UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-Q

(Mark One)

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

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** o

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. o

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

As of October 29, 2021, there were 405,449,527 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;

- 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;

- 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;
- legal and 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 or treatments that are or may become available as an alternative to our products;
- our ability to attract and retain key scientific or management personnel; and
- developments relating to our competitors and our industry.

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. Information contained on our website and social media channels shall not be deemed incorporated into, or be a part of this Form 10-Q.

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Item 1. Financial Statements

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

	September 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 5,550	$ 2,624
Investments	3,356	1,984
Accounts receivable	3,142	1,391
Inventory	965	47
Prepaid expenses and other current assets	412	252
Total current assets	13,425	6,298
Investments, non-current	6,442	639
Property and equipment, net	845	297
Right-of-use assets, operating leases	115	90
Restricted cash, non-current	11	11
Deferred tax assets	81	—
Other non-current assets	4	2
Total assets	$ 20,923	$ 7,337
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 87	$ 18
Accrued liabilities	1,076	470
Deferred revenue	7,977	3,867
Income taxes payable	565	—
Other current liabilities	252	34
Total current liabilities	9,957	4,389
Deferred revenue, non-current	498	177
Operating lease liabilities, non-current	105	97
Financing lease liabilities, non-current	238	110
Other non-current liabilities	1	3
Total liabilities	10,799	4,776
Commitments and contingencies (Note 12)		
Stockholders' equity:		
Preferred stock, par value $0.0001; 162 shares authorized as of September 30, 2021 and December 31, 2020; no shares issued or outstanding at September 30, 2021 and December 31, 2020	—	—
Common stock, par value $0.0001; 1,600 shares authorized as of September 30, 2021 and December 31, 2020; 405 and 399 shares issued and outstanding as of September 30, 2021 and December 31, 2020, respectively	—	—
Additional paid-in capital	5,003	4,802
Accumulated other comprehensive income	31	3
Retained earnings (accumulated deficit)	5,090	(2,244)
Total stockholders' equity	10,124	2,561
Total liabilities and stockholders' equity	$ 20,923	$ 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 September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Revenue:				
Product sales	$ 4,810	$ —	$ 10,740	$ —
Grant revenue	140	145	473	187
Collaboration revenue	19	12	47	45
Total revenue	4,969	157	11,260	232
Operating expenses:				
Cost of sales	722	—	1,665	—
Research and development	521	344	1,343	611
Selling, general and administrative	168	48	366	109
Total operating expenses	1,411	392	3,374	720
Income (loss) from operations	3,558	(235)	7,886	(488)
Interest income	4	6	11	21
Other expense, net	(10)	(3)	(22)	(6)
Income (loss) before income taxes	3,552	(232)	7,875	(473)
Provision for income taxes	219	1	541	1
Net income (loss)	$ 3,333	$ (233)	$ 7,334	$ (474)
Earnings (loss) per share:				
Basic	$ 8.27	$ (0.59)	$ 18.25	$ (1.26)
Diluted	$ 7.70	$ (0.59)	$ 17.00	$ (1.26)
Weighted average common shares used in calculation of earnings (loss) per share:				
Basic	404	395	402	376
Diluted	434	395	431	376

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 September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Net income (loss)	$ 3,333	$ (233)	$ 7,334	$ (474)
Other comprehensive income (loss), net of tax:				
Available-for-sales securities:				
Unrealized (losses) gains on available-for-sale debt securities	(3)	(3)	(10)	2
Less: net realized (gains) losses on available-for-sale securities reclassified in net income (loss)	(1)	—	(2)	1
Net (decrease) increase from available-for-sale debt securities	(4)	(3)	(12)	3
Cash flow hedges:				
Unrealized gains on derivative instruments	30	—	51	—
Less: net realized (gains) on derivative instruments reclassified in net income	(11)	—	(11)	—
Net increase from derivatives designated as hedging instruments	19	—	40	—
Total other comprehensive income (loss)	15	(3)	28	3
Comprehensive income (loss)	$ 3,348	$ (236)	$ 7,362	$ (471)

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

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

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Retained Earnings	Total Stockholders' Equity
	Shares	Amount				
Balance at June 30, 2021	403	$ —	$ 4,931	$ 16	$ 1,757	$ 6,704
Exercise of options to purchase common stock	2	—	32	—	—	32
Stock-based compensation	—	—	40	—	—	40
Other comprehensive income, net of tax	—	—	—	15	—	15
Net income	—	—	—	—	3,333	3,333
Balance at September 30, 2021	405	$ —	$ 5,003	$ 31	$ 5,090	$ 10,124

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at June 30, 2020	393	$ —	$ 4,677	$ 8	$ (1,738)	$ 2,947
Exercise of options to purchase common stock	2	—	27	—	—	27
Stock-based compensation	—	—	22	—	—	22
Other comprehensive loss, net of tax	—	—	—	(3)	—	(3)
Net loss	—	—	—	—	(233)	(233)
Balance at September 30, 2020	395	$ —	$ 4,726	$ 5	$ (1,971)	$ 2,760

	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	6	—	91	—	—	91
Purchase of common stock under employee stock purchase plan	—	—	5	—	—	5
Stock-based compensation	—	—	105	—	—	105
Other comprehensive income, net of tax	—	—	—	28	—	28
Net income	—	—	—	—	7,334	7,334
Balance at September 30, 2021	405	$ —	$ 5,003	$ 31	$ 5,090	$ 10,124

	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	10	—	133	—	—	133
Purchase of common stock under employee stock purchase plan	—	—	3	—	—	3
Stock-based compensation	—	—	67	—	—	67
Other comprehensive income, net of tax	—	—	—	3	—	3
Net loss	—	—	—	—	(474)	(474)
Balance at September 30, 2020	395	$ —	$ 4,726	$ 5	$ (1,971)	$ 2,760

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)

	Nine Months Ended September 30,	
	2021	2020
Operating activities		
Net income (loss)	$ 7,334	$ (474)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:		
Stock-based compensation	105	67
Depreciation and amortization	154	24
Amortization/accretion of investments	33	5
Deferred income taxes	(89)	—
Changes in assets and liabilities:		
Accounts receivable	(1,751)	(185)
Prepaid expenses and other assets	(186)	(68)
Inventory	(918)	—
Right-of-use assets, operating leases	(25)	(13)
Accounts payable	26	14
Accrued liabilities	600	132
Deferred revenue	4,431	1,240
Income taxes payable	565	—
Operating lease liabilities	8	14
Other liabilities	23	7
Net cash provided by operating activities	10,310	763
Investing activities		
Purchases of marketable securities	(10,279)	(2,326)
Proceeds from maturities of marketable securities	1,075	748
Proceeds from sales of marketable securities	1,983	140
Purchases of property and equipment	(164)	(44)
Net cash used in investing activities	(7,385)	(1,482)
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	96	136
Changes in financing lease liabilities	(96)	—
Net cash provided by financing activities	—	1,989
Net increase in cash, cash equivalents and restricted cash	2,925	1,270
Cash, cash equivalents and restricted cash, beginning of year	2,636	248
Cash, cash equivalents and restricted cash, end of period	$ 5,561	$ 1,518
Non-cash investing and financing activities		
Purchases of property and equipment included in accounts payable and accrued liabilities	$ 66	$ 13
Right-of-use assets obtained through finance lease modifications and reassessments	$ 364	$ 46
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 and marketed under the brand name Spikevax) in individuals 18 years of age or older. We have also received authorization for our COVID-19 vaccine from health agencies in more than 60 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 United Kingdom, European Union, Japan, Canada, Switzerland, Taiwan, Saudi Arabia, Australia, and the Philippines, and have pending applications for authorization to administer the vaccine to adolescents with regulatory agencies in the United States and other countries.

The FDA has approved an update to the EUA for the Moderna COVID-19 vaccine to include a third dose at the 100 µg level for immunocompromised individuals 18 years of age or older in the United States, as well as the administration of 50 µg booster doses for individuals age 65 and older, people aged 18 to 64 who are at high risk of severe COVID-19, and people aged 18 to 64 with frequent institutional or occupational exposure to SARS-CoV-2. In October 2021, the U.S. Advisory Committee on Immunization Practices (ACIP) also endorsed recommending the Moderna COVID-19 Vaccine as a booster, regardless of the original vaccine received by an individual in their primary series. The European Medicines Agency (EMA) has also authorized a third dose of the Moderna COVID-19 vaccine given at least 28 days after the second dose to severely immunocompromised individuals 12 years of age or older, as well as the administration of 50 µg booster doses for individuals 18 years of age and older. In August 2021, we completed the rolling submission process with the FDA for a Biologics License Application (BLA) for our COVID-19 vaccine, which is subject to Priority Review.

As of September 30, 2021, we had 37 mRNA development programs in our portfolio with 22 having entered the clinic. In the third quarter of 2021, we refined the way we track our development programs and now separately track each indication of our COVID-19 and RSV vaccine candidates, which resulted in an increase in the number of our development programs. 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 and vaccines against other respiratory diseases, 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 September 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 Moderna, Inc. 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 nine months ended September 30, 2021 are consistent with those described in our 2020 Form 10-K, except for “Derivative financial instruments” disclosed within Note 6.

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 nine months ended September 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
Other comprehensive (loss) income	(4)	19	15
Accumulated other comprehensive income, balance at September 30, 2021	$ (9)	$ 40	$ 31

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):

	September 30,	
	2021	2020
Cash and cash equivalents	$ 5,550	$ 1,506
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	$ 5,561	$ 1,518

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 September 30, 2021	Nine Months Ended September 30, 2021
United States	$ 1,197	$ 4,648
Rest of world	3,613	6,092
Total	$ 4,810	$ 10,740

There were no product sales for the three and nine months ended September 30, 2020. As of September 30, 2021, our COVID-19 vaccine was our only commercial product authorized for use.

