

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549
FORM 10-Q

(Mark One)

- ☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the quarterly period ended June 30, 2022
- 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 (IRS Employer
Organization) Identification No.)

200 Technology Square
Cambridge, Massachusetts 02139
(Address of Principal Executive Offices) (Zip Code)

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

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

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

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

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

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

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

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

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

As of July 29, 2022, there were 391,199,544 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) contains express or implied forward-looking statements. All statements other than those of historical facts contained in this Form 10-Q are based on our management's beliefs and assumptions and on information currently available to our management. 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), demand for COVID-19 vaccines, and third-party and governmental arrangements and potential arrangements;
 - our ability to contract with third-party suppliers, distributors 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 candidates, 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;
 - costs associated with the ramping up of manufacturing for our products, including our COVID-19 vaccine, both internal and external, as well as costs associated with winding down or terminating relationships or agreements with third-party manufacturers or suppliers in connection with the production of our COVID-19 vaccine;
 - 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 commercialize our products, if approved;
 - the pricing and reimbursement of our 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 that are or may become available;
- our ability to attract and retain key scientific or management personnel; and
- developments relating to our competitors and our industry.

Forward-looking statements often contain words 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. Although we believe that the expectations reflected in these forward-looking statements are reasonable, these statements relate to future events or our operational or financial performance, and involve risks, uncertainties, and other factors that may cause our actual results to differ materially from any future results expressed or implied by these forward-looking statements. Accordingly, you should not place undue reliance on these forward-looking statements. 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 results could differ materially from those expressed or implied by the forward-looking statements.

The forward-looking statements in this Form 10-Q represent our views as of the date of this Form 10-Q. We undertake no obligation to update any forward-looking statements, except as required by applicable securities 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. However, any further disclosures made on related subjects in our subsequent reports filed with the Securities and Exchange Commission should be consulted.

TRADEMARKS

This Form 10-Q contains references to our trademarks and to trademarks belonging to other entities. Solely for convenience, trademarks and trade names referred to may appear without the ® or ™ symbols, but such references are not intended to indicate that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto. We do not intend our reference to other companies’ trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

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, corporate blog and social media channels shall not be deemed incorporated into, or be a part of, this Form 10-Q.

Table of Contents

PART I.		Page
Item 1.	<u>Financial Statements (Unaudited)</u>	<u>5</u>
	<u>Condensed Consolidated Balance Sheets as of June 30, 2022 and December 31, 2021</u>	<u>5</u>
	<u>Condensed Consolidated Statements of Income for the three and six months ended June 30, 2022 and 2021</u>	<u>6</u>
	<u>Condensed Consolidated Statements of Comprehensive Income for the three and six months ended June 30, 2022 and 2021</u>	<u>7</u>
	<u>Condensed Consolidated Statements of Stockholders' Equity for the three and six months ended June 30, 2022 and 2021</u>	<u>9</u>
	<u>Condensed Consolidated Statements of Cash Flows for the six months ended June 30, 2022 and 2021</u>	<u>10</u>
	<u>Notes to Condensed Consolidated Financial Statements</u>	<u>11</u>
Item 2.	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	<u>29</u>
Item 3.	<u>Quantitative and Qualitative Disclosures about Market Risk</u>	<u>43</u>
Item 4.	<u>Controls and Procedures</u>	<u>43</u>
PART II.		
Item 1.	<u>Legal Proceedings</u>	<u>44</u>
Item 1A.	<u>Risk Factors</u>	<u>44</u>
Item 2.	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	<u>45</u>
Item 6.	<u>Exhibits</u>	<u>45</u>
SIGNATURES		<u>47</u>

