [***]

Increase: $879,476.60

Total: $879,476.60

SUBCLIN 0005AC:
Funding on SUBCLIN 0005AC is initiated as follows:

ACRN: AJ

CIN: [***]

Acctng Data: [***]

Increase: $879,476.60

Total: $879,476.60

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:
[***]
Joint COVID-19 Response Division
US Army Contracting Command
6472 Integrity Court (Building 4401)
Aberdeen Proving Ground, MD 21005-3013

Contract Specialist:
[***]
Joint COVID-19 Response Division

US Army Contracting Command
6472 Integrity Court (Building 4401)
Aberdeen Proving Ground, MD 21005-3013

G.2 **GOVERNMENT TECHNICAL POINT OF CONTACT**

[***]
Biologist/Project Officer
200 C Street, SW
Washington, DC 20201

G.3 **CONTRACTOR'S CONTRACT ADMINISTRATION**

[***]
Moderna US, 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 dated 4 May 2021. Upon achievement of the completion criteria, the contractor shall bill for the PBP for the base and each option I AW 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.miF.

(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:

(i) 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 2-in-1, 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

Field Name in HA IFF	*Data to be entered in WA WF*
Pay Official DoDAAC	HQ0337
Issue By DoDAAC	W911QY
Admin DoDAAC	S2206A
Inspect By DoDAAC	W56XNH
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_htm/current/PGI204_71.htm#payment_instructions

SECTION J - LIST OF DOCUMENTS; EXHIBITS AND OTHER ATTACHMENTS

The following have been modified:

Document Type	Description	Page #	Date
Exhibit A	CDRLs	15	11 Feb 2021
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	17	4 December 2020
Attachment 0009	HRPAS Moderna Letter	1	3 September 2020

(End of Summary of Changes)

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE | PAGE OF PAGES: 1 29

2. AMENDMENT/MODIFICATION NO.: **P00007**

3. EFFECTIVE DATE: **15-Jun-2021**

4. REQUISITION/PURCHASE REQ. NO.: **SEE SCHEDULE**

5. PROJECT NO.(If applicable)

6. ISSUED BY | CODE: **W58Po5**

W6QK ACC-APG NATICK DIVISION
BLDG 1 GENERAL GREENE AVENUE
NATICK MA 01760-5011

7. ADMINISTERED BY (If other than item 6) | CODE: **S2206A**

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)

MODERNA US, INC.
[***]
200 TECHNOLOGY SQ
CAMBRIDGE MA 02139-3578

CODE **8PTM0** FACILITY CODE

9A. AMENDMENT OF SOLICITATION NO.

9B. DATED (SEE ITEM 11)

X 10A. MOD. OF CONTRACT/ORDER NO. **W911QY20C0100**

X 10B. DATED (SEE ITEM 13) **09-Aug-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 Offer is extended, is not extended.

Offer mist 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)

See Schedule

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:

See Block 14 Continuation Page

D. OTHER (Specify type of modification and authority)

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.)
Modification Control Number: **[***]**

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 foil force and effect.

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

Stephane Bancel, CEO

15B. CONTRACTOR/OFFEROR
/s/ *Stephane Bancel*
(Signature of person authorized to sign)

15C. DATE SIGNED
6/15/2021

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

[***]
TEL: [***] EMAIL: [***]

16B. UNITED STATES OF AMERICA
BY
(Signature of Contracting Officer)

16C. DATE SIGNED
15 June 2021

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:
P00007
OBLIGATION AMOUNT: $3,300,000,000.00

a. The purpose of this modification (P00007) is to:

- Revise Section A (Authority FAR 43.103(a)(3), Mutual Agreement of the Parties)

- Exercise, revise delivery schedule for, and fund Option 3 and 4 CLINs 3001, 3001AA, 3001AB, 3001AC, 3001AD, 4001, 4001AA, 4001AB, 4001AC for a total of $3,300,000,00 (Authority FAR 52.217-7)

- Update Contracting Officer (Authority FAR 43.103(b))

- Add Performance Based Payments for Options 3 and 4; and revise the table in Section G, accordingly (Authority FAR 52.232-16)

- Add clause H.19 Product Variations (Authority FAR 43.103(a)(3), Mutual Agreement of the Parties)

- Revise Attachment 0007, Performance Based Payment (PBP) Milestone Schedule, and Attachment 0008, PBP Milestone Billing Plan (Authority FAR 52.243-1).

b. This modification was requested by the program office to meet the Government's mission requirements.

c. The total funded amount has increased by $3,300,000,000 from $4,845,591,662.60 to $8,145,591,662.60. The total contract value amount remains unchanged.

All other terms and conditions remain unchanged. Please see below for details.

SECTION A - SOLICITATION/CONTRACT FORM

The total cost of this contract was increased by $3,300,000,000.00 from $4,845,591,662.60 to $8,145,591,662.60.

The following have been modified:

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 ([***]) 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 to satisfy the delivery requirements of CLINs 0001, 1001, and 2001 are 100 pg doses which will be delivered in a multi-dose vial containing either 6.3mL fill volume (1260mcg) [***] or 8.0mL fill volume (1600mcg) [***] (as described in Moderna's COVID-19 Vaccine Authorized Fact Sheet and label).

Specifications of doses of mRNA-1273 Vaccine to satisfy the delivery requirements of CLINs 3001 and 4001 are described in Section H.19.

The delivery schedule for CLINs 3001 and 4001 may be concurrent with Moderna's Biologics License Application and FDA approval of the SARS-CoV-2 vaccine. Moderna agrees to continue to perform all regulatory efforts required to ensure that product delivered while the SARS-CoV-2 vaccine was under Emergency Use Authorization will remain available for use in the US.

SECTION B - SUPPLIES OR SERVICES AND PRICES

CLIN 3001

The CLIN extended description has changed from:

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.

To:

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), Clause no. H-19, and CDRLs (Exhibit A) on this contract.

The option status has changed from Option to Option Exercised.

SUB CLIN 3001AA

The CLIN description has changed from 33.4M Doses to 25M Doses.
The pricing detail quantity has decreased by 8,400,000.00 from 33,400,000.00 to 25,000,000.00.
The option status has changed from Option to Option Exercised.
The total cost of this line item has decreased by $138,600,000.00 from $551,100,000.00 to $412,500,000.00.

SUBCLIN 3001AB

The CLIN description has changed from 33.4M Doses to 25M Doses.
The pricing detail quantity has decreased by 8,400,000.00 from 33,400,000.00 to 25,000,000.00.
The option status has changed from Option to Option Exercised.
The total cost of this line item has decreased by $138,600,000.00 from $551,100,000.00 to $412,500,000.00.

SUB CLIN 3001 AC

The CLIN description has changed from 33.2M Doses to 30M Doses.
The pricing detail quantity has decreased by 3,200,000.00 from 33.200.000.00 to 30,000,000.00.
The option status has changed from Option to Option Exercised.
The total cost of tins line item has decreased by $52,800,000.00 from $547,800,000.00 to $495,000,000.00.

CLIN 4001

The CLIN extended description has changed from:

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.

To:

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), Clause no. 19, and CDRLs (Exhibit A) on this contract.

The option status has changed from Option to Option Exercised.

SUBCLIN 4001AA

The CLIN description has changed from 33.4M Doses to 10M Doses.
The pricing detail quantity has decreased by 23,400.000.00 from 33.400,000.00 to 10,000,000.00.
The option status has changed from Option to Option Exercised.
The total cost of this line item has decreased by $386,100,000.00 from $551,100,000.00 to $165,000,000.00.

SUBCLIN 4001AB

The CLIN description has changed from 33.4M Doses to 28M Doses.
The pricing detail quantity has decreased by 5.400.000.00 from 33.400.000.00 to 28,000,000.00.
The option status has changed from Option to Option Exercised.
The total cost of this line item has decreased by $89,100,000.00 from $551,100,000.00 to $462,000,000.00.

SUBCLIN 4001AC

The CLIN description has changed from 33.2M Doses to 28M Doses.
The pricing detail quantity has decreased by 5,200,000.00 from 33.200.000.00 to 28,000,000.00.
The option status has changed from Option to Option Exercised.
The total cost of this line item has decreased by $85,800,000.00 from $547,800,000.00 to $462,000,000.00.

SUBCLIN 3001AD is added as follows:

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
3001AD EXERCISED OPTION	20M Doses FFP	20,000,000	Each	$16.50	$330,000,000.00
	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 PURCHASE REQUEST NUMBER: [***] PROJECT: Operation Warp Speed PSC CD: 6505				
				NET AMT	$330,000,000.00
	ACRN AM CIN: GFEBS001166190500004				$330,000,000.00

SUBCLIN 4001AD is added as follows:

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
4001AD EXERCISED OPTION	34M Doses FFP	34,000,000	Each	$16.50	$561,000,000.00
	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 PURCHASE REQUEST NUMBER: [***] PROJECT: Operation Warp Speed PSC CD: 6505				
				NET AMT	$561,000,000.00
	ACRN AM				$561,000,000.00
	CIN: GFEBS001166190500008				

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-Co V-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 CO VID-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 [***], with overlapping options for a total of [***] if all options are exercised.