As of September 30, 2021 and December 31, 2020, we had deferred revenue of $8.3 billion and $3.8 billion, respectively, related to customer deposits. We expect $7.9 billion of our deferred revenue related to customer deposits as of September 30, 2021 to be realized in less than one year. 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 September 30, 2021, the committed funding, net of revenue earned, was $4 million. An additional $43 million of funding will 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 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 COVID-19. 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. In June 2021, the agreement with BARDA was further amended to award additional funding of $144 million to support pediatric clinical trials for mRNA-1273. The maximum award from BARDA, inclusive of the 2020 and 2021 amendments, was approximately $1.4 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 September 30, 2021, the remaining available funding, net of revenue earned, was $441 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 September 30, 2021, the remaining available funding, net of revenue earned, was $55 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 September 30, 2021, the available funding, net of revenue earned, was $7 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 September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
BARDA	$ 128	$ 143	$ 454	$ 183
Other grant revenue	12	2	19	4
Total grant revenue	$ 140	$ 145	$ 473	$ 187

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 September 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 others. 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 these collaboration agreements.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
Collaboration Revenue by Strategic Collaborator:	**2021**	**2020**	**2021**	**2020**
AstraZeneca	$ 3	$ —	$ 7	$ 17
Merck	7	6	11	18
Vertex	5	6	23	10
Other	4	—	6	—
Total collaboration revenue	$ 19	$ 12	$ 47	$ 45

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

	December 31, 2020	Additions	Deductions	September 30, 2021
Contract Assets:				
Accounts receivable	$ 6	$ 21	$ (21)	$ 6
Contract Liabilities:				
Deferred revenue	$ 240	$ 23	$ (45)	$ 218

As of September 30, 2021, the aggregated amount of the transaction price allocated to performance obligations under our collaboration agreements that are unsatisfied or partially unsatisfied was $310 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 September 30, 2021 and December 31, 2020 (in millions):

	September 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	$ 5,550	$ —	$ —	$ 5,550	$ 5,550	$ —	$ —
Available-for-sale:							
Certificates of deposit	85	—	—	85	—	85	—
U.S. treasury bills	95	—	—	95	—	95	—
U.S. treasury notes	6,557	1	(5)	6,553	—	2,046	4,507
Corporate debt securities	2,956	1	(4)	2,953	—	1,118	1,835
Government debt securities	113	—	(1)	112	—	12	100
Total	$ 15,356	$ 2	$ (10)	$ 15,348	$ 5,550	$ 3,356	$ 6,442

	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	1,788	4	—	1,792	—	1,239	553
Government debt securities	13	—	—	13	—	—	13
Total	$ 5,243	$ 4	$ —	$ 5,247	$ 2,624	$ 1,984	$ 639

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

	September 30, 2021	
	Amortized Cost	Estimated Fair Value
Due in one year or less	$ 3,356	$ 3,356
Due after one year through five years	6,450	6,442
Total	$ 9,806	$ 9,798

	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 non-credit-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 nine months ended September 30, 2021 and 2020. We did not recognize any credit-related allowance to available-for-sale securities as of September 30, 2021 and December 31, 2020.

As of September 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 September 30, 2021 and December 31, 2020 (in millions):

	Fair value at September 30, 2021	Fair Value Measurement Using	
		Level 1	Level 2
Assets:			
Money market funds	$ 4,606	$ 4,606	$ —
Certificates of deposit	85	—	85
U.S. treasury bills	95	—	95
U.S. treasury notes	6,553	—	6,553
Corporate debt securities	2,953	—	2,953
Government debt securities	112	—	112
Derivative instruments (Note 7)	51	—	51
Total	$ 14,455	$ 4,606	$ 9,849
Liabilities:			
Derivative instruments (Note 7)	$ 1	$ —	$ 1

	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	1,792	—	1,792
Government debt securities	13	—	13
Total	$ 3,283	$ 660	$ 2,623

As of September 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 other expense, net, in our condensed consolidated statements of operations. 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 as a component of other expense, net, in our condensed consolidated statements of operations. As of September 30, 2021, we had net deferred gains of $48 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):

	September 30, 2021		
		Fair Value	
	Notional Amount	Asset [1]	Liability [2]
Derivatives designated as cash flow hedging instruments:			
Foreign currency forward contracts	$ 1,436	$ 48	$ —
Derivatives not designated as hedging instruments:			
Foreign currency forward contracts	556	3	1
Total derivatives	$ 1,992	$ 51	$ 1

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

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

	Three Months Ended September 30, 2021	Nine Months Ended September 30, 2021
Derivatives in cash flow hedging relationships:		
Foreign currency forward contracts	$ 30	$ 51

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

	Statement of Operations Classification	Three Months Ended September 30, 2021	Nine Months Ended September 30, 2021
Derivatives in cash flow hedging relationships:			
Foreign currency forward contracts			
Net gain reclassified from AOCI into income	Product sales	$ (11)	$ (11)
Derivatives not designated as hedging instruments:			
Foreign currency forward contracts			
Net realized and unrealized gain (loss)	Other expense, net	$ 3	$ (16)

There were no hedging activities for the three and nine months ended September 30, 2020.

8. Inventory

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

	September 30, 2021	December 31, 2020
Raw materials	$ 605	$ 37
Work in progress	233	9
Finished goods	127	1
Total inventory	$ 965	$ 47

9. Property and Equipment, Net

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

	September 30, 2021	December 31, 2020
Laboratory equipment	$ 152	$ 121
Leasehold improvements	231	180
Furniture, fixtures and other	8	5
Computer equipment and software	15	13
Internally developed software	9	7
Right-of-use asset, financing (Note 11)	546	56
Construction in progress	158	35
Total	1,119	417
Less: Accumulated depreciation	(274)	(120)
Property and equipment, net	$ 845	$ 297

Depreciation and amortization expense for the three months ended September 30, 2021 and 2020 was $70 million and $8 million, respectively. Depreciation and amortization expense for the nine months ended September 30, 2021 and 2020 was $154 million and $24 million, respectively.

10. Other Balance Sheet Components

Prepaid Expenses and Other Current Assets

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

	September 30, 2021	December 31, 2020
Down payments to manufacturing vendors	$ 156	$ 217
Other prepaid expenses	105	7
Value added tax receivable	57	7
Derivative assets	51	—
Other current assets	43	21
Prepaid expenses and other current assets	$ 412	$ 252

Accrued Liabilities

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

	September 30, 2021	December 31, 2020
Clinical trials	$ 166	$ 98
Raw materials	141	78
Royalties	168	—
Development operations	125	29
Manufacturing	196	53
Other external goods and services	87	92
Compensation-related	105	95
Other	88	25
Accrued liabilities	$ 1,076	$ 470

Other Current Liabilities

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

	September 30, 2021	December 31, 2020
Lease liabilities - financing (Note 11)	$ 218	$ 24
Lease liabilities - operating (Note 11)	22	6
Other	12	4
Other current liabilities	$ 252	$ 34

Deferred Revenue

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

	December 31, 2020	Additions	Deductions	September 30, 2021
Product sales	$ 3,799	$ 9,615	$ (5,163)	$ 8,251
Grant revenue	5	20	(19)	6
Collaboration revenue	240	23	(45)	218
Total deferred revenue	$ 4,044	$ 9,658	$ (5,227)	$ 8,475

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 lease 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, our 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 September 30, 2021 and December 31, 2020, we had lease liabilities of $218 million and $24 million, respectively, related to the embedded leases. As of September 30, 2021 and December 31, 2020, we had right-of-use assets of $238 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 September 30, 2021 and December 31, 2020 were as follows (in millions):

	September 30, 2021	December 31, 2020
Assets:		
Right-of-use assets, operating, net [1] [2]	$ 115	$ 90
Right-of-use assets, financing, net [3] [4]	416	55
Total	$ 531	$ 145
Liabilities:		
Current:		
Operating lease liabilities [5]	$ 22	$ 6
Financing lease liabilities [5]	218	24
Total current lease liabilities	240	30
Non-current:		
Operating lease liabilities, non-current	105	97
Financing lease liabilities, non-current	238	110
Total non-current lease liabilities	$ 343	$ 207
Total	$ 583	$ 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 September 30, 2021, are as follows (in millions):

Fiscal Year	Operating Leases [1]	Financing Leases [1]
2021 (remainder of the year)	$ 7	$ 66
2022	31	173
2023	25	19
2024	16	19
2025	17	19
Thereafter	94	600
Total minimum lease payments	190	896
Less amounts representing interest or imputed interest	(63)	(440) [2]
Present value of lease liabilities	$ 127	$ 456

[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 September 30, 2021 and December 31, 2020. Please refer to Note 5 for our consolidated financial statements in our 2020 Form 10-K.

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 nine months ended September 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 September 30, 2021, we had $2.3 billion of non-cancelable purchase commitments related to raw materials and manufacturing agreements, which are expected to be paid through 2024. As of September 30, 2021, we had $69 million of non-cancelable purchase commitments related to clinical services and other goods and services which are expected to be paid through 2026. These amounts represent our minimum contractual obligations, including termination fees.

In addition to purchase commitments, we have agreements with third parties for various services, including services related to clinical operations and support and contract manufacturing, for which we are not contractually able to terminate for convenience and avoid any and all future obligations to the vendors. Certain agreements provide for termination rights subject to termination fees or wind down costs. Under such agreements, we are contractually obligated to make certain payments to vendors, mainly, to reimburse them for their unrecoverable outlays incurred prior to cancellation. At September 30, 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 September 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 nine months ended September 30, 2021, we recognized $168 million and $400 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 for the three and nine months ended September 30, 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 September 30, 2021.

Moderna Science Center

In September 2021, we announced an investment in our Moderna Science Center (MSC), in Cambridge, Massachusetts. MSC will integrate scientific and non-scientific spaces, including our principal executive offices, and is being built to support our growth as we continue to advance our pipeline of mRNA medicines. In relation to the investment, we entered into a lease agreement for approximately 462,000 square feet and will undergo an approximately two-year building project. Following the building project, the lease term is 15 years, subject to our right to extend the lease for up to two additional seven-year terms. Pursuant to this lease agreement, we are committed to approximately $1.1 billion non-cancellable rent payments for the initial lease term. Construction at the location has begun, and we expect to begin a phased move-in process in 2023.

13. Stock-Based Compensation

As of September 30, 2021, we had a total of 58 million shares reserved for future issuance under our Equity Plans, of which 31 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 nine months ended September 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	1.28	195.93	86.02		
Exercised	(5.69)	15.77	8.89		
Canceled/forfeited	(0.86)	26.97	14.51		
Outstanding at September 30, 2021	28.79	25.09	12.43	6.1 years	10,362
Exercisable at September 30, 2021	16.84	12.68	6.56	5.0 years	6,266
Expected to vest at September 30, 2021	11.95	42.56	20.71	7.6 years	4,096

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

The total intrinsic value of options exercised was $1.2 billion for the nine months ended September 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 $91 million for the nine months ended September 30, 2021.

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

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

	Units (in millions)	Weighted-Average Fair Value per Unit
Outstanding, non-vested at December 31, 2020	2.19	$ 30.85
Issued	0.63	198.19
Vested	(0.48)	27.41
Canceled/forfeited	(0.10)	43.72
Outstanding, non-vested at September 30, 2021	2.24	78.43

The total fair value of restricted stock units vested during the nine months ended September 30, 2021 was $13 million. The total intrinsic value of restricted stock units vested during the nine months ended September 30, 2021 was $108 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 nine months ended September 30, 2021. As of September 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 nine months ended September 30, 2021 and 2020 as follows (in millions):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Options	$ 27	$ 18	$ 73	$ 57
RSUs and PSUs	12	3	29	8
ESPP	1	1	3	2
Total	$ 40	$ 22	$ 105	$ 67
Cost of sales	$ 1	$ —	$ 13	$ —
Research and development	25	13	54	40
Selling, general and administrative	14	9	38	27
Total	$ 40	$ 22	$ 105	$ 67

As of September 30, 2021, there was $348 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 September 30, 2021.