Item 1. Financial Statements

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

	June 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	\$ 2,873	\$ 6,848
Investments	5,024	3,879
Accounts receivable	2,691	3,175
Inventory	1,921	1,441
Prepaid expenses and other current assets	1,054	728
Total current assets	13,563	16,071
Investments, non-current	10,162	6,843
Property and equipment, net	1,324	1,241
Right-of-use assets, operating leases	122	142
Restricted cash, non-current	12	12
Deferred tax assets	785	326
Other non-current assets	75	34
Total assets	\$ 26,043	\$ 24,669
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 181	\$ 302
Accrued liabilities	1,780	1,472
Deferred revenue	4,093	6,253
Income taxes payable	349	876
Other current liabilities	409	225
Total current liabilities	6,812	9,128
Deferred revenue, non-current	405	615
Operating lease liabilities, non-current	87	106
Financing lease liabilities, non-current	641	599
Other non-current liabilities	113	76
Total liabilities	8,058	10,524
Commitments and contingencies (Note 12)		
Stockholders' equity:		
Preferred stock, par value \$0.0001; 162 shares authorized as of June 30, 2022 and December 31, 2021; no shares issued or outstanding at June 30, 2022 and December 31, 2021	—	—
Common stock, par value \$0.0001; 1,600 shares authorized as of June 30, 2022 and December 31, 2021; 392 and 403 shares issued and outstanding as of June 30, 2022 and December 31, 2021, respectively	—	—
Additional paid-in capital	2,413	4,211
Accumulated other comprehensive loss	(240)	(24)
Retained earnings	15,812	9,958
Total stockholders' equity	17,985	14,145
Total liabilities and stockholders' equity	\$ 26,043	\$ 24,669

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Revenue:				
Product sales	\$ 4,531	\$ 4,197	\$ 10,456	\$ 5,930
Grant revenue	183	139	309	333
Collaboration revenue	35	18	50	28
Total revenue	4,749	4,354	10,815	6,291
Operating expenses:				
Cost of sales	1,381	750	2,398	943
Research and development	710	421	1,264	822
Selling, general and administrative	211	121	479	198
Total operating expenses	2,302	1,292	4,141	1,963
Income from operations	2,447	3,062	6,674	4,328
Interest income	40	3	55	7
Other expense, net	(13)	(2)	(26)	(12)
Income before income taxes	2,474	3,063	6,703	4,323
Provision for income taxes	277	283	849	322
Net income	\$ 2,197	\$ 2,780	\$ 5,854	\$ 4,001
Earnings per share:				
Basic	\$ 5.55	\$ 6.93	\$ 14.66	\$ 9.98
Diluted	\$ 5.24	\$ 6.46	\$ 13.85	\$ 9.30
Weighted average common shares used in calculation of earnings per share:				
Basic	396	402	399	401
Diluted	419	431	423	430

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Net income	\$ 2,197	\$ 2,780	\$ 5,854	\$ 4,001
Other comprehensive (loss) income, net of tax:				
Available-for-sales securities:				
Unrealized losses on available-for-sale debt securities	(80)	(5)	(258)	(7)
Less: net realized losses (gains) on available-for-sale securities reclassified in net income	8	(1)	15	(1)
Net decrease from available-for-sale debt securities	(72)	(6)	(243)	(8)
Cash flow hedges:				
Unrealized gains on derivative instruments	46	21	71	21
Less: net realized (gains) on derivative instruments reclassified in net income	(30)	—	(44)	—
Net increase from derivatives designated as hedging instruments	16	21	27	21
Total other comprehensive (loss) income	(56)	15	(216)	13
Comprehensive income	\$ 2,141	\$ 2,795	\$ 5,638	\$ 4,014

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

MODERNA, INC.
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
FOR THE THREE MONTHS AND SIX MONTHS ENDED JUNE 30, 2022 AND 2021
(Unaudited, in millions)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Retained Earnings	Total Stockholders' Equity
	Shares	Amount				
Balance at March 31, 2022	400	\$ —	\$ 3,644	\$ (184)	\$ 13,615	\$ 17,075
Exercise of options to purchase common stock	1	—	8	—	—	8
Purchase of common stock under employee stock purchase plan	—	—	9	—	—	9
Stock-based compensation	—	—	50	—	—	50
Other comprehensive loss, net of tax	—	—	—	(56)	—	(56)
Repurchase of common stock	(9)	—	(1,298)	—	—	(1,298)
Net income	—	—	—	—	2,197	2,197
Balance at June 30, 2022	392	\$ —	\$ 2,413	\$ (240)	\$ 15,812	\$ 17,985