C.1.3 Consistent with the Updated EUA Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) dated 01 April 2021, up to [***] may be extracted from Moderna's newly authorized multidose vials with 8.0mL fill volume (1600mcg). The Government and Moderna agree that [***] per vial are only attainable using premium low dead volume (LDV) syringes, which are in short supply globally. Utilizing initial ancillary equipment, vaccine administration personnel can reliably extract [***] from these vials; however, the Government has identified needle/syringe combinations that can be used to extract [***].

C.1.3.1 Given the two parties' shared interest in reducing vaccine waste and accelerating the availability of Moderna's SARS-CoV-2 vaccine doses, the Government and Moderna intend that the Moderna vaccines doses be administered with needles and syringes compatible with extraction of [***] when possible. Toward this end, the Government shall maintain a list of syringe and/or needle combinations which will allow extraction of [***] per 8.0mL vial, which list shall be updated jointly by the Government and Moderna as any additional syringe and/or needle combinations compatible with extraction of [***]/vial are identified. Furthermore, the Government will, to the extent that appropriate needles and syringes are available, assemble and ship kits containing sufficient quantities of syringes and needles compatible with extraction of [***] per vial (Kit Moderna [***]) with Moderna's SARS-CoV-2 vaccine. The Government expects that these kits will be available beginning 01 May 2021 for a significant portion of Moderna's remaining deliveries. If, however, appropriate syringes and needles are not available, the Government will revert to shipping the Kit Moderna [***] with Moderna's SARS-CoV-2 vaccine.

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=tme&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 [***]. (Based on FDP stability data that supports a [***] 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 [***].

C.3.1.1.4 [***].

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 [***] 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 biologies 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 [***]. (Based on FDP stability data that supports a [***] 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 [***].

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 biologies 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 [***]. (Based on FDP stability data that supports a [***] 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 [***].

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 AOOL

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 am 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 biologies 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 [***]. (Based on FDP stability data that supports a [***] 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 [***].

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 [***]. (Based on FDP stability data that supports a [***] 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 [***].

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 biologies 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, 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 (SCRP). The contractor shall provide, in accordance with CDRL A010 and CDRL Attachment 0001, a comprehensive SCRP 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 [***].

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 [***] 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 AO 17.

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 AO 18.

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 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 A02L 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 CO VID-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 AO 19, 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 [***], 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 [***] 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 qualify. 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 [***].

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 [***]. 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 E - INSPECTION AND ACCEPTANCE

The following Acceptance/Inspection Schedule was added for SUBCLIN 3001AD:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
Origin	Government	Origin	Government

The following Acceptance/Inspection Schedule was added for SUBCLIN 4001AD:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
Origin	Government	Origin	Government

SECTION F - DELIVERIES OR PERFORMANCE

The following Delivery Schedule item for SUBCLIN 3001AA has been changed from:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
[***]	[***]	[***] FOB: Destination	[***]

To:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
[***]	[***]	[***] FOB: Destination	[***]

The following Delivery Schedule item for SUBCLIN 3001AB has been changed from:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
[***]	[***]	[***] FOB: Destination	[***]

To:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
[***]	[***]	[***] FOB: Destination	[***]

The following Delivery Schedule item for SUBCLIN 3001AC has been changed from:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
[***]	[***]	[***] FOB: Destination	[***]

To:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
[***]	[***]	[***] FOB: Destination	[***]

The following Delivery Schedule for SUBCLIN 3001 AD has been added:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
[***]	[***]	[***] FOB: Destination	[***]

The following Delivery Schedule item for SUBCLIN 4001AA has been changed from:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
[***]	[***]	[***] FOB: Destination	[***]

To:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
[***]	[***]	[***] FOB: Destination	[***]

The following Delivery' Schedule item for SUBCLIN 4001AB has been changed from:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
[***]	[***]	[***] FOB: Destination	[***]

To:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
[***]	[***]	[***] FOB: Destination	[***]

The following Delivery Schedule item for SUBCLIN 4001AC has been changed from:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
[***]	[***]	[***] FOB: Destination	[***]

To:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
[***]	[***]	[***] FOB: Destination	[***]

The following Delivery Schedule for SUBCLIN 4001AD has been added:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	DODAAC / CAGE
[***]	[***]	[***] FOB: Destination	[***]

SECTION G - CONTRACT ADMINISTRATION DATA

Accounting and Appropriation Summary for the Payment Office

As a result of this modification, the total funded amount for this document was increased by $3,300,000,000.00 from $4,845,591,662.60 to $8,145,591,662.60.

SUBCLIN 3001AA:

AK: [***] was increased by $412,500,000.00 from $0.00 to $412,500,000.00
The contract ACRN AK has been added.
The CIN [***] has been added.
The Cost Code [***] has been added.

SUBCLIN 3001AB:

AK: [***] was increased by $412,500,000.00 from $0.00 to $412,500,000.00
The contract ACRN AK has been added.
The CIN [***] has been added.
The Cost Code [***] has been added.

SUBCLIN 3001 AC:

AL: [***] was increased by $495,000,000.00 from $0.00 to $495,000,000.00
The contract ACRN AL has been added.

The CIN [***] has been added.
The Cost Code [***] has been added.

SUBCLIN 3001 AD:

Funding on SUBCLIN 3001AD is initiated as follows:

ACRN: AM

CIN: GFEBS001166190500004

Acctng Data: 021202120222040000066565425 5 S.0074658.5.58.1 6100.9000021001

Increase: $330,000,000.00

Total: $330,000,000.00

Cost Code: [***]

SUBCLIN 4001AA:

AK: [***] was increased by $165,000,000.00 from $0.00 to $165,000,000.00
The contract ACRN AK has been added.
The CIN [***] has been added.
The Cost Code [***] has been added.

SUBCLIN 4001AB:

AN: [***] was increased by $462,000,000.00 from $0.00 to $462,000,000.00
The contract ACRN AN has been added.
The CIN [***] has been added.
The Cost Code [***] has been added.

SUBCLIN 4001AC:

AN: [***] was increased by $462,000,000.00 from $0.00 to $462,000,000.00
The contract ACRN AN has been added.
The CIN [***] has been added.
The Cost Code [***] has been added.

SUBCLIN 4001AD:

Funding on SUBCLIN 4001AD is initiated as follows:

ACRN: AM

CIN: [***]

AcctngData: [***]

Increase: $561,000,000.00

Total: $561,000,000.00

Cost Code: [***]

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:
[***]
Joint COVID-19 Response Division
US Army Contracting Command
6472 Integrity Court (Building 4401)
Aberdeen Proving Ground, MD 21005-3013

Contract Specialist:
[***]
Joint COVID-19 Response Division
US Army Contracting Command
6472 Integrity Court (Building 4401)
Aberdeen Proving Ground, MD 21005-3013

G.2 **GOVERNMENT TECHNICAL POINT OF CONTACT**

[***]
Biologist/Project Officer
200 C Street, SW
Washington, DC 20201

G.3 **CONTRACTOR'S CONTRACT ADMINISTRATION**

[***]
Moderna US, 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 dated 4 May 2021. Upon achievement of the completion criteria, the contractor shall bill for the PBP for the base and each option I AW 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.

SECTION H - SPECIAL CONTRACT REQUIREMENTS

The following have been modified:

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 maimer 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), biologies 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 [***] of award.

b. [***].

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 CO VID 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 CO VID-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 CO VID-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 CO VID-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 Contractors 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.9 **[***].**

H.10 **[***].**

H.11 **[***].**

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.

H.15 **Base & Option 1 Delivery Acceleration**

In an effort to accelerate production of the mRNA-1273 vaccine, [***] within the Option 1 period via a Modification to the contract. If these manufacturing slots are successfully utilized, [***] funded above what was projected by Moderna and assumed within the price per dose for the doses of mRNA-1273 vaccine delivered in the Base Period and Option 1. However, [***], the Government is entitled to an adjustment under the conditions outlined. The Government and Moderna agree to the following:

1. If the Government exercises Option 2 (NLT 15 May):

a. Moderna will reduce the cost of Option 2 by [***] for each successfully accelerated drug product fill under the Base Period [***] and [***] for each successfully accelerated drag product fill under Option 1 [***].