Share Repurchase Program

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.

During the three and nine months ended September 30, 2021, we did not make any repurchases under the Share Repurchase Program.

14. Income Taxes

We are subject to U.S. federal and state and foreign income taxes. For the three and nine months ended September 30, 2021, we recorded provisions for income taxes of $219 million and $541 million, respectively, compared to $1 million in each of the same periods in 2020. Our effective tax rate for the three and nine months ended September 30, 2021 was 6% 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 and other deferred tax assets, the benefit of the foreign derived intangible income deduction, as well as a discrete item for excess tax benefits related to stock-based compensation. Our effective tax rate for the three and nine months ended September 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 nine months ended September 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.

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 nine months ended September 30, 2021 and 2020 were calculated as follows (in millions, except per share data):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Numerator:				
Net income (loss)	$ 3,333	$ (233)	$ 7,334	$ (474)
Denominator:				
Basic weighted-average common shares outstanding	404	395	402	376
Effect of dilutive securities	30	—	29	—
Diluted weighted-average common shares outstanding	434	395	431	376
Basic EPS	$ 8.27	$ (0.59)	$ 18.25	$ (1.26)
Diluted EPS	$ 7.70	$ (0.59)	$ 17.00	$ (1.26)

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

	September 30, 2020
Stock options	37
Restricted common stock units	2
Total	39

For the three and nine months ended September 30, 2021, we had an immaterial number of securities that were not included in the diluted earnings per share calculation because the effect would have been anti-dilutive.

16. Subsequent Events

Subsequent to September 30, 2021, we have entered into additional commitments and supply agreements with customers to provide up to 58 million doses of our COVID-19 vaccine and our updated variant booster vaccine candidate based on the initial confirmed volume, subject to modifications.

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 seven modalities to date:

- prophylactic vaccines;
- systemic secreted and cell surface therapeutics;
- cancer vaccines;
- intratumoral immuno-oncology;
- localized regenerative therapeutics;
- systemic intracellular therapeutics; and
- inhaled pulmonary 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, 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 and marketed under the brand name Spikevax) 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 (WHO). 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 United Kingdom, European Union, Japan, Canada, Switzerland, Taiwan, Saudi Arabia, Australia and the Philippines, and have pending applications for authorization to administer the vaccine to adolescents with regulatory agencies in the United States and other countries.

The FDA has approved an update to the EUA for the Moderna COVID-19 Vaccine to include a third dose for immunocompromised individuals 18 years of age or older in the United States, as well as the administration of 50 µg booster doses for individuals age 65 and older, people aged 18 to 64 who are at high risk of severe COVID-19, and people aged 18 to 64 with frequent institutional or occupational exposure to SARS-CoV-2. In October 2021, the U.S. Advisory Committee on Immunization Practices (ACIP) also endorsed recommending the Moderna COVID-19 Vaccine as a booster, regardless of the original vaccine received by an individual in their primary series. The European Medicines Agency (EMA) has also authorized a third dose of the Moderna COVID-19 vaccine given at least 28 days after the second dose to severely immunocompromised individuals 12 years of age or older, as well as the administration of 50 µg booster doses for individuals 18 years of age and older. In August 2021, we completed the rolling submission process with the FDA for a Biologics License Application (BLA) for our COVID-19 vaccine, which is subject to Priority Review.

On October 29, 2021, the FDA informed us that the agency will require additional time to evaluate recently conducted international analyses of the risk of myocarditis (inflammation of the heart muscle) after vaccination in connection with our requested EUA to administer the Moderna COVID-19 Vaccine in adolescents (12-17 years of age). The FDA notified us that this review may not be completed before January 2022. An increased risk of myocarditis has been described for mRNA COVID-19 vaccines, including the Moderna COVID-19 vaccine, particularly in young men and following the second dose. The U.S. Centers for Disease Control (CDC) and Prevention and the WHO have stated that myocarditis following vaccination with mRNA vaccines has been rare and generally mild. We are committed to conducting our own careful review of new external analyses as they become available. We do not yet have access to data from some recent international analyses. We currently expect that we will also delay filing a request for EUA of our COVID-19 vaccine at the 50 µg dose level in the pediatric population (6-11 years of age) while the FDA completes its review of the adolescent EUA request.

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) and the African Union 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 September 30, 2021, we had approximately $8.3 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 third quarter of 2021, we delivered approximately 73 million doses of our COVID-19 vaccine to the U.S. Government and approximately 136 million doses to other governments, and recognized $4.8 billion in product sales. For the nine months ended September 30, 2021, we delivered approximately 287 million doses of our COVID-19 vaccine to the U.S. Government and approximately 222 million doses to other governments, and recognized $10.7 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. 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/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.

We currently anticipate that we will be supply between 700 million and 800 million doses of our COVID-19 vaccine in 2021, at the 100 µg dose. Key variables impacting output include longer delivery lead times for international shipments and exports that may shift deliveries to early 2022, temporary impact from expansion of fill/finish capacity and ramp up of product release to market. The ultimate number of doses that we anticipate delivering in 2022 is subject to a number of factors, including demand for the vaccine as the COVID-19 pandemic shifts to an anticipated endemic phase, demand for presentations of our vaccine, the dosage for the vaccine (including different dose amounts for primary series, booster series and pediatric vaccines), and other factors.

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 United States. 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. We have received authorization for our COVID-19 vaccine for use in adolescents in the United Kingdom, European Union, Japan, Canada, Switzerland, Taiwan, Saudi Arabia, Australia and the Philippines. We have filed for an EUA for adolescents with the FDA and a determination is pending, as described in further detail above.

The Phase 2/3 KidCOVE study of mRNA-1273 in the pediatric population ages 6 months to 11 years is ongoing. We expect to enroll more than 12,000 healthy pediatric participants in the U.S. and Canada into this two-part, dose escalation study. Data from the KidCOVE study two weeks after the first dose of mRNA-1273 at the 50 µg dose level showed a vaccine efficacy of 100%, using the Phase 3 COVE study primary case definition for COVID-19. Additionally, for asymptomatic infection two weeks after the first dose, vaccine efficacy was 65% (95% CI: .16, .85). For SARS-CoV-2 infection regardless of symptoms, vaccine efficacy was 80% (95% CI: .62, .90) two weeks after the first dose. On October 24, the Company announced positive top line top line data from the Phase 2/3 study of mRNA-1273 in children 6 to 11 years of age. GMR comparing the response in children to the response in young adults from the Phase 3 COVE study was 1.5 (95% CI: 1.3, 1.8), with a seroresponse rate of 99.3%. Two 50 µg doses of mRNA-1273 were generally well tolerated. The Company plans to submit results to the U.S. FDA, EMA and regulatory agencies around the world. The age groups are 6 years to <12 years, 2 years to <6 years and 6 months to <2 years. In part 1, each age group tests one of two dose levels. Following an interim analysis, a dose will be selected for part 2, a placebo-controlled expansion portion of the study, which is expected to enroll 4,000 participants. We are in part 1 of the study for the two other age groups, 2 years to <6 years and 6 months to <2 years old. Dose selection studies are underway for the 2 to <6 years and 6 months to <2 years age groups.

The Phase 1 study of mRNA-1283 is fully enrolled and ongoing. An interim analysis of data from the Phase 1 study of mRNA-1283 at three dose levels indicates that a lower dose of mRNA-1283 achieved similar neutralizing antibody responses compared to a primary series of mRNA-1273. mRNA-1283 had an acceptable tolerability profile. The Company is preparing to begin a Phase 2 booster study of mRNA-1283. mRNA-1283 is a next-generation vaccine candidate against COVID-19 that encodes for the portions of the SARS-CoV-2 spike protein critical for neutralization, specifically the Receptor Binding Domain (RBD) and N-terminal Domain (NTD). The encoded mRNA-1283 antigen is shorter than mRNA-1273 and is being developed as a potential refrigerator-stable mRNA vaccine that will facilitate easier distribution and administration by healthcare providers.

Variant-Specific Booster Candidates

In February 2021, 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 published in Nature Medicine. 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.

Other Business Updates

On November 1, 2021, we announced that, as part of our commitment to sustainability, we will work to achieve net-zero carbon emissions from our operations globally by 2030. These efforts to reduce our environmental impact are expected to include implementing key initiatives to reduce the carbon footprint from both our existing and future facilities, encouraging green transportation and working with our suppliers as they move toward their own carbon reduction goals.

On November 2, 2021, we announced that we have entered into a strategic research and development collaboration with Metagenomi, Inc., focused on advancing novel gene editing technologies for *in vivo* human therapeutic applications. The collaboration will utilize Metagenomi's next generation gene editing tools and leverage Moderna's mRNA platform, as well as LNP delivery technologies, with the goal of developing curative therapies for patients with serious genetic diseases.

Key Updates for our Other Development Candidates

- **Cytomegalovirus (CMV) vaccine (mRNA-1647):** Our vaccine against 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, known as the CMVictory study, which will evaluate the prevention of primary CMV infection in seronegative women ages 16-40 years. We plan to enroll up to a total of 8,000 participants, including 6,900 women of child-bearing age from approximately 150 sites across the U.S., Europe and Asia-Pacific into the Phase 3 study, and the first participant was dosed in the Phase 3 study on October 26, 2021. 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. Phase 1 interim data from the older adult cohort showed that a single mRNA-1345 vaccination at 50 µg, 100 µg or 200 µg boosted neutralizing antibody titers against RSV-A by approximately 14-fold and against RSV-B by approximately 10-fold. We are preparing for a global Phase 2/3 study with approximately 34,000 participants, which will test the 50 µg dose and we expect the trial to begin by the end of 2021. 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 FDA has granted Fast Track designation for mRNA-1345 in adults older than 60 years of age. 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, and the Phase 1 portion of the Phase1/2 study is fully enrolled. Preparation for the Phase 2 portion of the study are ongoing. 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, a COVID-19 variant booster and RSV. Moderna owns worldwide commercial rights to mRNA-1010.

- **Human metapneumovirus (hMPV) and parainfluenza type 3 (PIV3) vaccine (mRNA-1653):** We are enrolling seropositive pediatric participants (12-36 months of age) in the Phase 1 study of hMPV/PIV3 study (mRNA-1653). The first cohort in this study is fully enrolled. Moderna owns worldwide commercial rights to mRNA-1653.

- **Pediatric RSV and hMPV combination vaccine (mRNA-1365):** mRNA-1365 is a vaccine against RSV encoding for the prefusion F glycoprotein and the hMPV F protein. Moderna owns worldwide commercial rights to mRNA-1365.

- **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 (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. Geometric mean titers (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 and the first cohort is fully enrolled. 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 (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):** Enrollment for the Phase 1/2 clinical trial for mRNA-3705, our therapy for the treatment of methylmalonic acidemia, or MMA, is ongoing and the first patient has been dosed. 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.