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

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Retained Earnings	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2021	403	\$ —	\$ 4,211	\$ (24)	\$ 9,958	\$ 14,145
Exercise of options to purchase common stock	2	—	20	—	—	20
Purchase of common stock under employee stock purchase plan	—	—	9	—	—	9
Stock-based compensation	—	—	94	—	—	94
Other comprehensive loss, net of tax	—	—	—	(216)	—	(216)
Repurchase of common stock	(13)	—	(1,921)	—	—	(1,921)
Net income	—	—	—	—	5,854	5,854
Balance at June 30, 2022	392	\$ —	\$ 2,413	\$ (240)	\$ 15,812	\$ 17,985

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

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

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

	Six Months Ended June 30,	
	2022	2021
Operating activities		
Net income	\$ 5,854	\$ 4,001
Adjustments to reconcile net income to net cash provided by operating activities:		
Stock-based compensation	94	65
Depreciation and amortization	155	84
Amortization/accretion of investments	29	13
Deferred income taxes	(376)	(72)
Other non-cash items	15	—
Changes in assets and liabilities:		
Accounts receivable	484	(629)
Prepaid expenses and other assets	(324)	(110)
Inventory	(480)	(596)
Right-of-use assets, operating leases	20	(14)
Accounts payable	(56)	44
Accrued liabilities	305	367
Deferred revenue	(2,370)	3,433
Income taxes payable	(527)	377
Operating lease liabilities	(19)	8
Other liabilities	263	63
Net cash provided by operating activities	3,067	7,034
Investing activities		
Purchases of marketable securities	(8,734)	(6,559)
Proceeds from maturities of marketable securities	1,409	860
Proceeds from sales of marketable securities	2,506	1,706
Purchases of property and equipment	(219)	(65)
Investment in convertible notes	(35)	—
Net cash used in investing activities	(5,073)	(4,058)
Financing activities		
Proceeds from issuance of common stock through equity plans	29	64
Repurchase of common stock	(1,921)	—
Changes in financing lease liabilities	(77)	(62)
Net cash (used in) provided by financing activities	(1,969)	2
Net (decrease) increase in cash, cash equivalents and restricted cash	(3,975)	2,978
Cash, cash equivalents and restricted cash, beginning of year	6,860	2,636
Cash, cash equivalents and restricted cash, end of period	\$ 2,885	\$ 5,614
Non-cash investing and financing activities		
Purchases of property and equipment included in accounts payable and accrued liabilities	\$ 49	\$ 45
Right-of-use assets obtained through finance lease modifications and reassessments	\$ —	\$ 363
Right-of-use assets obtained in exchange for financing lease liabilities	\$ 94	\$ 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) is a biotechnology company pioneering messenger RNA (mRNA) therapeutics and vaccines to create a new generation of transformative medicines to improve the lives of patients. Our platform builds on continuous advances in basic and applied mRNA science, delivery technology, and manufacturing, providing us the capability to pursue in parallel a robust pipeline of new development candidates. We are developing therapeutics and vaccines for infectious diseases, immuno-oncology, rare diseases, autoimmune and cardiovascular diseases, independently and with our strategic collaborators.

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®) as a two-dose, 100 µg primary series in individuals 18 years of age or older. In January 2022, we received full commercial approval for Spikevax as a two-dose, 100 µg primary series to prevent COVID-19 in individuals 18 years of age and older in the United States, and Spikevax is approved or authorized in individuals 18 years and older in more than 80 countries. In addition, we have received authorization from the FDA and global regulators in more than 40 countries for our COVID-19 vaccine as a two-dose, 100 µg primary series in adolescents aged 12-17 years and as a two-dose, 50 µg primary series in children ages 6 through 11 years old. Additionally, a two-dose, 25 µg primary series of our COVID-19 vaccine is authorized in young children aged 6 months to 5 years old in the United States, Canada, Australia, and other jurisdictions.

The FDA, European Medicines Agency (EMA), Swissmedic and other health agencies around the world have authorized a booster dose of our COVID-19 vaccine at 50 µg dose level for adults ages 18 years and older. The FDA and other health agencies have also authorized a second booster dose at the 50 µg dose level for adults 50 years and older and adults 18 years of age and older with certain kinds of immunocompromise.