2. If the Government does not exercise Option 2 (NLT 15 May):

a. In the event Moderna timely cancels the manufacturing slots and/or is able to otherwise fully utilize the slots originally reserved for production in the Option 2 period. Moderna agrees to credit the Government [***] for [***] and [***] for [***]. In no case shall the number of drug product manufacturing slots credited exceed the number of successfully accelerated drag product manufacturing fills under the Base Period and Option 1. It is understood that Moderna will make all good-faith efforts to fill reserved slots or cancel reservations in a timely manner (i.e. within the time period required by the subcontractor).

b. In the event that Moderna is unable to fill those reserved slots (i.e. due to lack of demand) and cancels slots, Moderna shall be entitled to recoup those reservation cancellation costs from the USG. The process is outlined as follows:

1.) Moderna shall submit documentation to the USG of the following:

i.) Cancellation notice to the subcontractor,
ii.) The basis of the cancellation, and
iii.) Cancellation fees incurred.

2.) Moderna shall reduce credits to the USG under paragraph 2a) of this clause. IAW agreed cancellation costs incurred.

3.) Bi-lateral agreement of the final credit shall be included in a modification to the contract. Net credit shall be deducted from final payments under the contract.

H.16 **Delivery Schedule, as revised 11 Feb 2021 via modification P00004**

[***]

Moderna confirms that it will provide the USG with the first 300M doses manufactured within its US-based supply chain [***], with the exception of doses required for clinical studies. The delivery schedule assumes that Moderna will work to further maximize fill/finish capacity by working with the FDA to increase fill volumes, [***]. Both parties acknowledge that resulting revisions to future accounting, invoicing, acceptance and delivery of doses subject to the revised label will be implemented via a subsequent modification.

H.17 **Post-Termination Disposition of Undelivered Product**

For the avoidance of doubt, if the USG elects to terminate the exercised CLINs prior to acceptance and delivery in full of the required quantities of mRNA-1273, Moderna will be free to direct any unaccepted/undelivered supplies of mRNA-1273 to customers other than the USG, at its discretion, without further obligation of either party with regard to such unaccepted/undelivered supplies of mRNA-1273. The contract will be bilaterally modified to decrease the quantities by the agreed upon volume.

H.18 **[***].**

In order to facilitate projections and invoicing, the Government shall provide or direct a third party [***] to provide to Moderna (1) actual quantities of Moderna [***] with 8.0mL vials during the reporting period; (2) actual quantities of Moderna [***] with 8.0mL vials during the reporting period; and (3) the number of [***] remaining in inventory

and available for upcoming shipments. This information will be provided to Moderna at a frequency of at least twice monthly.

For each 8.0mL fill volume (1600mcg) vial of vaccine shipped with [***].

Both parties acknowledge that the delivery schedule is based [***] 8.0mL fill volume (1600mcg) vial delivered. In accordance with the agreed approach for invoicing and counting doses toward Moderna's delivery requirement, [***]. Specifically for purposes of adhering to the scheduled delivery dates set forth in this contract for the Base Period, Option 1 and Option 2, schedule shall be deemed to have been met once doses are released by Moderna and are available for order.

H.19 **Product [***] (as added via P00007)**

Specific to CLINs 3001 and 4001, Moderna will deliver to the Government [***]:

- mRNA-1273 Primary Series (0.2mg/mL, 100pg, 2-dose)
- [***]

All doses delivered in calendar year 2021 will be delivered in multi-dose vials [***].

The Government and Moderna agree that total monthly delivery quantities for each of CLIN 3001 and 4001 will follow the schedule in the table below. The Government and Moderna also agree on the following points specific to product ordering:

[***]

SECTION J - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

The following have been modified:

Document Type	Description	Page #	Date
Exhibit A	CDRLs	15	11 Feb 2021
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	1	14 June 2021
Attachment 0008	Performance Base Payment Milestone Billing Plan	16	14 June 2021
Attachment 0009	HRPAS Moderna Letter	1	3 September 2020

(End of Summary of Changes)

Attachment 0008

Performance Based Payment (PBP) Milestone Billing Plan
14 June 2021

Pages 16

[***]

Attachment 0007

Performance Based Payment (PBP) Milestone Schedule

14 June 2021

CLIN	Milestone	Severable / Cumulative	Price	Milestone Completion Verification Method
0001	Capacity and Raw Material Severable Reservation	Severable	$601,400,000	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.
1001			[***]	
2001			[***]	
3001			[***]	
4001			[***]	

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE	PAGE OF PAGES
	1 12

2. AMENDMENT/MODIFICATION NO.:	EFFECTIVE DATE	4. REQUESTION/PURCHASE REQ. NO.	5. PROJECT NO. (If applicable)
P00008	16-Jun-2021	SEE SCHEDULE	

6. ISSUED BY CODE	W58P05	7. ADMINISTERED BY (If other than item6) CODE	S2206A
ACC-APG-COVID RESPONSE-W58P05 6472 INTEGRITY COURT (BUILDING 4401) ABERDEEN PROVING GROUND MD 21005-3012		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
CODE 8PTM0	FACILITY CODE	X 10B. DATED (SEE ITEM 13) 09-Aug-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 Offer is extended, is not extended. Offer mist 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 CONTRACT BORDERS.
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:
See Block 14 Continuation Page

D. OTHER (Specify type of modification and authority)

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.) Modification Control Number: [***]

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.

15 A. NAME AND TITLE OF SIGNER (Type or print)		16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)	
Stephen Hoge, President		[***] tel: [***] email: [***]	
15B. CONTRACTOR/OFFEROR */s/ Stephen Hoge*	15C. DATE SIGNED **June 16, 2021**	16B. UNITED STATES OF AMERICA BY	16C. DATE SIGNED **June 16, 2021**
(Signature person authorized to sign)		(Signature of Contracting Officer)	

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:
P00008
OBLIGATION AMOUNT: $0.00

a. The purpose of this modification (P00008) is to:
   - Add H.20 Donation of Excess Product and Exhibit B (Authority FAR 43.103(a)(3), Mutual Agreement of the Parties)
b. This modification was requested by the program office to meet the Government's mission requirements.
c. The total contract value and total funded amount remain unchanged.

All other terms and conditions remain unchanged. Please see below for details.

SECTION H - SPECIAL CONTRACT REQUIREMENTS

The following have been modified:

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 Contractors 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 tins 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), biologies 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 [***] of award.

b. [***].

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 CO VID 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 CO VID-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 CO VID-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 CO VID-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 Contractors 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.9 [***].

H.10 [***].

H.11 [***].

H.12 Transportation to Final Destination

During the course of performance under this contract, the Government may require storage of the filled drag 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.

H.15 Base & Option 1 Delivery Acceleration

In an effort to accelerate production of the mRNA-1273 vaccine, [***] within the Option 1 period via a Modification to the contract. If these manufacturing slots are successfully utilized, [***] funded above what was projected by Moderna and assumed within the price per dose for the doses of mRNA-1273 vaccine delivered in the Base Period and Option 1. However, because the Government is funding the additional slots within the Base and Option 1 periods in order to accelerate production, the Government is entitled to an adjustment under the conditions outlined. The Government and Moderna agree to the following:

1. If the Government exercises Option 2 (NLT 15 May):

a. Moderna will reduce the cost of Option 2 by [***] for each successfully accelerated drug product fill under the Base Period [***] and [***] for each successfully accelerated drug product fill under Option 1 [***].

2. If the Government does not exercise Option 2 (NLT 15 May):

a. In the event Moderna timely cancels the manufacturing slots and/or is able to otherwise fully utilize the slots originally reserved for production in the Option 2 period, Moderna agrees to credit the Government [***] for [***] and [***] for [***]. In no case shall the number of drug product manufacturing slots credited exceed the number of successfully accelerated drag product manufacturing fills under the Base Period and Option 1. It is understood that Moderna will make all good-faith efforts to fdl reserved slots or cancel reservations in a timely manner (i.e. within the time period required by the subcontractor).

b. In the event that Moderna is unable to fill those reserved slots (i.e. due to lack of demand) and cancels slots, Moderna shall be entitled to recoup those reservation cancellation costs from the USG. The process is outlined as follows:

1.) Moderna shall submit documentation to the USG of the following:
   i.) Cancellation notice to the subcontractor,
   ii.) The basis of the cancellation, and
   iii.) Cancellation fees incurred.

2.) Moderna shall reduce credits to the USG under paragraph 2a) of this clause, IAW agreed cancellation costs incurred.

3.) Bi-lateral agreement of the final credit shall be included in a modification to the contract. Net credit shall be deducted from final payments under the contract.

H.16 Delivery Schedule, as revised 11 Feb 2021 via modification P00004

[***]

H.17 Post-Termination Disposition of Undelivered Product

For the avoidance of doubt, if the USG elects to terminate the exercised CLINs prior to acceptance and delivery in full of the required quantities of mRNA-1273, Moderna will be free to direct any unaccepted/undelivered supplies of mRNA-1273 to customers other than the USG, at its discretion, without further obligation of either party with regard to such unaccepted/undelivered supplies of mRNA-1273. The contract will be bilaterally modified to decrease the quantities by the agreed upon volume.