- **Glycogen storage disease type 1a (GSD1a) (mRNA-3745):** The FDA has granted mRNA-3745 Orphan Drug Designation and completed its review of the IND application allowing it to proceed to clinic. Individuals with GSD1a have a deficiency in glucose-6-phosphatase resulting in pathological blood glucose imbalance. mRNA-3745 is an IV-administered mRNA encoding human G6Pase enzyme, designed to restore the deficient or defective intracellular enzyme activity in patients with GSD1a. Moderna owns worldwide commercial rights to mRNA-3745.

- **Crigler-Najjar Syndrome Type 1 (CN-1) (mRNA-3351):** mRNA-3351 encodes for the human UGT1A1 and is designed to restore the missing or dysfunctional proteins that causes Crigler-Najjar Syndrome Type 1. mRNA-3351 has been granted Rare Pediatric Disease designation by the FDA. We are providing investigational mRNA-3351 to the nonprofit Institute for Life Changing Medicines (ILCM) free of charge. ILCM will be responsible for the clinical development of mRNA-3351 and plans to initiate clinical studies of mRNA-3351 in 2022.

- **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.

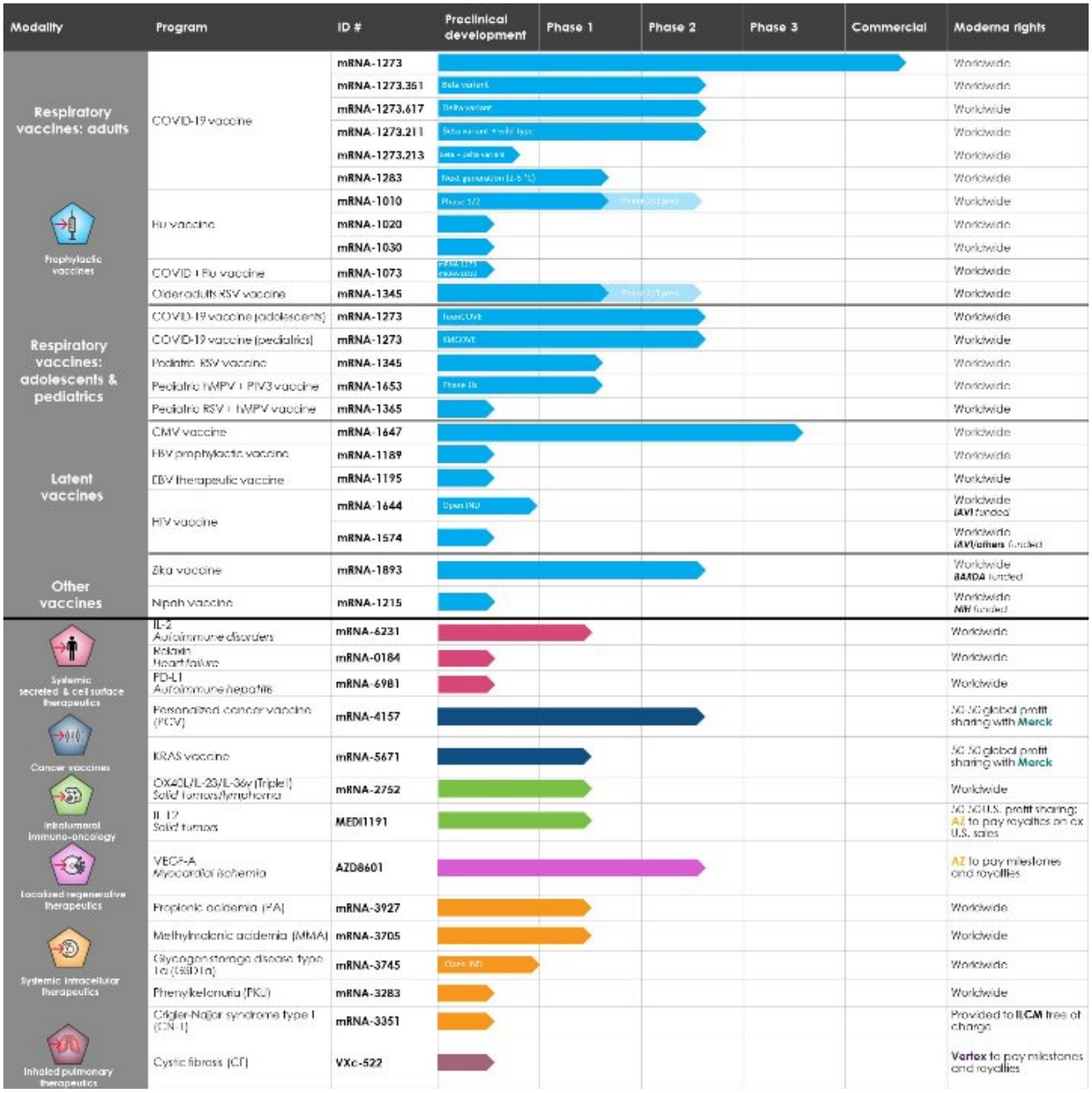
- **Intratumoral Immuno-Oncology:** The Phase 1 trial evaluating Triplet (mRNA-2752), which includes OX40L and two proinflammatory cytokines, IL-23, and IL-36γ, encapsulated in our proprietary LNP, is ongoing. New expansion cohorts are also enrolling.

- **Personalized cancer vaccine (mRNA-4157):** Our personalized cancer vaccine, or PCV, is currently being evaluated in a Phase 1 and Phase 2 study. The randomized, placebo-controlled Phase 2 study investigating a 1 mg dose of mRNA-4157 in combination with Merck's pembrolizumab (KEYTRUDA®), compared to pembrolizumab alone, for the adjuvant treatment of high-risk resected melanoma is fully enrolled (n=150). The primary endpoint of the Phase 2 study is recurrence-free survival at 12 months. The Phase 1 in multiple cohorts is ongoing and the expanded head and neck cohort is recruiting additional patients. Moderna shares worldwide commercial rights to mRNA-4157 with Merck.

- **Cystic Fibrosis (CF) (VXc-522):** VXc-522 is an mRNA therapeutic that we are designing in collaboration with Vertex Pharmaceuticals. VXc-522 is designed to treat the underlying cause of CF by enabling cells in the lungs to produce functional cystic fibrosis transmembrane conductance regulator (CFTR) protein for the treatment of the 10% of patients who do not produce any CFTR protein. IND-enabling studies are underway and Vertex expects to submit an IND for this program in 2022. VXc-522 is being advanced by Vertex.

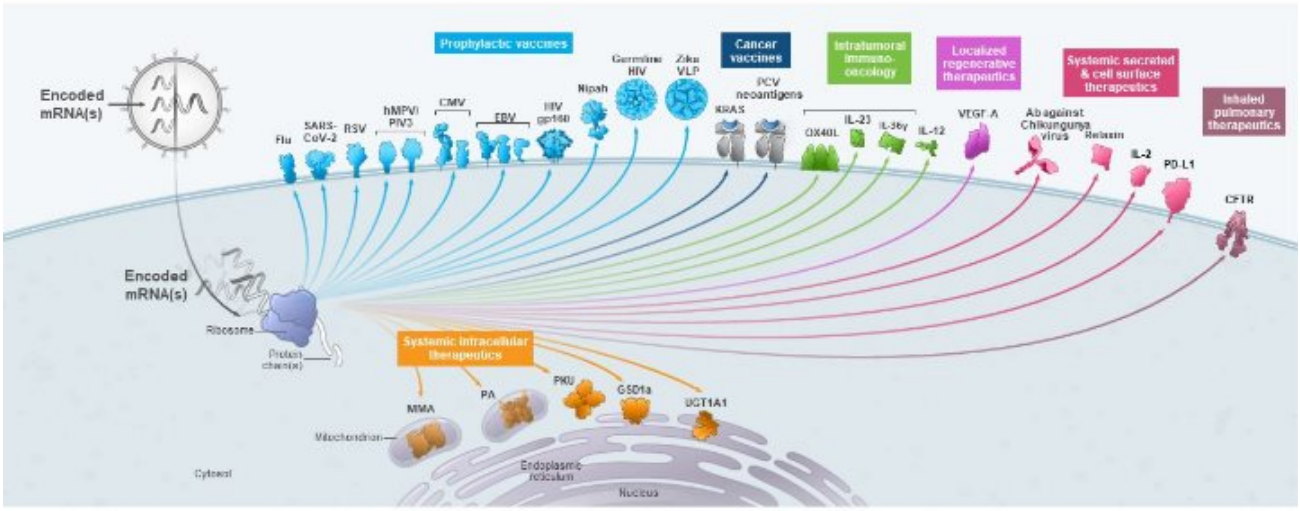
Our Pipeline

The following chart shows our current pipeline of 37 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. In the third quarter of 2021, we refined the way we track our development programs and now separately track each indication of our COVID-19 and RSV vaccine candidates, which resulted in an increase in the number of our development.



Abbreviations: AZ, AstraZeneca; BARDA, Biomedical Advanced Research and Development Authority; CMV, Cytomegalovirus; DARPA, Defense Advanced Research Projects Agency; EBV, Epstein-Barr virus; HIV, human immunodeficiency virus; hMPV, human metapneumovirus; IAVI, International AIDS Vaccine Initiative; ILCM, Institute for Life Changing Medicines; IL-2, interleukin 2; IL-12, interleukin 12; IL-23, interleukin 23; IL-36γ, interleukin-36 gamma; NIH, National Institutes of Health; OX40L, wildtype OX40 ligand; RSV, respiratory syncytial virus; VEGF-A, vascular endothelial growth factor A.

The breadth of biology addressable using mRNA technology is reflected in our current development pipeline of 37 programs. The diversity of proteins made from mRNA within our development pipeline is shown in the figure below.



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

- **Prophylactic vaccines:** Our prophylactic vaccines modality currently includes 23 development programs, 13 of which have entered into clinical trials. We have ongoing Phase 1 trials for our RSV vaccine in pediatrics and older adults (mRNA-1345), flu vaccine (mRNA-1010), and hMPV/PIV3 vaccine (mRNA-1653). We have ongoing Phase 2 studies for our Zika vaccine (mRNA-1893) and CMV vaccine (mRNA-1647). The Phase 3 trial for our CMV vaccine commenced in October 2021. Our COVID-19 vaccine (mRNA-1273) is described in detail above. Our ten preclinical programs within our prophylactic vaccines modality are for our COVID-19 variant- specific candidate (mRNA-1273.213), our combined COVID-19 and flu vaccine and flu vaccine (mRNA-1073), our seasonal flu vaccines (mRNA-1020 and mRNA-1030), our combination pediatric RSV and hMPV vaccine (mRNA-1365), Epstein-Barr virus (EBV) (mRNA-1189), EBV therapeutic vaccine (mRNA-1195), Nipah virus (mRNA-1215) and HIV (mRNA-1644 and mRNA-1574). Three other vaccines as part of public health programs have had positive Phase 1 readouts—H10N8 vaccine (mRNA-1440), H7N9 flu vaccine (mRNA-1851), and Chikungunya vaccine (mRNA-1388)— 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, but we do not have plans to advance to a Phase 2 study. Our IL-2 program (mRNA-6231) is currently in a Phase 1 study, and is our 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, which is fully enrolled. 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). 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. The Phase 2a study of AZD8601 VEGF-A, which is being developed for patients with ischemic heart disease undergoing coronary artery bypass grafting surgery with moderately impaired systolic function, led by AstraZeneca, has completed recruitment after enrollment of the low dose cohort (n=11). Moderna has licensed worldwide commercial rights to AZD8601 to AstraZeneca.