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, 2021 (2021 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 audited consolidated financial statements in our 2021 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 six months ended June 30, 2022 are consistent with those described in our 2021 Form 10-K. The results of operations for the three and six months ended June 30, 2022 are not necessarily indicative of the operating results to be expected for the full fiscal year or future operating periods.

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, income taxes, valuation allowance on deferred tax assets, leases, fair value of financial instruments, derivative financial instruments, inventory, firm purchase commitment liabilities, useful lives of property and equipment, research and development expenses, and stock-based compensation. The actual results that we experience may differ materially from our estimates.

Comprehensive Income

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

The components of accumulated other comprehensive loss for the three and six months ended June 30, 2022 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 loss, balance at December 31, 2021	\$ (40)	\$ 16	\$ (24)
Other comprehensive loss	(171)	11	(160)
Accumulated other comprehensive loss, balance at March 31, 2022	(211)	27	(184)
Other comprehensive loss	(72)	16	(56)
Accumulated other comprehensive loss, balance at June 30, 2022	<u>\$ (283)</u>	<u>\$ 43</u>	<u>\$ (240)</u>

Restricted Cash

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

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

	June 30,	
	2022	2021
Cash and cash equivalents	\$ 2,873	\$ 5,603
Restricted cash, non-current	12	11
Total cash, cash equivalents and restricted cash shown in the condensed consolidated statements of cash flows	<u>\$ 2,885</u>	<u>\$ 5,614</u>

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

Product sales are primarily associated with our COVID-19 vaccine supply agreements with the U.S. Government, other international governments and Gavi (on behalf of the COVAX Facility).

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
United States	\$ 1,450	\$ 2,093	\$ 2,395	\$ 3,451
Europe	1,390	1,056	3,466	1,340
Rest of world ⁽¹⁾	1,691	1,048	4,595	1,139
Total	\$ 4,531	\$ 4,197	\$ 10,456	\$ 5,930

⁽¹⁾ Includes product sales recognized under the agreement with Gavi, which facilitates the allocation and distribution of our COVID-19 vaccine around the world, particularly for low- and middle-income countries.

As of June 30, 2022, our COVID-19 vaccine (marketed under the brand name Spikevax) was our only commercial product authorized for use.

As of June 30, 2022 and December 31, 2021, we had deferred revenue of \$4.3 billion and \$6.7 billion, respectively, related to customer deposits. We expect \$4.0 billion of our deferred revenue related to customer deposits as of June 30, 2022 to be realized in less than one year. Timing of product manufacturing, delivery, and receipt of marketing approval will determine the period in which product sales are 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 therapeutics and vaccines. As of June 30, 2022, the committed funding, net of revenue earned was \$7 million. An additional \$30 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. The agreement was amended in both 2020 and 2021 to provide for additional commitments to support various late-stage clinical development efforts of mRNA-1273, including a 30,000 participant Phase 3 study, pediatric clinical trials and pharmacovigilance studies. In March 2022, we entered into a further amendment to the BARDA agreement, increasing the amount of potential reimbursements by \$308 million, in connection with costs associated with the clinical development for the adolescent and pediatric studies and the Phase 3 pivotal study. The maximum award from BARDA, inclusive of the 2020, 2021 and 2022 amendments, was approximately \$1.7 billion. All contract options have been exercised. As of June 30, 2022, the remaining available funding, net of revenue earned was \$203 million.

In September 2016, we received from BARDA an award of up to \$126 million, subsequently adjusted to \$117 million in 2021, to help fund our Zika vaccine program. Three of the four contract options have been exercised. As of June 30, 2022, the remaining available funding, net of revenue earned was \$42 million, with an additional \$8 million available if the final contract option is exercised. The performance period of the grant will expire on September 30, 2022 and any remaining funding at expiry will be forfeited.