H.18 [***]

In order to facilitate projections and invoicing, the Government shall provide or direct a third party [***] to provide to Moderna (1) actual quantities of Moderna [***] with 8.0mL vials during the reporting period; (2) actual quantities of Moderna [***] with 8.0mL vials during the reporting period; and (3) the number of [***] remaining in inventory and available for upcoming shipments. This information will be provided to Moderna at a frequency of at least twice monthly.

For each 8.0mL fill volume (1600mcg) vial of vaccine shipped with [***].

Both parties acknowledge that the delivery schedule is based on [***] 8.0mL fill volume (1600mcg) vial delivered. In accordance with the agreed approach for invoicing and counting doses toward Moderna's delivery requirement, [***]. Specifically for purposes of adhering to the scheduled delivery dates set forth in this contract for the Base Period, Option 1 and Option 2, schedule shall be deemed to have been met once doses are released by Moderna and are available for order.

H.19 Product [***] (as added via P00007)

Specific to CLINs 3001 and 4001, Moderna will deliver to the Government [***]:

- mRNA-1273 Primary Series (0.2mg/mL, l00pg, 2-dose)
- [***]

All doses delivered in calendar year 2021 will be delivered in multi-dose vials [***].

The Government and Moderna agree that total monthly delivery quantities for each of CLIN 3001 and 4001 will follow the schedule in the table below. The Government and Moderna also agree on the following points specific to product ordering:

[***]

H.20 Donation of Excess Product

a. If the Government determines that a quantity of doses of mRNA-1273 supplied to the Government under this contract is no longer needed by the Government, the Government may donate such doses to a foreign nation or non-governmental organization (NGO) facilitating donation to a foreign nation, subject to the remainder of this

Clause H.20. The Government shall notify Contractor in writing prior to any proposed donation to a foreign nation or NGO, which notice will include [***].

b. Contractor must verify in writing that all of the required conditions below are met before any such donation is made, [***].

[***]

c. The Government's donations will be from supplies of vaccine delivered to and accepted by the Government. To the extent the Government commits to deliver doses that have not yet been physically delivered to the Government, such donation will not occur until such doses have been delivered to the Government. The Government will be responsible for delivery of the donated doses to, and coordination of delivery with, the receiving foreign nation or NGO, as applicable. The Government or the receiving foreign nation or NGO, as applicable, will (i) satisfy all customs shipping requirements for import and export of the product; and (ii) as the exporter, file any required FDA export notifications. To the extent not already provided to the Government, the Contractor will provide all information necessary to complete any requirements identified in this paragraph in advance of shipment.

d. When the conditions above are met for any donation, the Parties will [***].

e. [***].

f. Shipment of any donated doses under this Article does not constitute a violation of the Defense Production Act.

SECTION J - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

The following have been modified:

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1. CONTRACT ID CODE	PAGE OF PAGES
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2. AMENDMENT/MODIFICATION NO.:	EFFECTIVE DATE	4. REQUESTION/PURCHASE REQ. NO.	5. PROJECT NO. (If applicable)
P00009	16-Jun-2021	SEE SCHEDULE	

6. ISSUED BY CODE	W58P05	7. ADMINISTERED BY (If other than item 6) CODE	S2206A
ACC-APG-COVID RESPONSE-W58P05 6472 INTEGRITY COURT (BUILDING 4401) ABERDEEN PROVING GROUND MD 21005-3013		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
CODE 8PTM0	FACILITY CODE	X	10B. DATED (SEE ITEM 13) 09-Aug-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 Offer is extended, is not extended. Offer mist 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 CONTRACT BORDERS.
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:
See Continuation Page

D. OTHER (Specify type of modification and authority)

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.) Modification Control Number: [***]

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.

15 A. NAME AND TITLE OF SIGNER (Type or print)		16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)	
Stephen Hoge, President		[***] tel: [***] email: [***]	
15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
/s/ Stephen Hoge	**June 16, 2021**	BY	**June 16, 2021**
(Signature person authorized to sign)		(Signature of Contracting Officer)	

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:
P00009
OBLIGATION AMOUNT: $0.00

a. The purpose of this modification (P00009) is to:
   - Update Exhibit B as outlined in clause H.20 with donation information for donation to Canada (Authority FAR 43.103(a)(3), Mutual Agreement of the Parties)
b. This modification was requested by the program office to meet the Government's mission requirements.
c. The total contract value and total funded amount remains unchanged.

SECTION J - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

The following have been modified:

Document Type	Description	Page #	Date
Exhibit A	CDRLs	15	11 Feb 2021
Exhibit B	Donation of Excess Product	1	16 June 2021
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	1	14 June 2021
Attachment 0008	Performance Base Payment Milestone Billing Plan	16	14 June 2021
Attachment 0009	HRPAS Moderna Letter	1	3 September 2020

(End of Summary of Changes)

Exhibit B - Donation of Excess

Product As of 16 June 2021

Country	Mod No	Batch	Exp Date	COVID Vaccine Type	DS Source	Fill Finish Site	Dose Total
[***]	[***]	[***]	[***]	mRNA-1273 [***]	[***]	[***]	[***]

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE	PAGE OF PAGES
	1 2

2. AMENDMENT/MODIFICATION NO.:	EFFECTIVE DATE	4. REQUESTION/PURCHASE REQ. NO.	5. PROJECT NO. (If applicable)
P00010	17-Jun-2021	SEE SCHEDULE	

6. ISSUED BY CODE	W58P05	7. ADMINISTERED BY (If other than item 6) CODE	S2206A
ACC-APG-COVID RESPONSE-W58P05 6472 INTEGRITY COURT (BUILDING 4401) ABERDEEN PROVING GROUND MD 21005-3013		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
CODE FACILITY CODE	X	10B. DATED (SEE ITEM 13) 09-Aug-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 Offer is extended, is not extended. Offer mist 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 CONTRACT BORDERS.
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.

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X C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:

See Block 14 Continuation Page

D. OTHER (Specify type of modification and authority)

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.) Modification Control Number: [***]
See Block 14 Continuation

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.

15 A. NAME AND TITLE OF SIGNER (Type or print)		16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)	
Stephen Hoge, President		[***] tel: [***] email: [***]	
15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
/s/ Stephen Hoge	**June 17, 2021**	BY	**June 17, 2021**
(Signature person authorized to sign)		(Signature of Contracting Officer)	

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:
P00010

OBLIGATION AMOUNT: $0.00

a. The purpose of this modification (P00010) is to:
   - Update Exhibit B as outlined in clause H.20 with donation information for donation to Taiwan (Authority FAR 43.103(a)(3), Mutual Agreement of the Parties)
b. This modification was requested by the program office to meet the Government's mission requirements.
c. The total contract value and total funded amount remains unchanged.

SECTION J - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

The following have been modified:

Document Type	Description	Page#	Date
Exhibit A	CDRLs	15	11 Feb 2021
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Attachment 0003	Dose Tracking Template Draft Moderna	Excel	15 July 2020
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Attachment 0005	[***]	2	7 August 2020
Attachment 0006	ModernaTx, Inc. Background Intellectual Property	3	6 August 2020
Attachment 0007	Performance Base Payment Milestone Schedule	1	14 June 2021
Attachment 0008	Performance Base Payment Milestone Billing Plan	16	14 June 2021
Attachment 0009	HRPAS Moderna Letter	1	3 September 2020

(End of Summary of Changes)

Exhibit B - Donation of Excess Product

As of 17 June 2021

Recipient	Mod No	Batch	Exp Date	COVID Vaccine Type	DS Source	Fill Finish Site	Dose Total
[***]	[***]	[***]	[***]	mRNA-1273 [***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	mRNA-1273 [***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	mRNA-1273 [***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	mRNA-1273 [***]	[***]	[***]	[***]

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE	PAGE OF PAGES
	1 12

2. AMENDMENT/MODIFICATION NO.:	EFFECTIVE DATE	4. REQUESTION/PURCHASE REQ. NO.	5. PROJECT NO. (If applicable)
P00011	01-Jul-2021	SEE SCHEDULE	

6. ISSUED BY CODE	W58P05	7. ADMINISTERED BY (If other than item6) CODE	S2206A
ACC-APG-COVID RESPONSE-W58P05 6472 INTEGRITY COURT (BUILDING 4401) ABERDEEN PROVING GROUND MA 21005-3013		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
CODE 8PTM0	FACILITY CODE	X	10B. DATED (SEE ITEM 13) 09-Aug-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 Offer is extended, is not extended. Offer mist 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 CONTRACT BORDERS.
IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

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X C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:
See Block 14 Continuation Page

D. OTHER (Specify type of modification and authority)

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.) Modification Control Number: [***]
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.