- **Systemic intracellular therapeutics:** We have five systemic intracellular therapeutics development candidates in our pipeline. Our intracellular programs address propionic acidemia, or PA (mRNA-3927), methylmalonic acidemia (MMA) (mRNA-3705), phenylketonuria (PKU) (mRNA-3283), glycogen storage disorder type 1a (GSD1a) (mRNA-3745) and Crigler-Najjar Syndrome Type 1 (CN-1) (mRNA-3351). We have an ongoing Phase 1 clinical trials for PA (mRNA-3927) and MMA (mRNA-3705). PKU (mRNA-3283), GSD1a (mRNA-3745) and CN-1 (mRNA-3351) are currently in preclinical development. The FDA has granted Orphan Drug Designation for mRNA-3745 and has completed its review of the IND application allowing it to proceed to clinic. We have entered into a collaboration agreement with the Institute for Life Changing Medicines (ILCM) to license mRNA-3351 to ILCM with no upfront fees, and without any downstream payments. ILCM will be responsible for the clinical development of mRNA-3351.

- **Inhaled pulmonary therapeutics:** We have one inhaled pulmonary therapeutic development candidate in our pipeline. Our program addresses cystic fibrosis, or CF (VXc-522), in collaboration partnership with Vertex Pharmaceuticals. VXc-522 is an mRNA therapeutic designed to treat the underlying cause of CF by enabling cells in the lungs to produce functional cystic fibrosis transmembrane conductance regulator (CFTR) protein for the treatment of the 10% of patients who do not produce any CFTR protein. IND-enabling studies are underway and Vertex expects to submit an IND for this program in 2022. Moderna has licensed worldwide commercial rights to VXc-522 to Vertex.

Financial Operations Overview

Revenue

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Revenue:				
Product sales	$ 4,810	$ —	$ 10,740	$ —
Grant revenue	140	145	473	187
Collaboration revenue	19	12	47	45
Total revenue	$ 4,969	$ 157	$ 11,260	$ 232

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 September 30, 2021, we recognized $4.8 billion of product sales from our COVID-19 vaccine, of which $1.2 billion was generated in the United States and $3.6 billion was generated from the rest of the world. For the nine months ended September 30, 2021, we recognized $10.7 billion of product sales from our COVID-19 vaccine, of which $4.6 billion was generated in the United States and $6.1 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 September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Grant revenue:				
BARDA [1]	$ 128	$ 143	$ 454	$ 183
Other	12	2	19	4
Total grant revenue	$ 140	$ 145	$ 473	$ 187

[1] For the three months ended September 30, 2021, $124 million of BARDA grant revenue was related to our mRNA-1273 program and $4 million was related to our Zika vaccine program. For the nine months ended September 30, 2021, $447 million of BARDA grant revenue was related to our mRNA-1273 program and $7 million was related to our Zika vaccine program.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Collaboration revenue:				
AstraZeneca	$ 3	$ —	$ 7	$ 17
Merck	7	6	11	18
Vertex	5	6	23	10
Other	4	—	6	—
Total collaboration revenue	$ 19	$ 12	$ 47	$ 45

We expect our product sales to significantly increase in 2021 compared to 2020. As of September 30, 2021, we had signed supply agreements of approximately $25.1 billion for the future supply of our COVID-19 vaccine through 2023 and had deferred revenue of $8.3 billion associated with customer deposits received or billable under these agreements. Additional supply agreements have been agreed upon since September 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 September 30, 2021, the remaining available funding, net of revenue, earned under our agreement with BARDA for the development of our mRNA-1273 vaccine was $441 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 nine months ended September 30, 2021 and 2020 (in millions):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Program expenses by modality:				
Prophylactic vaccines	$ 271	$ 163	$ 760	$ 208
Cancer vaccines	11	8	35	24
Intratumoral immuno-oncology	6	4	19	7
Systemic secreted and cell surface therapeutics	3	1	5	2
Systemic intracellular therapeutics	6	2	17	15
Total program-specific expenses by modality [(1)]	297	178	836	256
Other research and development expenses:				
Discovery programs	15	16	43	37
Platform research	28	24	80	64
Technical development and unallocated manufacturing expenses	79	80	165	138
Shared discovery and development expenses	77	33	165	76
Stock-based compensation	25	13	54	40
Total research and development expenses	$ 521	$ 344	$ 1,343	$ 611

(1) Includes a total of 34 and 23 development candidates at September 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. Our newest modality, for inhaled pulmonary therapeutics, was added subsequent to the end of the third quarter of 2021.

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 potential development of 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 September 30, 2021, the remaining available funding, net of revenue earned was $441 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 September 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 September 30,		Change 2021 vs. 2020	
	2021	2020	$	%
Revenue:				
Product revenue	$ 4,810	$ —	$ 4,810	100%
Grant revenue	140	145	(5)	(3)%
Collaboration revenue	19	12	7	58%
Total revenue	4,969	157	4,812	3,065%
Operating Expenses:				
Cost of sales	722	—	722	100%
Research and development	521	344	177	51%
Selling, general and administrative	168	48	120	250%
Total operating expenses	1,411	392	1,019	260%
Income (loss) from operations	3,558	(235)	3,793	1,614%
Interest income	4	6	(2)	(33)%
Other expense, net	(10)	(3)	(7)	233%
Income (loss) before income taxes	3,552	(232)	3,784	1,631%
Provision for income taxes	219	1	218	21,800%
Net income (loss)	$ 3,333	$ (233)	$ 3,566	1,530%

	Nine Months Ended September 30,		Change 2021 vs. 2020	
	2021	2020	$	%
Revenue:				
Product revenue	$ 10,740	$ —	$ 10,740	100%
Grant revenue	473	187	286	153%
Collaboration revenue	47	45	2	4%
Total revenue	11,260	232	11,028	4,753%
Operating Expenses:				
Cost of sales	1,665	—	1,665	100%
Research and development	1,343	611	732	120%
Selling, general and administrative	366	109	257	236%
Total operating expenses	3,374	720	2,654	369%
Income (loss) from operations	7,886	(488)	8,374	1,716%
Interest income	11	21	(10)	(48)%
Other expense, net	(22)	(6)	(16)	267%
Income (loss) before income taxes	7,875	(473)	8,348	1,765%
Provision for income taxes	541	1	540	54,000%
Net income (loss)	$ 7,334	$ (474)	$ 7,808	1,647%

Revenue

Total revenue increased by $4.8 billion for the three months ended September 30, 2021, compared to the same period in 2020, due to increases in product sales. Product revenue was $4.8 billion for the three months ended September 30, 2021 from sales of our COVID-19 vaccine. For the three months ended September 30, 2021, we delivered approximately 73 million doses to the U.S. Government and approximately 136 million doses to other governments of our COVID-19 vaccine. We did not have product sales until December 2020.

Total revenue increased by $11.0 billion for the nine months ended September 30, 2021, compared to the same period in 2020, due to increases in product sales and grant revenue. Product revenue was $10.7 billion for the nine months ended September 30, 2021 from sales of our COVID-19 vaccine. For the nine months ended September 30, 2021, we delivered approximately 287 million doses to the U.S. Government and approximately 222 million doses to other governments. We did not have product sales until December 2020. Grant revenue increased by $286 million for the nine months ended September 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 $722 million, or 15%, of our product sales, for the three months ended September 30, 2021, including third-party royalties of $168 million. Our cost of sales was $1.7 billion, or 16%, of our product sales, for the nine months ended September 30, 2021, including third-party royalties of $400 million. A portion of the inventory costs associated with our product sales for the nine months ended September 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 nine months ended September 30, 2021 was valued at cost, our cost of sales for the period would have been $1.9 billion, or 17%, 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 remainder of 2021.

Research and development expenses

Research and development expenses increased by $177 million, or 51%, for the three months ended September 30, 2021, compared to the same period in 2020. The increase was primarily attributable to an increase in clinical trial expenses of $155 million and an increase in personnel-related costs of $40 million.

Research and development expenses increased by $732 million, or 120%, for the nine months ended September 30, 2021, compared to the same period in 2020. The increase was primarily attributable to an increase in clinical trial expenses of $591 million, an increase in personnel-related costs of $77 million, and an increase in consulting and outside services of $45 million.

These increases for both the three and nine 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 $120 million, or 250%, for the three months ended September 30, 2021, compared to the same period in 2020. The increase was mainly due to an increase in consulting and outside services of $30 million, an increase in distributor fees of $29 million, an increase in marketing expenses of $23 million, and an increase in personnel-related costs of $17 million.

Selling, general and administrative expenses increased by $257 million, or 236%, for the nine months ended September 30, 2021, compared to the same period in 2020. The increase was mainly due to an increase in consulting and outside services of $80 million, an increase in personnel-related costs of $48 million, an increase in marketing expenses of $41 million, and an increase in distributor fees of $32 million.

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

Interest income

Interest income decreased by $2 million, or 33%, for the three months ended September 30, 2021, compared to the same period in 2020. Interest income decreased by $10 million, or 48%, for the nine months ended September 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 nine 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 September 30,		Change 2021 vs. 2020	
	2021	2020	$	%
Interest expense	(4)	$ (2)	(2)	100%
Other expense, net	(6)	(1)	(5)	500%
Total other expense, net	$ (10)	$ (3)	$ (7)	233%

	Nine Months Ended September 30,		Change 2021 vs. 2020	
	2021	2020	$	%
Gain on investments	$ 2	$ 1	$ 1	100%
Interest expense	(12)	$ (6)	(6)	100%
Other expense, net	(12)	(1)	(11)	1,100%
Total other expense, net	$ (22)	$ (6)	$ (16)	267%

Total other expense, net was immaterial for each of the three months ended September 30, 2021 and 2020. Total other expense, net increased by $16 million, or 267%, for the nine months ended September 30, 2021, compared to the same period in 2020. The increase in other expense, net for the nine-month period in 2021 was primarily due to losses related to our balance sheet hedging activities, partially offset by gains on foreign currency transactions and remeasurements. Our interest expense is primarily related to our finance leases.