In January 2016, we entered a global health project framework agreement with the Bill and Melinda Gates Foundation (Gates Foundation) to advance mRNA-based development projects for various infectious diseases, including human immunodeficiency virus (HIV). As of June 30, 2022, 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 for the periods presented (in millions):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
BARDA	\$ 179	\$ 134	\$ 301	\$ 326
Other grant revenue	4	5	8	7
Total grant revenue	\$ 183	\$ 139	\$ 309	\$ 333

5. Collaboration Agreements

We have entered into collaboration agreements with strategic collaborators to accelerate the discovery and advancement of potential mRNA medicines across therapeutic areas. As of June 30, 2022 and December 31, 2021, 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 2021 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):

Collaboration Revenue by Strategic Collaborator:	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
AstraZeneca	\$ 4	\$ 4	\$ 4	\$ 4
Merck	5	4	15	4
Vertex	25	9	29	18
Other	1	1	2	2
Total collaboration revenue	<u>\$ 35</u>	<u>\$ 18</u>	<u>\$ 50</u>	<u>\$ 28</u>

The following table presents changes in the balances of our receivables and contract liabilities related to our strategic collaboration agreements during the six months ended June 30, 2022 (in millions):

	December 31, 2021	Additions	Deductions	June 30, 2022
Contract Assets:				
Accounts receivable	\$ 9	\$ 13	\$ (11)	\$ 11
Contract Liabilities:				
Deferred revenue	\$ 204	\$ 6	\$ (43)	\$ 167

As of June 30, 2022, the aggregated amount of the transaction price allocated to performance obligations under our collaboration agreements that are unsatisfied or partially unsatisfied was \$236 million.

In addition to the collaboration agreements mentioned above, we have other collaborative and licensing arrangements that we do not consider to be individually significant to our business at this time. Pursuant to these agreements, we may be required to make upfront payments and payments upon achievement of various development, regulatory and commercial milestones, which in the aggregate could be significant. Future milestone payments, if any, will be reflected in our consolidated financial statements when the corresponding events become probable. In addition, we may be required to pay significant royalties on future sales if products related to these arrangements are commercialized.

6. Financial Instruments

Cash and Cash Equivalents and Investments

The following tables summarize our cash and available-for-sale securities by significant investment category at June 30, 2022 and December 31, 2021 (in millions):

June 30, 2022							
	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value	Cash and Cash Equivalents	Current Marketable Securities	Non-Current Marketable Securities
Cash and cash equivalents	\$ 2,873	\$ —	\$ —	\$ 2,873	\$ 2,873	\$ —	\$ —
Available-for-sale:							
Certificates of deposit	348	—	—	348	—	348	—
U.S. treasury bills	259	—	(2)	257	—	257	—
U.S. treasury notes	8,231	—	(189)	8,042	—	3,054	4,988
Corporate debt securities	6,597	—	(181)	6,416	—	1,352	5,064
Government debt securities	129	—	(6)	123	—	13	110
Total	<u>\$ 18,437</u>	<u>\$ —</u>	<u>\$ (378)</u>	<u>\$ 18,059</u>	<u>\$ 2,873</u>	<u>\$ 5,024</u>	<u>\$ 10,162</u>
December 31, 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	\$ 6,848	\$ —	\$ —	\$ 6,848	\$ 6,848	\$ —	\$ —
Available-for-sale:							
Certificates of deposit	80	—	—	80	—	80	—
U.S. treasury bills	479	—	—	479	—	479	—
U.S. treasury notes	6,595	—	(31)	6,564	—	1,984	4,580
Corporate debt securities	3,508	—	(20)	3,488	—	1,323	2,165
Government debt securities	112	—	(1)	111	—	13	98
Total	<u>\$ 17,622</u>	<u>\$ —</u>	<u>\$ (52)</u>	<u>\$ 17,570</u>	<u>\$ 6,848</u>	<u>\$ 3,879</u>	<u>\$ 6,843</u>

The amortized cost and estimated fair value of available-for-sale securities by contractual maturity at June 30, 2022 and December 31, 2021 were as follows (in millions):

June 30, 2022		
	Amortized Cost	Estimated Fair Value
Due in one year or less	\$ 5,079	\$ 5,024
Due after one year through five years	10,485	10,162
Total	<u>\$ 15,564</u>	<u>\$ 15,186</u>
December 31, 2021		
	Amortized Cost	Estimated Fair Value
Due in one year or less	\$ 3,882	\$ 3,879
Due after one year through five years	6,892	6,843
Total	<u>\$ 10,774</u>	<u>\$ 10,722</u>

In accordance with our investment policy, we place investments in investment grade securities with high credit quality issuers, and generally limit the amount of credit exposure to any one issuer. We evaluate securities for impairment at the end of each reporting period. Impairment is evaluated considering numerous factors, and their relative significance varies depending on the situation.