15 A. NAME AND TITLE OF SIGNER (Type or print)		16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)	
Stephen Hoge, President		[***] tel: [***] email: [***]	
15B. CONTRACTOR/OFFEROR */s/ Stephen Hoge*	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA BY	16C. DATE SIGNED 07-20-21
(Signature person authorized to sign)		(Signature of Contracting Officer)	

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:
P00011
OBLIGATION AMOUNT: $0.00

a. The purpose of this modification (P00011) is to:
   - Update language in H.16 to remove the requirement to deliver 300M doses prior to sale or export (Authority FAR 43.103(a)(3), Mutual Agreement of the Parties).
   - Update Exhibit B as outlined in clause H.20 with donation information for multiple recipients identified within the past 10 business days (Authority FAR 43.103(a)(3), Mutual Agreement of the Parties).
   - Update language in H.20(d) to reflect current operating procedures (Authority FAR 43.103(a)(3), Mutual Agreement of the Parties).

b. The modification was requested by the program office to meet the Government's mission requirements.
c. The total contract value and total funded amount remains unchanged.

SECTION H - SPECIAL CONTRACT REQUIREMENTS

The following have been modified:

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), biologies 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 [***] of award.

b. [***].

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 CO VID-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 Contractors 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 CO VID-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.9 [***].

H.10 [***].

H.11 [***].

H.12 Transportation to Final Destination

During the course of performance under this contract, the Government may require storage of the filled drag 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.

H.15 Base & Option 1 Delivery Acceleration

In an effort to accelerate production of the mRNA-1273 vaccine, [***] within the Option 1 period via a Modification to the contract. If these manufacturing slots are successfully utilized, [***] above what was projected by Moderna and assumed within the price per dose for the doses of mRNA-1273 vaccine delivered in the Base Period and Option 1. However, because the Government is funding the additional slots within the Base and Option 1 periods in order to accelerate production, the Government is entitled to an adjustment under the conditions outlined. The Government and Moderna agree to the following:

1. If the Government exercises Option 2 (NLT 15 May):

a. Moderna will reduce the cost of Option 2 by [***] for each successfully accelerated drug product fill under the Base Period [***]) and [***] for each successfully accelerated drug product fill under Option 1 [***].

2. If the Government does not exercise Option 2 (NLT 15 May):

a. In the event Moderna timely cancels the manufacturing slots and/or is able to otherwise fully utilize the slots originally reserved for production in the Option 2 period, Moderna agrees to credit the Government [***] for [***] and [***] for [***]. In no case shall the number of drug product manufacturing slots credited exceed the number of successfully accelerated drug product manufacturing fills under the Base Period and Option 1. It is understood that Moderna will make all good-faith efforts to fill reserved slots or cancel reservations in a timely manner (i.e. within the time period required by the subcontractor).

b. In the event that Moderna is unable to fill those reserved slots (i.e. due to lack of demand) and cancels slots, Moderna shall be entitled to recoup those reservation cancellation costs from the USG. The process is outlined as follows:

1.) Moderna shall submit documentation to the USG of the following:

i.) Cancellation notice to the subcontractor,

ii.) The basis of the cancellation, and

iii.) Cancellation fees incurred.

2.) Moderna shall reduce credits to the USG under paragraph 2a) of this clause, IAW agreed cancellation costs incurred.

3.) Bi-lateral agreement of the final credit shall be included in a modification to the contract. Net credit shall be deducted from final payments under the contract.

H.16 Delivery Schedule, as revised 11 Feb 2021 **via modification P00004**

[***]

H.17 Post-Termination Disposition of Undelivered Product

For the avoidance of doubt, if the USG elects to terminate the exercised CLINs prior to acceptance and delivery in full of the required quantities of mRNA-1273, Moderna will be free to direct any unaccepted/undelivered supplies of mRNA-1273 to customers other than the USG, at its discretion, without further obligation of either party with regard to such unaccepted/undelivered supplies of mRNA-1273. The contract will be bilaterally modified to decrease the quantities by the agreed upon volume.

H.18 [***]

In order to facilitate projections and invoicing, the Government shall provide or direct a third party (e.g., McKesson) to provide to Moderna (1) actual quantities of Moderna [***] with 8.0mL vials during the reporting period; (2) actual quantities of Moderna [***] with 8.0mL vials during the reporting period; and (3) the number of [***] remaining in inventory and available for upcoming shipments. This information will be provided to Moderna at a frequency of at least twice monthly.

For each 8.0mL fill volume (1600mcg) vial of vaccine shipped with [***].

Both parties acknowledge that the delivery schedule is based on [***] 8.0mL fill volume (1600mcg) vial delivered. In accordance with the agreed approach for invoicing and counting doses toward Moderna's delivery requirement, [***]. Specifically for purposes of adhering to the scheduled delivery dates set forth in this contract for the Base Period, Option 1 and Option 2, schedule shall be deemed to have been met once doses are released by Moderna and are available for order.

H.19 Product [***] (as added via P00007)

Specific to CLINs 3001 and 4001, Moderna will deliver to the Government [***]

- mRNA-1273 Primary Series (0.2mg/mL, 100pg, 2-dose)
- [***]

All doses delivered in calendar year 2021 will be delivered in multi-dose vials [***].

The Government and Moderna agree that total monthly delivery quantities for each of CLIN 3001 and 4001 will follow the schedule in the table below. The Government and Moderna also agree on the following points specific to product ordering:

[***]

H.20 Donation of Excess Product

a. If the Government determines that a quantity of doses of mRNA-1273 supplied to the Government under this contract is no longer needed by the Government, the Government may donate such doses to a foreign nation or non-governmental organization (NGO) facilitating donation to a foreign nation, subject to the remainder of this Clause H.20. The Government shall notify Contractor in writing prior to any proposed donation to a foreign nation or NGO, which notice will include [***].

b. Contractor must verify in writing that all of the required conditions below are met before any such donation is made, [***].

c. The Government's donations will be from supplies of vaccine delivered to and accepted by the Government. To the extent the Government commits to deliver doses that have not yet been physically delivered to the Government such donation will not occur until such doses have been delivered to the Government. The Government will be responsible for delivery of the donated doses to, and coordination of delivery with, the receiving foreign nation or NGO, as applicable. The Government or the receiving foreign nation or NGO, as applicable, will (i) satisfy all customs shipping requirements for import and export of the product; and (ii) as the exporter, file any required FDA export notifications. To the extent not already provided to the Government, the Contractor will provide all information necessary to complete any requirements identified in this paragraph in advance of shipment.

d. When the conditions above are met for any donation, the Parties will [***].

e. [***].

f. Shipment of any donated doses under this Article does not constitute a violation of the Defense Production Act.

(End of Summary of Changes)

Exhibit B - Donation of Excess Product

As of 1 July 2021

Country	Mod No	Batch	Exp Date	COVID Vaccine Type	DS Source	NGO Facilitator (if applicable)	Fill Finish Site	Dose Total
[***]	[***]	[***]	[***]	mRNA-1273 [***]	[***]		[***]	[***]
[***]	[***]	[***]	[***]	mRNA-1273 [***]	[***]		[***]	[***]
[***]	[***]	[***]	[***]	mRNA-1273 [***]	[***]		[***]	[***]
[***]	[***]	[***]	[***]	mRNA-1273 [***]	[***]		[***]	~~[***]~~
[***]	[***]	[***]	[***]	mRNA-1273 [***]	[***]		[***]	[***]
[***]	[***]	[***]	[***]	mRNA-1273 [***]	[***]		[***]	[***]
[***]	[***]	[***]	[***]	mRNA-1273 [***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	mRNA-1273 [***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	mRNA-1273 [***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	mRNA-1273 [***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	mRNA-1273 [***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	mRNA-1273 [***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	mRNA-1273 [***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	mRNA-1273 [***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	mRNA-1273 [***]	[***]	[***]	[***]	[***]

[***]	[***]	[***]	[***]	mRNA-1273 [***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	mRNA-1273 [***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	mRNA-1273 [***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	mRNA-1273 [***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	mRNA-1273 [***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	mRNA-1273 [***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	mRNA-1273 [***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	mRNA-1273 [***]	[***]	[***]	[***]	[***]

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE

PAGE OF PAGES
1 2

2. AMENDMENT/MODIFICATION NO.:	EFFECTIVE DATE	4. REQUESTION/PURCHASE REQ. NO.	5. PROJECT NO. (If applicable)
P00012	20-Jul-2021	SEE SCHEDULE	

6. ISSUED BY CODE	W58P05	7. ADMINISTERED BY (If other than item6) CODE	S2206A
ACC-APG-COVID RESPONSE-W58P05 6472 INTEGRITY COURT (BUILDING 4401) ABERDEEN PROVING GROUND MA 21005-3013		DCMA BOSTON 495 SUMMER STREET BOSTON MA 02210-2138	

8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code)
MODERNA US, INC.
[***]
200 TECHNOLOGY SQ
CAMBRIDGE MA 02139-3578

CODE 8PTM0 FACILITY CODE

9A. AMENDMENT OF SOLICITATION NO.