Income taxes

Our provision for income taxes for the three and nine months ended September 30, 2021 was $219 million and $541 million, respectively, compared to $1 million for each of the same periods in 2020. Our effective tax rate for the three and nine months ended September 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 and other deferred tax assets, the benefit of the foreign derived intangible income deduction, as well as a discrete item for excess tax benefits related to stock-based compensation. Our effective tax rate for the three and nine months ended September 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 September 30, 2021, we continue to maintain a valuation allowance on certain state tax attributes.

Liquidity and capital resources

As of September 30, 2021, we had cash, cash equivalents and investments of $15.3 billion. Cash, cash equivalents and investments are invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation. Investments, consisting primarily of government and corporate debt securities, are stated at fair value. As of September 30, 2021, we had current and non-current investments of approximately $3.4 billion and $6.4 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 September 30, 2021, we had $8.3 billion in deferred revenue related to customer deposits received or billable. In addition, as of September 30, 2021, BARDA has committed to fund up to $1.4 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 September 30, 2021, the remaining available funding from BARDA, net of revenue earned, was $441 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):

	Nine Months Ended September 30,	
	2021	2020
Net cash provided by (used in):		
Operating activities	$ 10,310	$ 763
Investing activities	(7,385)	(1,482)
Financing activities	—	1,989
Net increase in cash, cash equivalents and restricted cash	$ 2,925	$ 1,270

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.

Net cash provided by operating activities for the nine months ended September 30, 2021 was $10.3 billion and consisted of net income of $7.3 billion and non-cash adjustments of $203 million, plus a net change in assets and liabilities of $2.8 billion. Non-cash items included depreciation and amortization of $154 million, stock-based compensation of $105 million, deferred income taxes of $89 million, and amortization of investment premium and discount of $33 million. The net change in assets and liabilities was mainly due to an increase in deferred revenue of $4.4 billion, an increase in accrued liabilities of $600 million, an increase in income taxes payable of $565 million, and an increase in accounts payable of $26 million, partially offset by an increase in accounts receivable of $1.8 billion, an increase in inventory of $918 million, an increase in prepaid expenses and other assets of $186 million, and an increase in operating lease right-of-use assets of $25 million.

Net cash provided by operating activities for the nine months ended September 30, 2020 was $763 million and consisted of net loss of $474 million and non-cash adjustments of $96 million, plus a net change in assets and liabilities of $1.1 billion. Non-cash items primarily included stock-based compensation of $67 million, depreciation and amortization of $24 million, and amortization of investment premium and discount of $5 million. The net change in assets and liabilities was mainly due to an increase in deferred revenue of $1.2 billion and an increase in accrued liabilities of $132 million, partially offset by an increase in accounts receivable of $185 million.

Investing activities

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

Net cash used in investing activities for the nine months ended September 30, 2021 was $7.4 billion, which included purchases of marketable securities of $10.3 billion and purchases of property and equipment of $164 million, partially offset by proceeds from sales of marketable securities of $2.0 billion and proceeds from maturities of marketable securities of $1.1 billion.

Net cash used in investing activities for the nine months ended September 30, 2020 was $1.5 billion, which included purchases of marketable securities of $2.3 billion and purchases of property and equipment of $44 million, partially offset by proceeds from maturities of marketable securities of $748 million and proceeds from sales of marketable securities of $140 million.

Financing activities

There was no net cash provided by financing activities for the nine months ended September 30, 2021.

Net cash provided by financing activities for the nine months ended September 30, 2020 was $2.0 billion, 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 $136 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 nine months of 2021 in connection with our product sales. We have retained earnings of $5.1 billion as of September 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 September 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 September 30, 2021, other than disclosed within 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 September 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 September 30, 2021 and December 31, 2020, we had cash, cash equivalents, and investments in marketable securities of $15.3 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 September 30, 2021, the net fair value of our marketable securities would decrease by approximately $144 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 September 30, 2021, carried at fair value, had maturities of up to 12 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 September 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 September 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 $138 million. As of September 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 $28 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 September 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 (the Exchange Act) means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of September 30, 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 September 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 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 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. P00012, P00013, P00014, P00015, P00016 and P00017 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 No. 10 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:
November 4, 2021

By: /s/ Stéphane Bancel

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

Date:
November 4, 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 (i) is not material and (ii) is the type of information that the registrant treats as private or confidential.

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE	PAGE OF PAGES
	1 2

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

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

8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code)		9A. AMENDMENT OF SOLICIT AT ION 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 must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended by one of the following methods:
(a) By completing Items 8 and 15, and returning copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required)

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

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

15A. 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	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
/s/ Stephane Bancel (Signature of person authorized to sign)	7/20/2021	BY [***] (Signature of Contracting Officer)	07/20/2021

EXCEPTION TO SF 30
APPROVED BY OIRM 11-84

30-105-04

STANDARD FORM 30 (Rev. 10-83)
Prescribed by GSA
FAR (48 CFR) 53.243

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

SUMMARY OF CHANGES

SECTION 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)

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE	PAGE OF PAGES
	1 | 14

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO.(If applicable)
P00013	30 Jul 2021	SEE SCHEDULE	

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

8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code)		
MODERNA US, INC. [***] 200 TECHNOLOGY SQ CAMBRIDGE MA 02139-3578		9A. AMENDMENT OF SOLICITATION NO.
		9B. DATED (SEE ITEM 11)
	X	10A. MOD. OF CONTRACT/ORDER NO. W911QY20C0100
		10B. DATED (SEE ITEM 13)
CODE 8PTM0 FACILITY CODE	X	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 must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended by one of the following methods:
(a) By completing Items 8 and 15, and returning copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN
REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required)

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

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

15A. NAME AND TITLE OF SIGNER (Type or print)	16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)
Stephane Bancel, CEO	[***] TEL: [***] EMAIL: [***]

15 . CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
/s/ Stephane Bancel (Signature of person authorized to sign)	07/30/2021	BY [***] (Signature of Contracting Officer)	07/30/2021

EXCEPTION TO SF 30
APPROVED BY OIRM 11-84

30-105-04

STANDARD FORM 30 (Rev. 10-83)
Prescribed by GSA
FAR (48 CFR)

53.243

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

SUMMARY OF CHANGES

SECTION SF 30 - BLOCK 14 CONTINUATION PAGE

The following have been added by full text: P00013
OBLIGATION AMOUNT: $0.00

a. The purpose of this modification (P00013) is to:

- Update the Performance Base Payment Table in Section G and the associated Attachment 0008, Performance Base Payment Milestone Billing Plan (Authority FAR 52.232-16)

- Update H.1 Key Personnel (Authority FAR 43.103(a)(3), Mutual Agreement of the Parties)

- Update H.19 Product [***] to reflect a change on the notification of product date for deliveries in September 2021 through December 2021 (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 7 business days (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.

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:
[***]
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 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
[***]	[***]	$[***]	
[***]	[***]	$[***]	
[***]	[***]	$[***]	
	TOTAL		$[***]
[***]	[***]	$[***]	
[***]	[***]	$[***]	
[***]	[***]	$[***]	
	TOTAL		$[***]

[***]	[***]	$[***]	
[***]	[***]	$[***]	
[***]	[***]	$[***]	
[***]	[***]	$[***]	
	TOTAL		$[***]
[***]	[***]	$[***]	
[***]	[***]	$[***]	
[***]	[***]	$[***]	
[***]	[***]	$[***]	
	TOTAL		$[***]

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 manner which states or implies DoD approval or endorsement of the product(s) or service(s) provided.

d. The contractor shall include this clause, including this section (d) in all subcontracts where the subcontractor may propose publishing the results of its work under the subcontract. The contractor shall acknowledge the support of the Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority whenever publicizing the work under this contract in any media by including an acknowledgement substantially as follows:

"This project has been funded in whole or in part with Federal funds from the Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority, under Contract Number W911QY-20-C-0100."

H.5 Confidentiality of Information

a. Confidential information, as used in this article, means non-public information or data of a personal nature about an individual, or proprietary information or data submitted by or pertaining to an institution or organization.

b. The Contracting Officer and the Contractor may, by mutual consent, identify elsewhere in this contract specific information and/or categories of information which the Government will furnish to the Contractor or that the Contractor is expected to generate which is confidential. Similarly, the Contracting Officer and the Contractor may, by mutual consent, identify such confidential information from time to time during the performance of the contract. Failure to agree will be settled pursuant to the "Disputes" clause.

c. If it is established elsewhere in this contract that information to be utilized under this contract, or a portion thereof, is subject to the Privacy Act, the Contractor will follow the rules and procedures of disclosure set forth in the Privacy Act of 1974, 5 U.S.C. 552a, and implementing regulations and policies, with respect to systems of records determined to be subject to the Privacy Act.

d. Confidential information, as defined in paragraph (a) of this article, shall not be disclosed without the prior written consent of the individual, institution, or organization.

e. Whenever the Contractor is uncertain with regard to the proper handling of material under the contract, or if the material in question is subject to the Privacy Act or is confidential information subject to the provisions of this article, the Contractor shall obtain a written determination from the Contracting Officer prior to any release, disclosure, dissemination, or publication.

f. Contracting Officer Determinations will reflect the result of internal coordination with appropriate program and legal officials.

g. The provisions of paragraph (d) of this article shall not apply to conflicting or overlapping provisions in other Federal, State or local laws.

ALL REQUIREMENTS OF THIS SECTION H.5 MUST BE PASSED TO ALL SUB-CONTRACTOR.

H.6 Regulatory Rights

This contract involves supply of a product that requires FDA pre-market approval or clearance before commercial authorization. Contractor is seeking FDA authorization or clearance for the commercialization of mRNA-1273, Moderna vaccine for SARS-CoV-2 Coronavirus (the "Technology"). The Contractor is the Sponsor of the Regulatory Application (an investigational new drug application (IND), investigational device exemption (IDE), emergency use authorization (EUA), new drug application (NDA), biologics license application (BLA), premarket approval application (PMA), or 510(k) pre-market notification filing (510(k)) or another regulatory filing submitted to FDA) for the technology. As the Sponsor of the Regulatory Application to FDA (as the terms "sponsor" and "applicant" are defined or used in at 21 CFR §§3.2(c), 312.5, 600.3(t), 812.2(b), 812 Subpart C, or 814.20), the Contractor has certain standing before the FDA that entitles it to exclusive communications related to the Regulatory Application.

Accordingly, the Contractor and the Government agree to the following:

a. DoD Medical Product Priority. PL 115-92 allows the DoD to request, and FDA to provide, assistance to expedite development of products to diagnose, treat, or prevent serious or life-threatening diseases or conditions facing American military personnel. The contractor recognizes that only the DoD can utilize PL 115-92. As such, the

contractor will work proactively with the Government to leverage this law to its maximum potential under this contract. The contractor shall submit Public Law 115-92 Sponsor Authorization Letter that will be delivered to the designated OWS POC(s) within [***] 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 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 Ensuring Sufficient Supply of the Product

1. In recognition of the Government's significant funding for the development and manufacturing of the product in this contract and the Government's need to provide sufficient quantities of a COVID-19 vaccine to protect the United States population, the Government shall have the remedy described in this section to ensure sufficient supply of the product to meet the needs of the public health or national security. This remedy is not available to the Government unless and until both of the following conditions ((a) and (b)) are met:

a. Moderna gives written notice, required to be submitted to the Government [***], of:

(i) any formal management decision to terminate manufacturing of this product vaccine prior to delivery of any doses to USG under this contract, including all exercised options, other than as a result of clinical failure, or serious technical or safety reasons or;

(ii) any formal management decision to discontinue sale of this product vaccine to the Government prior to delivery of any doses to USG under this contract, including all exercised options, other than as a result of clinical failure, or serious technical or safety reasons; or

(iii) any filing that anticipates Federal bankruptcy protection; and

b. Moderna has submitted an Emergency Use Authorization application under §564 of the FD&C Act or a biologics license application provisions of §351(a) of the Public Health Service Act (PHSA).

2. If both conditions listed in section 1 occur, Moderna, upon the request of the Government, shall provide the following items necessary for the Government to pursue manufacturing of this product vaccine with a third party for exclusive sale to the U.S. Government:

a. a writing evidencing a non-exclusive, nontransferable, irrevocable (except for cause), royalty-free paid-up license to practice or have practiced for or on behalf of the U.S. Government any Moderna Background Patent, Copyright, other Moderna Intellectual Property, Moderna Know-How, Moderna Technical Data rights necessary to manufacture doses of the mRNA-1273 vaccine;

b. necessary FDA regulatory filings or authorizations owned or controlled by Moderna related to this product vaccine and any confirmatory instrument pertaining thereto; and

c. any outstanding Deliverables contemplated or materials purchased under this contract.

3. This remedy will remain available until the end of the contract.

H.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 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 11Feb2021 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 a [***].

Both parties acknowledge that the delivery schedule is based on an [***] 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, 100µg, 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, [***]:

(i) [***];

(ii) [***];

(iii) [***]; and

(iv) [***].

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:

Document Type	Description	Page #	Date
Exhibit A	CDRLs	15	11 February 2021
Exhibit B	Donation of Excess Product	8	28 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	8 July 2021
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 12

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO.(If applicable)
P00014	8 Aug 2021	SEE SCHEDULE	

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

8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code)		
MODERNA US, INC. [***] 200 TECHNOLOGY SQ CAMBRIDGE MA 02139-3578		9A. AMENDMENT OF SOLICITATION NO.
		9B. DATED (SEE ITEM 11)
	X	10A. MOD. OF CONTRACT/ORDER NO. W911QY20C0100
	X	10B. DATED (SEE ITEM 13) 09-Aug-2020

CODE 8PTM0	FACILITY CODE

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

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

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

12. ACCOUNTING AND APPROPRIATION DATA (If required)

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

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

15A. 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	15C. DAT E SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
/s/ Stephane Bancel (Signature of person authorized to sign)	8/8/2021	BY [***] (Signature of Contracting Officer)	8/8/2021

EXCEPTION TO SF 30
APPROVED BY OIRM 11-84

30-105-04

STANDARD FORM 30 (Rev. 10-83)
Prescribed by GSA
FAR (48 CFR)
53.243

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

SUMMARY OF CHANGES

SECTION SF 30 - BLOCK 14 CONTINUATION PAGE

The following have been added by full text: P00014
OBLIGATION AMOUNT: $0.00

a. The purpose of this modification (P00014) is to:

- Update H.19 Product [***] to reflect a change on the notification of product date for deliveries in September 2021 through December 2021 (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.

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), biologics license application (BLA), premarket approval application (PMA), or 510(k) pre-market notification filing (510(k)) or another regulatory filing submitted to FDA) for the technology. As the Sponsor of the Regulatory Application to FDA (as the terms “sponsor” and “applicant” are defined or used in at 21 CFR §§3.2(c), 312.5, 600.3(t), 812.2(b), 812 Subpart C, or 814.20), the Contractor has certain standing before the FDA that entitles it to exclusive communications related to the Regulatory Application.

Accordingly, the Contractor and the Government agree to the following:

a. DoD Medical Product Priority. PL 115-92 allows the DoD to request, and FDA to provide, assistance to expedite development of products to diagnose, treat, or prevent serious or life-threatening diseases or conditions facing American military personnel. The contractor recognizes that only the DoD can utilize PL 115-92. As such, the contractor will work proactively with the Government to leverage this law to its maximum potential under this contract. The contractor shall submit Public Law 115-92 Sponsor Authorization Letter that will be delivered to the designated OWS POC(s) within [***] 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 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 Ensuring Sufficient Supply of the Product

1. In recognition of the Government's significant funding for the development and manufacturing of the product in this contract and the Government's need to provide sufficient quantities of a COVID-19 vaccine to protect the United States population, the Government shall have the remedy described in this section to ensure sufficient supply of the product to meet the needs of the public health or national security. This remedy is not available to the Government unless and until both of the following conditions ((a) and (b)) are met:

a. Moderna gives written notice, required to be submitted to the Government [***], of:

(i) any formal management decision to terminate manufacturing of this product vaccine prior to delivery of any doses to USG under this contract, including all exercised options, other than as a result of clinical failure, or serious technical or safety reasons or;

(ii) any formal management decision to discontinue sale of this product vaccine to the Government prior to delivery of any doses to USG under this contract, including all exercised options, other than as a result of clinical failure, or serious technical or safety reasons; or

(iii) any filing that anticipates Federal bankruptcy protection; and

b. Moderna has submitted an Emergency Use Authorization application under §564 of the FD&C Act or a biologics license application provisions of §351(a) of the Public Health Service Act (PHSA).

2. If both conditions listed in section 1 occur, Moderna, upon the request of the Government, shall provide the following items necessary for the Government to pursue manufacturing of this product vaccine with a third party for exclusive sale to the U.S. Government:

a. a writing evidencing a non-exclusive, nontransferable, irrevocable (except for cause), royalty-free paid-up license to practice or have practiced for or on behalf of the U.S. Government any Moderna Background Patent, Copyright, other Moderna Intellectual Property, Moderna Know-How, Moderna Technical Data rights necessary to manufacture doses of the mRNA-1273 vaccine;

b. necessary FDA regulatory filings or authorizations owned or controlled by Moderna related to this product vaccine and any confirmatory instrument pertaining thereto; and

c. any outstanding Deliverables contemplated or materials purchased under this contract.

3. This remedy will remain available until the end of the contract.

H.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 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 11Feb2021 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 a [***].

Both parties acknowledge that the delivery schedule is based on an [***] 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, 100µg, 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, [***]:

(i) [***];
(ii) [***];
(iii) [***]; and
(iv) [***]

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 [***].

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)

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE	PAGE OF PAGES
	1 12

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO.(If applicable)
P00015	12-Aug-2021	SEE SCHEDULE	

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

8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code)			
MODERNA US, INC. [***] 200 TECHNOLOGY SQ CAMBRIDGE MA 02139-3578			9A. AMENDMENT OF SOLICITATION NO.
			9B. DATED (SEE ITEM 11)
		X	10A. MOD. OF CONTRACT/ORDER NO. W911QY20C0100
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 must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended by one of the following methods: (a) By completing Items 8 and 15, and returning copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required)

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

	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.
	B. THE ABOVE NUMBERED CONTRACT /ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUT HORIT Y 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 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.

15A. NAME AND TITLE OF SIGNER (Type or print)		16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print) [***] TEL: [***] EMAIL: [***]	
15B. CONTRACTOR/OFFEROR (Signature of person authorized to sign)	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA BY [***] (Signature of Contracting Officer)	16C. DATE SIGNED 12-Aug-2021

EXCEPTION TO SF 30
APPROVED BY OIRM 11-84

30-105-04

ST ANDARD FORM 30 (Rev. 10-83)
Prescribed by GSA
FAR (48 CFR)
53.243

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: P00015
OBLIGATION AMOUNT: $0.00

a. The purpose of this modification (P00015) is to:

- Update delivery notification table in H.19 (Authority Special Contract Requirements H.19)

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.

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), biologics license application (BLA), premarket approval application (PMA), or 510(k) pre-market notification filing (510(k)) or another regulatory filing submitted to FDA) for the technology. As the Sponsor of the Regulatory Application to FDA (as the terms “sponsor” and “applicant” are defined or used in at 21 CFR §§3.2(c), 312.5, 600.3(t), 812.2(b), 812 Subpart C, or 814.20), the Contractor has certain standing before the FDA that entitles it to exclusive communications related to the Regulatory Application.

Accordingly, the Contractor and the Government agree to the following:

a. DoD Medical Product Priority. PL 115-92 allows the DoD to request, and FDA to provide, assistance to expedite development of products to diagnose, treat, or prevent serious or life-threatening diseases or conditions facing American military personnel. The contractor recognizes that only the DoD can utilize PL 115-92. As such, the contractor will work proactively with the Government to leverage this law to its maximum potential under this contract. The contractor shall submit Public Law 115-92 Sponsor Authorization Letter that will be delivered to the designated OWS POC(s) within [***] of award.

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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).

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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 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.

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a. Moderna gives written notice, required to be submitted to the Government [***], of:

(i) any formal management decision to terminate manufacturing of this product vaccine prior to delivery of any doses to USG under this contract, including all exercised options, other than as a result of clinical failure, or serious technical or safety reasons or;

(ii) any formal management decision to discontinue sale of this product vaccine to the Government prior to delivery of any doses to USG under this contract, including all exercised options, other than as a result of clinical failure, or serious technical or safety reasons; or

(iii) any filing that anticipates Federal bankruptcy protection; and

b. Moderna has submitted an Emergency Use Authorization application under §564 of the FD&C Act or a biologics license application provisions of §351(a) of the Public Health Service Act (PHSA).

2. If both conditions listed in section 1 occur, Moderna, upon the request of the Government, shall provide the following items necessary for the Government to pursue manufacturing of this product vaccine with a third party for exclusive sale to the U.S. Government:

a. a writing evidencing a non-exclusive, nontransferable, irrevocable (except for cause), royalty-free paid-up license to practice or have practiced for or on behalf of the U.S. Government any Moderna Background Patent, Copyright, other Moderna Intellectual Property, Moderna Know-How, Moderna Technical Data rights necessary to manufacture doses of the mRNA-1273 vaccine;

b. necessary FDA regulatory filings or authorizations owned or controlled by Moderna related to this product vaccine and any confirmatory instrument pertaining thereto; and

c. any outstanding Deliverables contemplated or materials purchased under this contract.

3. This remedy will remain available until the end of the contract.

H.11 [***].

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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 11Feb2021 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 a [***].

Both parties acknowledge that the delivery schedule is based on an [***] 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, 100µg, 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, [***]:

(i) [***];
(ii) [***];
(iii)[***]; and
(iv)[***].