9B. DATED (SEE ITEM 11)

X 10A. MOD. OF CONTRACT/ORDER NO.
W911QY20C0100

X 10B. DATED (SEE ITEM 13)
09-Aug-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 Offer is extended, is not extended. Offer mist 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 CONTRACT BORDERS.
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:
See Block 14 Continuation Page

D. OTHER (Specify type of modification and authority)

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.) Modification Control Number: [***]
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.

15 A. NAME AND TITLE OF SIGNER (Type or print)		16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)	
Stephane Bancel, CEO		[***] tel: [***] email: [***]	
15B. CONTRACTOR/OFFEROR */s/ Stephane Bancel*	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA BY	16C. DATE SIGNED 07-20-21
(Signature person authorized to sign)		(Signature of Contracting Officer)	

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:
P00012
OBLIGATION AMOUNT: $0.00

a. The purpose of this modification (P00012) it to:
- Update Exhibit B as outlined in clause H.20 with donation information for multiple recipients identified with the past 7 business days (Authority FAR 43.103(a)(3), Mutual Agreement of the Parties).
b. The modification was required by the program office to meet the Government's mission requirements.
c. The total contract value and total funded amount remains unchanged.

SECTION J - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

The following have been modified:

Document Type	Description	Page#	Date
Exhibit A	CDRLs	15	11 Feb 2021
Exhibit B	Donation of Excess Product	3	13 July 2021
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	1	14 June 2021
Attachment 0008	Performance Base Payment Milestone Billing Plan	16	12 July 2021
Attachment 0009	HRPAS Moderna Letter	1	3 September 2020

(End of Summary of Changes)

Exhibit B - Donation of Excess Product

As of 13 July 2021

Country	Mod No	Batch	Exp Date	COVID Vaccine Type	DS Source	Fill Finish Site	Dose Total
[***]	[***]	[***]	[***]	mRNA-1273 [***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	mRNA-1273 [***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	mRNA-1273 [***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	mRNA-1273 [***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	~~mRNA-1273~~ ~~[***]~~	[***]	[***]	[***]
[***]	[***]	[***]	[***]	~~mRNA-1273~~ ~~[***]~~	[***]	[***]	[***]
[***]	[***]	[***]	[***]	mRNA-1273 [***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	mRNA-1273 [***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	mRNA-1273 [***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	mRNA-1273 [***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	mRNA-1273 [***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	mRNA-1273 [***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	mRNA-1273 [***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	mRNA-1273 [***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	mRNA-1273 [***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	mRNA-1273 [***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	mRNA-1273 [***]	[***]	[***]	[***]

[***]	[***]	[***]	[***]	mRNA-1273 [***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	mRNA-1273 [***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	mRNA-1273 [***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	mRNA-1273 [***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	mRNA-1273 [***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	mRNA-1273 [***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	mRNA-1273 [***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	mRNA-1273 [***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	mRNA-1273 [***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	mRNA-1273 [***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	mRNA-1273 [***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	mRNA-1273 [***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	mRNA-1273 [***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	mRNA-1273 [***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	mRNA-1273 [***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	mRNA-1273 [***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	mRNA-1273 [***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	mRNA-1273 [***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	mRNA-1273 [***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	mRNA-1273 [***]	[***]	[***]	[***]

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE | PAGE OF PAGES: 1 13

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO.(If applicable)
P00008	See Block 16C	OS273940	

6. ISSUED BY — CODE: ASPR-BARDA

ASPR-BARDA
200 Independence Ave., S.W.
Room 640-G
Washington DC 20201

7. ADMINISTERED BY (If other than item 6) — CODE: ASPR-BARDA02

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)

MODERNAUS, INC.
[***]
200 TECHNOLOGY SQ
CAMBRIDGE MA 02139-3578

CODE 1492235 FACILITY CODE

9A. AMENDMENT OF SOLICITATION NO.

9B. DATED (SEE ITEM 11)

X 10A. MOD. 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 Offer is extended, is not extended.
Offer mist 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)

See Schedule Net Increase: $236, 364, 615.00

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).

C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:

X FAR 52.243- 2 Alternate 1 (APR 1984) Changes - Cost-Reimbursement

D. OTHER (Specify type of modification and authority)

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
This contract (75A50120C00034 - Moderna COVID-19 Vaccine)was awarded under
BAA-18-100-SOL-00003 - Development of an mRNA Vaccine for SARS-CoV-2.

The purpose of this modification is to support the additional scope of the Clinical Development Plan (CLIN 0002)which includes increases the P301(Efficacy)(WBS 1.4.3.1); Clinical(FTEs and digital clinical system)(WBS 1.4);Biologics License Application BLA (WBS 1.5.2) and Pharmacovigilance (supporting EUA) (WBS 1.5.3.1).

The obligated amount of CLIN 0002 is increased from $961,387,795 by $236,364,615 to Continued ...

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in foil 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)
[***]

15B. CONTRACTOR/OFFEROR
/s/ Stephane Bancel
(Signature of person authorized to sign)

15C. DATE SIGNED

16B. UNITED STATES OF AMERICA
BY
(Signature of Contracting Officer)

16C. DATE SIGNED
04/18/2021

NAME OF OFFEROR OR CONTRACTOR
MODERNATX, INC. 1492235

Item No. (A)	Supplies/Services (B)	Quantity (C)	Unit (D)	Unit Price (E)	Amount (F)

$1,197,752,410.

CLIN 0002 is the only CLIN changed by the issuance of this modification. CLIN 0002 remains cost plus fixed fee (CPFF). Fee was not applied to the additional scope.

	Prior Contract Value	Additional Funding	Revised Contract Value
CLIN 0001	$ 3,212,541	$ -	$ 3,212,541
CLIN 0002	$ 961,387,795	$ 236,364,615	$ 1,197,752,410
CLIN 0003	$ 53,000,000	$ -	$ 53,000,000
Total	$ 1,017,600,336	$ 236,364,615	$ 1,253,964,951

All other contract terms and conditions remain unchanged.
Period of Performance: 04/03/2020 to 08/31/2023

Change Item 2 to read as follows(amount shown is the obligated amount):

2	Base CLIN 0002 - Development of mRNA vaccine to BLA				236,364,615.00
	Accounting Info:				
	2020.199COV1.25103 Appr. Yr.: 2020 CAN: 199COV1 Object Class:		25103		
	Funded: $0.00				
	Accounting Info:				
	2020.199C014.25103 Appr. Yr.: 2020 CAN: 199C014 Object Class:		25103		
	Funded: $0.00				
	Accounting Info:				
	2021.199C035.25103 Appr. Yr.: 2021 CAN: 199C035 Object Class:		25103		
	Funded: $0.00				
	Accounting Info:				
	2021.199C035.25103 Appr. Yr.: 2021 CAN: 199C035 Object Class:		25103		
	Funded: $236,364,615.00				

C. Statement of Work
Updated with Modification P00008

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) - Updated with Mod P00007***
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, Medical Affairs, Market Access and Launch Readiness in support of vaccine deployment under Emergency Use Authorization 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 the program objective of licensure. The PL will be the point of accountability for the development and deployment of mRNA-1273. [***]. The Sub Principal Investigator will be responsible for ensure sufficient manufacturing capacity and production 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. *Moderna will contribute a portion of the subcontractor program management effort to support the contract.*

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)
The CoV spike protein expressed by the mRNA-1273 vaccine is stabilized in the prefusion conformation which should be optimal for inducing high quality antibody responses with low binding antibody to neutralizing antibody ratios. mRNA delivery and induction of CD8 T cells and Th1 CD4 T cells will avoid Th2-biased responses. The SARS-CoV-2 S protein expressed by the mRNA-1273 vaccine is stabilized in the pre-fusion conformation which should be optimal for inducing high functional antibody responses with low binding antibody to neutralizing antibody ratios, as it has been seen in RSV DS-Cav1 clinical trials and 2P-stabilized CoV S animal studies. In addition, mRNA vaccines induce Th1 skewed response as has been evident in several pre-clinical and clinical vaccine programs at Moderna, including pandemic flu and CMV (PMID 28457665, 29456015). By expressing pre-fusion SARS-CoV-2 S delivered with mRNA we should induce CD8 T cells and Th1-biased CD4 T cell responses as shown in both human, NHP, and murine studies, thus avoiding a Th2- biased response.

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. [***]

[***]

Ralph Baric is also developing a human ACE-2 transgenic mouse model, resulting in viremia and lung pathology upon wild-type SARS-CoV-2 infection. This model should facilitate evaluation of wild-type SARS- CoV-2 virus and will also be used to evaluation protection from mRNA-1273 vaccination. This model is however still under development and data are unlikely to become available before June/July 2020.