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)

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE	PAGE OF PAGES
	1 | 4

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO.(If applicable)
P00016	14-Sep-2021	SEE SCHEDULE	

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

8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code)			
MODERNA US, INC. [***] 200 TECHNOLOGY SQ CAMBRIDGE MA 02139-3578			9A. AMENDMENT OF SOLICITATION NO.
			9B. DATED (SEE ITEM 11)
		X	10A. MOD. OF CONTRACT/ORDER NO. W911QY20C0100
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 must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended by one of the following methods:
(a) By completing Items 8 and 15, and returning copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN
REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required)

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

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

15A. NAME AND TITLE OF SIGNER (Type or print)		16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)	
Shaun Ryan, SVP & Deputy General Counsel		[***] TEL: [***] EMAIL: [***]	
15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
/s/ Shaun Ryan (Signature of person authorized to sign)	9-12-2021	BY [***] (Signature of Contracting Officer)	14-Sep-2021

EXCEPTION TO SF 30
APPROVED BY OIRM 11-84

30-105-04

STANDARD FORM 30 (Rev. 10-83)
Prescribed by GSA
FAR (48 CFR)
53.243

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

SUMMARY OF CHANGES

SECTION SF 30 - BLOCK 14 CONTINUATION PAGE

The following have been added by full text: P00016
OBLIGATION AMOUNT: $0.00

a. The purpose of this modification (P00016) is to:

– Revise the PBP table in Section G and Attachment 0008 due to an administrative error on modification no. P00013 (Authority FAR 52.232.16)

– Update Exhibit B as outlined in clause H.20 with donation information for multiple recipients identified within the past 7 business days (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.

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:
[***]
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 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
[***]	[***]	$[***]	
[***]	[***]	$[***]	
[***]	[***]	$[***]	
	TOTAL		$[***]
[***]	[***]	$[***]	
[***]	[***]	$[***]	
[***]	[***]	$[***]	
	TOTAL		$[***]
[***]	[***]	$[***]	
[***]	[***]	$[***]	
[***]	[***]	$[***]	
[***]	[***]	$[***]	
	TOTAL		$[***]
[***]	[***]	$[***]	

[***]	[***]	$[***]
[***]	[***]	$[***]
[***]	[***]	$[***]
TOTAL		$[***]

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 J - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

The following have been modified:

Document Type	Description	Page #	Date
Exhibit A	CDRLs	15	11 February 2021
Exhibit B	Donation of Excess Product	10	3 September 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	3 September 2021
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
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2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO.(If applicable)
P00017	30-Sep-2021	SEE SCHEDULE	

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

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

12. ACCOUNTING AND APPROPRIATION DATA (If required)

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

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

15A. NAME AND TITLE OF SIGNER (Type or print)		16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print) [***] TEL: [***] EMAIL: [***]	
15B. CONTRACTOR/OFFEROR (Signature of person authorized to sign)	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA BY [***] (Signature of Contracting Officer)	16C. DATE SIGNED 30-Sep-2021

EXCEPTION TO SF 30
APPROVED BY OIRM 11-84

30-105-04

STANDARD FORM 30 (Rev. 10-83)
Prescribed by GSA
FAR (48 CFR)
53.243

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

SUMMARY OF CHANGES

SECTION SF 30 - BLOCK 14 CONTINUATION PAGE

The following have been added by full text: P00017

OBLIGATION AMOUNT: $0.00
a. The purpose of this modification (P00017) is to indicate January 2022 product [***] for delivery in accordance with Clause H.19.
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.

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), biologics license application (BLA), premarket approval application (PMA), or 510(k) pre-market notification filing (510(k)) or another regulatory filing submitted to FDA) for the technology. As the Sponsor of the Regulatory Application to FDA (as the terms “sponsor” and “applicant” are defined or used in at 21 CFR §§3.2(c), 312.5, 600.3(t), 812.2(b), 812 Subpart C, or 814.20), the Contractor has certain standing before the FDA that entitles it to exclusive communications related to the Regulatory Application.

Accordingly, the Contractor and the Government agree to the following:

a. DoD Medical Product Priority. PL 115-92 allows the DoD to request, and FDA to provide, assistance to expedite development of products to diagnose, treat, or prevent serious or life-threatening diseases or conditions facing American military personnel. The contractor recognizes that only the DoD can utilize PL 115-92. As such, the contractor will work proactively with the Government to leverage this law to its maximum potential under this contract. The contractor shall submit Public Law 115-92 Sponsor Authorization Letter that will be delivered to the designated OWS POC(s) within [***] 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 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 Ensuring Sufficient Supply of the Product

1. In recognition of the Government's significant funding for the development and manufacturing of the product in this contract and the Government's need to provide sufficient quantities of a COVID-19 vaccine to protect the United States population, the Government shall have the remedy described in this section to ensure sufficient supply of the product to meet the needs of the public health or national security. This remedy is not available to the Government unless and until both of the following conditions ((a) and (b)) are met:

a. Moderna gives written notice, required to be submitted to the Government [***], of:

(i) any formal management decision to terminate manufacturing of this product vaccine prior to delivery of any doses to USG under this contract, including all exercised options, other than as a result of clinical failure, or serious technical or safety reasons or;

(ii) any formal management decision to discontinue sale of this product vaccine to the Government prior to delivery of any doses to USG under this contract, including all exercised options, other than as a result of clinical failure, or serious technical or safety reasons; or

(iii) any filing that anticipates Federal bankruptcy protection; and

b. Moderna has submitted an Emergency Use Authorization application under §564 of the FD&C Act or a biologics license application provisions of §351(a) of the Public Health Service Act (PHSA).

2. If both conditions listed in section 1 occur, Moderna, upon the request of the Government, shall provide the following items necessary for the Government to pursue manufacturing of this product vaccine with a third party for exclusive sale to the U.S. Government:

a. a writing evidencing a non-exclusive, nontransferable, irrevocable (except for cause), royalty-free paid-up license to practice or have practiced for or on behalf of the U.S. Government any Moderna Background Patent, Copyright, other Moderna Intellectual Property, Moderna Know-How, Moderna Technical Data rights necessary to manufacture doses of the mRNA-1273 vaccine;

b. necessary FDA regulatory filings or authorizations owned or controlled by Moderna related to this product vaccine and any confirmatory instrument pertaining thereto; and

c. any outstanding Deliverables contemplated or materials purchased under this contract.

3. This remedy will remain available until the end of the contract.

H.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 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 11Feb2021 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 a [***].

Both parties acknowledge that the delivery schedule is based on an [***] 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, 100µg, 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, [***]:

(i) [***];
(ii) [***];
(iii)[***]; and
(iv)[***].

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)

Certain confidential portions of this exhibit have been omitted and replaced with "[***]." Such identified information has been excluded from this exhibit because it (i) is not material and (ii) is the type of information that the registrant treats as private or confidential.

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE | PAGE OF PAGES: 1 5

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO.(If applicable)
P00010	See Block 16C		

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 SQ
CAMBRIDGE MA 02139-3578

CODE 1492235 FACILITY CODE

X 9A. AMENDMENT OF SOLICITATION NO.

9B. DATED (SEE ITEM 11)

X 10A. MOD. OF CONTRACT/ORDER NO. 75A50120C00034

10B. DATED (SEE ITEM 13) 04/03/2020

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of 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.

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 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 D. OTHER (Specify type of modification and authority)
FAR 43.103(a)

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

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

Tax ID Number: 27-0226313
DUNS Number: 069723520
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 rescind the Defense Priority and Allocations System (DPAS) rating on contract # 75A50120C00034 effective the date of the letter dated July 13, 2021. The DPAS priority rating was added with modification P00004. In addition, Section H.3 Key Personnel, has been updated.

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

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)

Shaun Ryan, SVP & Deputy General Counsel

15B. CONTRACTOR/OFFEROR
/s/ Shaun Ryan
(Signature of person authorized to sign)

15C. DATE SIGNED
09/07/2021

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

[***]

16B. UNITED STATES OF AMERICA
[***]
(Signature of Contracting Officer)

16C. DATE SIGNED

Previous edition unusable

STANDARD FORM 30 (REV. 11/2016)
Prescribed by GSA FAR (48 CFR) 53.243

CONTINUATION PAGE

The purpose of this modification is to rescind the Defense Priority and Allocations System (DPAS) rating on contract # 75A50120C00034 effective the date of the letter dated July 13, 2021. The DPAS priority rating was added in modification P00004. In addition, Section H.3 Key Personnel, has been updated.

B.4 Advanced Understandings

~~**B.4.14 DPAS PRIORITY RATING**~~

~~This is a **DO rated order** for the purpose of emergency preparedness and the Contractor shall follow all the provisions of the Defense Priorities and Allocations System regulation (15 CFR Part700). If the contractor needs to utilize industrial resources to fulfill this rated order for capacity and industrial expansion, it is authorized pursuant to 15 CFR §700.16(b) to place the same priority rating and program identification symbol on its orders for industrial resources with its suppliers.~~

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

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

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

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

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

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

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

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

~~The Contractor agrees that the Government's right to exercise priorities and allocations authority with respect to this contract to include the use of directives constitutes a no-cost change to this contract. The written signature on a manually placed order, or the digital signature or name on an electronically placed order, of an individual authorized to sign rated orders for the person placing the order is provided. The signature, manual or digital, certifies that the rated contract is authorized under this regulation and that the requirements of this regulation are being followed. This language shall be added to the contract or task order by modification, if previously awarded.~~

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

~~The Parties agree that this modification includes the following documents:~~

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

DEPARTMENT OF HEALTH & HUMAN

Office of the

Assistant Secretary for Preparedness & Response Washington, D.C. 20201

July 13, 2021

[***]
[***]
Moderna Therapeutics, Inc.
200 Technology Square
Cambridge, MA 02139-3578
[***]

Subject: Rescission of DPAS rating on HHS Contract 75A50120C00034 Dear [***],

This letter is to notify you that the U.S. Department of Health and Human Services has rescinded the Defense Priority and Allocations System (DPAS) rating for the subject agreement, as of the date of this letter. Any materials or consumables acquired with this priority rating must still be used on this, or at the direction of the Contracting Officer, another US Government agreement before being used for any other purpose. Please note that a bilateral modification to remove the subject rating from the agreements will be forthcoming from the contracting officer.

Please notify any suppliers with whom Moderna has placed rated orders of this rescission as soon as possible and confirm with [***] the notifications have been sent. Please feel free to reach out to [***] if you have any questions.

Sincerely,

/s/ [***]

[***]
[***]

H.3 Key Personnel

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

Table with detail provided.

mRNA vaccine Project Team	Name	Title
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]

Updated Key Personnel

mRNA vaccine Project Team	Name	Title
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]

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: November 4, 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: November 4, 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 September 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: November 4, 2021

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

Date: November 4, 2021

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