Finally, Vincent Munster (NIH/NIAID) has developed a Rhesus macaque model of SARS-CoV infection. After challenge animals get sick but infection is not lethal. Decreased respiration and irregular breathing, weight loss, fever spike at day 1 and evidence of pneumonia are all observed. In addition, hematological evidence of disease is seen, as well as viremia and shedding in nose, throat, and rectum up to day 10. Unlike what is observed clinically a high challenge dose of virus is required, and animals recover without intervention. Animals will be immunized with limiting doses of mRNA-1273 to allow breakthrough infection and endpoints relevant for disease enhancement will be collected. Results from these challenge studies may become available by end of June 2020.

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) -- Updated with Mod P00008***
A Phase 1 study of mRNA-1273 in 120 healthy subjects 18-55 years of age will evaluate the safety and immunogenicity of two injections (28 days apart) at four dose levels (25, 50, 100 and 250 ^g). The proposed Phase 2 study will enroll n=600 healthy subjects (>18 years) to receive two injections, 28 days apart, of placebo or 50 or 100 ^g mRNA-1273, at 1:1:1, age stratified (18-55 yrs; >55 yrs).

The total safety database from the mRNA-1273 Phase 1 and Phase 2 studies will be approximately 445 adult participants exposed and approximately 245 adult participants at the highest dose level. The proposed Phase 2 study (synopsis included below) is intended to support entry to subsequent Phase 3 study(ies). [***].

***** Phase 2 Safety and Immunogenicity Study (WBS 1.4.2.1) - Updated with Mod P00007***
Immediately following dose selection in the initial Phase 1 study the program will initiate a Phase 2 clinical study. The P201 study will confirm the safety and immunogenicity results from the open-label Phase 1, again testing a two-dose administration series 28d apart. Its assumed that 600 participants, randomized 1:1:1 active: placebo, testing a two dose levels of mRNA-1273. Enrollment will be age-stratified participants 18 year of age and above into two age cohorts. Primary objectives will include standard clinical safety evaluation with conventional safety and SARS-CoV-2-specific IgG endpoints though a neutralizing antibody assay would be preferred if available. Secondary objectives will evaluate of the specific humoral response against SARS-CoV-2 by binding and neutralizing antibody (nAb) response. Safety will be followed through 6 months post-last vaccination and primary immunogenicity endpoint will be measured at D57. The study will enroll in the US under IND. The study will assess COVID-19 as exploratory endpoint which may extend the duration of follow-up accordingly. Clinical trial assessments will include measurement of SARS-CoV-2 S-specific binding antibody and neutralizing activity in sera. This will provide an indication of vaccine-induced antibody quality and relative potency. Historically, immune-complex mediated lung pathology has been associated with a high ratio of binding to functional antibody activity. In addition, vaccine-induced T cell responses will be evaluated by peptide pool stimulation to define the pattern of cytokine production. [***]. To support the EUA, an interim clinical study synopsis will be drafted based on D57 safety and immunogenicity data.

***** Pediatrics (WBS 1.4.2.3 Updated with Mod P00007*** and WBS 1.4.2.4)
Moderna will conduct an initial pediatric study plan (PSP) under Pediatric Research Equity Act requirements during the IND phase. A deferral will be requested for children less than 6 months

of age at the time of initial BLA approval. Having demonstrated the mRNA-1273 is safe, tolerated, and effective in adults, Moderna will test the safety and immunogenicity of mRNA-1273 in a pediatric population with an aged-based step-down design.

The P203 study is a Phase 2/3, randomized, observer-blind, placebo controlled, study to evaluate the safety, reactogenicity, and effectiveness of mRNA-1273 SARS-CoV-2 vaccine in 3000 healthy adolescents 12 to < 18 years of age. Participants will be randomly assigned to receive injections of either 100 ^g of mRNA-1273 vaccine or a placebo control in a 2:1 randomization ratio. The goal of the study is to seek an indication for use of mRNA 1273 (100 ^g IM, given as 2 injections, 28 days apart) in the 12 to < 18 year age group. The basis for demonstrating vaccine effectiveness is proposed to be met by serum antibody (Ab) response measured in this adolescent age group. The approach to inferring vaccine effectiveness will depend on whether or not an accepted serum Ab threshold conferring protection against COVID-19 has been established. If an Ab threshold of protection has been established, effectiveness will be inferred based on the proportion of adolescent study participants with serum Ab levels (on study Day 57) meeting or exceeding the Ab threshold. If an Ab threshold of protection has not been established, effectiveness will be inferred based on demonstrating non-inferiority of the geometric mean value of serum nAb from adolescent participants compared to the geometric mean value of serum nAb from adults enrolled in the ongoing clinical endpoint efficacy trial (Study P301).

This adolescent study will monitor all participants for a total of 12 months following the second dose of vaccine or placebo. Safety assessments will include solicited ARs (7 days post each injection), unsolicited AEs (28 days post each injection), medically attended adverse events (MAAEs), serious adverse events (SAEs), and adverse event of special interest (AESI) (pediatric MIS C) throughout the study period.

The 204 study is a Phase 2/3, randomized, observer-blind, placebo controlled, study to evaluate the safety, reactogenicity, and effectiveness of mRNA-1273 SARS-CoV-2 vaccine in approximately 6,000 healthy children 6 months to < 12 years of age. Approximately 6,000 participants will be enrolled in a dose-escalation, age de-escalation design testing 50 and 100 ug dose levels across three age groups: 6 to <12 years of age, 2 to <6 years of age and 6 month to <2 years of age. Safety and Immunogenicity endpoints will follow the P203. The study will enroll in the US and up to two ex-US countries (e.g. Canada and/or Australia).

***** Phase 3 Pivotal Study (WBS 1.4.3.1) - — Updated with Mod P00008***

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. Secondary objectives will evaluate: the efficacy of mRNA-1273 to prevent severe COVID-19; the efficacy of mRNA-1273 to prevent virologically confirmed SARS-CoV-2 infection or COVID-19 regardless of symptomatology or severity; VE against a broad definition of COVID-19 disease; VE to prevent

death due to COVID-19 disease; VE against all-cause mortality; the efficacy of mRNA-1273 to prevent COVID-19 after the first dose of investigational product (IP); the efficacy of mRNA-1273 to prevent COVID-19 in all study participants, regardless of evidence of prior SARS-CoV-2 infection; the efficacy of mRNA-1273 to prevent asymptomatic SARS-CoV-2 infection.

The sample size of this Phase 3 is driven by the total number of cases to demonstrate VE (mRNA-1273 vs. placebo) to prevent COVID-19. [***].

[***]

On issuance of the EUA, in agreement with the FDA and OWS, the P301 study will offer vaccine to participants that were randomized to receive placebo and the study will transition to an open label study. All 30K participants will return for a Participant Decision Visit. Participants will complete an updated ICF, a sera and NP swab sample will be collected to test for asymptomatic infection, and participants randomized to the placebo arm will be offered vaccine. After unblinding the sponsor will continue to leverage the clinical trial infrastructure. Doubling the exposed population will reduce the incidence of rare events potentially detectable with high confidence in the trial to approximately 1/10,000 or 0.01%.

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.

Post-Authorization Safety and Effectiveness Studies (WBS 1.4.4.1, 1.4.4.2, 1.4.4.3 and 1.4.4.4)
During EUA, Moderna will conduct signal refinement analyses using tokenized real-world data within the United States. The population complements but does not duplicate the populations under observation in the CDC's Vaccine Safety DataLink and the FDA's CMS programs. This real-world data infrastructure will significantly decrease the time between safety signal identification and evaluation. Using the tokenized data the sponsor will be able to conduct an early post-authorization general safety study at a point in time approximately 8-12 months after the initiation of the study to provide further reassurance that prespecified adverse events of interest are being addressed during the EUA period.

Further, Moderna is planning to establish an observational pregnancy cohort study, (e.g., with the Vaccines and Medications in Pregnancy Surveillance System (VAMPSS) Mother to Baby cohort). Unlike a traditional passive pregnancy registry this approach will enable the calculation of incidence rates for adverse pregnancy and birth outcomes. It will also enable the identification of key confounders and non-medically attended outcomes (e.g., spontaneous abortions) that are incompletely recorded in secondary healthcare records.

With respect to continued evaluation of effectiveness after crossover, early in the EUA period, tokenized real- world data will provide COVID-19 incidence rates within geographic zones surrounding the clinical trial sites as a proxy for rates among unvaccinated individuals. The Moderna envisions conducting one descriptive analysis involving both trial and geographic incidence rates 3-6 months after EUA and before broad product distribution removes the utility of this early approach. Simultaneously, a prospective cohort study within a large integrated

healthcare delivery system (e.g., a Kaiser Permanente region) will be initiated to formally evaluate the vaccine effectiveness (VE) and long-term effectiveness of mRNA-1273 at the patient level with a concurrent comparator group. Effectiveness outcomes to be evaluated include effectiveness against severe COVID-19, Follow-up time will be two years after the last dose, and interim analyses will be performed based on the number of events of the primary effectiveness outcome to assess durability of protection. A final analysis including 1-dose VE and 2-dose VE will be evaluated. *Moderna will contribute by funding these EUA studies. The USG will obtain access to the data.*

Medical Affairs (WBS 1.4.6.1) — Updated with Mod P00007
The Medical Affairs group will provide scientific and clinical support for mRNA-1273 through the EUA period. This will include developing patient and healthcare provider materials to support vaccine deployment under EUA and establishing a non-promotional call center to support vaccine distribution and administration. Given the importance of vaccine confidence during EUA, special consideration will be given to scientific communication on the mRNA platform, vaccine development in a pandemic, and the safety, immunogenicity and effectiveness data of mRNA-1273. *Moderna will contribute by funding these activities. The USG will obtain access to the data.*

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. Moderna will file for Emergency Use Authorization, following the FDA guidance of EUA for COVID-19 vaccines. A product-specific VRBPAC will be held.

******BLA Submission (WBS 1.5.2.1) - Updated with ModP00008***
Moderna will submit a Biologics License Application (BLA) and seek approval for the mRNA-1273 vaccine.

****** The Pharmacovigilance (WBS 1.5.3.1) Updated with Mod P00008***
Moderna will conduct standard pharmacovigilance for all active mRNA-1273 clinical studies.

CMC (WBS 1.6)
CTM Manufacture for Phase 2 (WBS 1.6.3.2)
Clinical trial materials for the P201 study will be supplied using the AMP process. The target yield of each lot is approximately [***] vials; consequently, manufacture of up to five drug product (DP) lots is expected to deliver [***] total vials. The DP will be a frozen liquid stored at

[***]. The DP vials will be labeled and packaged by Moderna to support clinical testing in the US.

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 (WBS1.6.4.1)
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.

[***]

Controls (Analytical and Validation) (WBS 1.6.5)
Potency Assay Development and Implementation (WBS 1.6.5.1)
[***]

Analytical Method Development and Validation (WBS 1.6.5.2)
Moderna has established a set of analytical methods that are applied to the release and stability testing of intermediates and DP. These methods are sufficient to assure the identity, strength, quality, purity and potency of the final product, and will have been qualified for use for mRNA-1273 as part of the Phase 2 CTM campaign. Robustness of product release and stability methods, structural characterization and identification of impurities to further support product specifications, product comparability assessment will continue to support Phase 3 development and licensure.

Characterization Assay Development and Implementation (WBS 1.6.5.3)
A heightened characterization panel of analytical techniques will be used to assess any process modifications and to confirm process reproducibility for both drug substance and drug product during process development and scale up. As the applicability of the methods used in the heightened panel to elucidate quality attributes of drug substance and drug product is determined, these methods may be elevated to the respective release panel.

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.

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE	PAGE OF PAGES
	1 3

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. *(if applicable)*
P00009	See Block 16C	OS277805	

6. ISSUED BY CODE ASPR-BARDA

ASPR-BARDA
200 Independence Ave., S.W.
Room 640-G
Washington DC 20201

7. ADMINISTERED BY *(if other than Item 6)* CODE ASPR-BARDA02

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

CODE 1492235 FACILITY CODE

(X) 9A. AMENDMENT OF SOLICITATION NO.

9B. DATED *(SEE ITEM 11)*

X 10A. MODIFICATION OF CONTACT/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)*
See Schedule Net Increase: $144,140,941.00

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).

X C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:

FAR 52.243- 2 Alternate 1 (APR 1984) Changes - Cost-Reimbursement

D. OTHER *(Specify type of modification and authority)*

E. IMPORTANT: Contractor is not is required to sign this document and return _____ 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
This contract (75A50120C00034 - Moderna COVID-19 Vaccine)was awarded under
BAA-18-100-SOL-00003 - Development of an mRNA Vaccine for SARS-CoV-2.

The purpose of this modification is to support the additional scope of the Clinical Development Plan (CLIN 0002)for the P204 Pediatrics study (0-<12) WBS 1.4.2.4 in the amount of $144,140,941.

The P204 study is a Phase 2/3 study to evaluate the safety of mRNA-1273 SARS-CoV-2 vaccine in healthy children 6 months to < 12 years of age.
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)*		16A. NAME AND TITLE OF CONTRACTING OFFICER *(Type or print)*	
Stephane Bancel, CEO		[***]	
15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
/s/ Stephane Bancel			
(Signature of person authorized to sign)		*(Signature of Contracting Officer)*	

NAME OF OFFEROR OR CONTRACTOR
MODERNATX, INC 1492235

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)

The obligated amount of CLIN 0002 is increased from $1,197,752,410 by $144,140,941 to $1,341,893,351.

CLIN 0002 is the only CLIN changed by the issuance of this modification. CLIN 0002 remains cost plus fixed fee (CPFF). Fee was not applied to the additional scope.

	Prior Contract Value	Additional Funding	Revised Contract Value
CLIN 0001	$3,212,541	$-	$3,212,541
CLIN 0002	$1,197,752,410	$144,140,941	$1,341,893,351
CLIN 0003	$53,000,000	$-	$53,000,000
Total	$1,253,964,951	$144,140,941	$1,398,105,892

All other contract terms and conditions remain unchanged.
Period of Performance: 04/03/2020 to 08/31/2023

Change Item 2 to read as follows (amount shown is the obligated amount):

Base CLIN 0002 – Development of mRNA vaccine to BLA

2 144,140,941.00

Accounting Info:
2020.199cov1.25103 Appr. Yr.: 2020 CAN: 199cov1 Object Class: 25103
Funded: $0.00

Accounting Info:
2020.199co014.25103 Appr. Yr.: 2020 CAN: 199co14 Object Class: 25103
Funded: $0.00

Accounting Info:
2021.199co35.25103 Appr. Yr.: 2021 CAN: 199co035 Object Class: 25103
Funded: $0.00

Accounting Info:
2021.199co35.25103 Appr. Yr.: 2021 CAN: 199co035 Object Class: 25103
Funded: $0.00

Accounting Info:
2021.199co35.25103 Appr. Yr.: 2021 CAN: 199co035 Object Class: 25103
Funded: $144,140,941.00

Statement of Work (SOW) P204 - Modification P00009

P204 Pediatrics (WBS 1.4.2.4)

mRNA-1273-P204 is a Phase 2/3, 2-part, open-label, dose-escalation, age de-escalation, randomized, observer-blind, placebo-controlled, expansion study intended to infer the effectiveness of mRNA-1273 in children aged 6 months to < 12 years. The study population will be divided into 3 age groups (6 to < 12 years, 2 to < 6 years, and 6 months to < 2 years) and up to 3 dose levels (25, 50, and 100 ^g) of mRNA- 1273 will be evaluated.

The study will be conducted in 2 parts. Part 1 of the study will be open label and consist of dose-escalation, age de-escalation in 750 participants (see Table below for the number of participants in each age group) to select the dose for each age group. Part 2 of the study will be placebo-controlled, observer-blind evaluation of the selected dose in 6,000 participants (2,000 participants in each age group). No participants in Part 1 will participate in Part 2 of the study. The total participants in mRNA-1273-P204 study is 6,750 participants.

The study will begin with the oldest age group (6 to < 12 year) and age de-escalate. Each age group will begin with Part 1 and advance to Part 2. The mRNA-1273 investigational vaccine or placebo will be administered as 2 intramuscular (IM) injections, approximately 28 days apart.

The mRNA-1273 dose levels that will be evaluated in each age group in Part 1 and Part 2 of the study are given in the Table below. Only the 6-month to < 2-year age group will receive the 25 ^g dose level.

	Part 1			Part 2	
Age Group	**mRNA-1273 25 gg**	**mRNA-1273 50 gg**	**mRNA-1273 100 gg**	**Selected Dose Level of mRNA-1273 From Part 1**	**Placebo**
6 to < 12 years		Study arm 1 (n=75)	Study arm 2 (n=75)	Study arm 8 (n=1500)	Study arm 9 (n=500)
2 to < 6 years		Study arm 3 (n=75)	Study arm 4 (n=75)	Study arm 10 (n=1500)	Study arm 11 (n=500)
6 months to < 2 years	Study arm 5 (n=150)	Study arm 6 (n=150)	Study arm 7 (n=150)	Study arm 12 (n=1500)	Study arm 13 (n=500)

The study will enroll in the US and Canada. The result of mRNA-1273-P204 study is to expand the label indication to 6 months to < 12 years old.

Exhibit 31.1

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: August 5, 2021

By: /s/ Stéphane Bancel

Stéphane Bancel
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

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: August 5, 2021

By: /s/ David W. Meline

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

Exhibit 32.1

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 June 30, 2021 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: August 5, 2021

By: /s/ Stéphane Bancel
Stéphane Bancel
Chief Executive Officer
(Principal Executive Officer)

Date: August 5, 2021

By: /s/ David W. Meline
David W. Meline
Chief Financial Officer
(Principal Financial Officer)