Factors considered include whether a decline in fair value below the amortized cost basis is due to credit-related factors or 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 six months ended June 30, 2022 and 2021. We did not record any credit-related allowance to available-for-sale securities as of June 30, 2022 and December 31, 2021.

The following table summarizes the amount of gross unrealized losses and the estimated fair value for our available-for-sale securities in an unrealized loss position by the length of time the securities have been in an unrealized loss position at June 30, 2022 and December 31, 2021 (in millions):

	Less than 12 Months		12 Months or More		Total	
	Gross Unrealized Losses	Estimated Fair Value	Gross Unrealized Losses	Estimated Fair Value	Gross Unrealized Losses	Estimated Fair Value
As of June 30, 2022:						
U.S. treasury bills	\$ (2)	\$ 256	\$ —	\$ —	\$ (2)	\$ 256
U.S. treasury notes	(185)	7,873	(4)	132	(189)	8,005
Corporate debt securities	(164)	5,388	(17)	385	(181)	5,773
Government debt securities	(6)	123	—	—	(6)	123
Total	<u>\$ (357)</u>	<u>\$ 13,640</u>	<u>\$ (21)</u>	<u>\$ 517</u>	<u>\$ (378)</u>	<u>\$ 14,157</u>
As of December 31, 2021:						
U.S. treasury bills	\$ —	\$ 329	\$ —	\$ —	\$ —	\$ 329
U.S. treasury notes	(31)	6,332	—	—	(31)	6,332
Corporate debt securities	(20)	2,573	—	1	(20)	2,574
Government debt securities	(1)	112	—	—	(1)	112
Total	<u>\$ (52)</u>	<u>\$ 9,346</u>	<u>\$ —</u>	<u>\$ 1</u>	<u>\$ (52)</u>	<u>\$ 9,347</u>

At June 30, 2022 and December 31, 2021, we held 634 and 384 available-for-sale securities, respectively, out of our total investment portfolio that were in a continuous unrealized loss position. We neither intend to sell these investments, nor do we believe that we are more-likely-than-not to conclude we will have to sell them before recovery of their carrying values. We also believe that we will be able to collect both principal and interest amounts due to us at maturity.

Assets and Liabilities Measured at Fair Value on a Recurring Basis

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

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

The following tables summarize our financial assets and liabilities measured at fair value on a recurring basis as of June 30, 2022 and December 31, 2021 (in millions):

	Fair value at June 30, 2022	Fair Value Measurement Using	
		Level 1	Level 2
Assets:			
Money market funds	\$ 1,242	\$ 1,242	\$ —
Certificates of deposit	348	—	348
U.S. treasury bills	257	—	257
U.S. treasury notes	8,042	—	8,042
Corporate debt securities	6,416	—	6,416
Government debt securities	123	—	123
Derivative instruments (Note 7)	58	—	58
Total	\$ 16,486	\$ 1,242	\$ 15,244
Liabilities:			
Derivative instruments (Note 7)	\$ 2	\$ —	\$ 2

	Fair value at December 31, 2021	Fair Value Measurement Using	
		Level 1	Level 2
Assets:			
Money market funds	\$ 2,329	\$ 2,329	\$ —
Certificates of deposit	80	—	80
U.S. treasury bills	479	—	479
U.S. treasury notes	6,564	—	6,564
Corporate debt securities	3,488	—	3,488
Government debt securities	111	—	111
Derivative instruments (Note 7)	21	—	21
Total	\$ 13,072	\$ 2,329	\$ 10,743
Liabilities:			
Derivative instruments (Note 7)	\$ 7	\$ —	\$ 7

As of June 30, 2022 and December 31, 2021, 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.

In addition, as of June 30, 2022, we had \$30 million in equity investments without readily determinable fair values, which are recorded within other non-current assets in our condensed consolidated balance sheets and excluded from the fair value measurement tables above. We did not have equity investments as of December 31, 2021.

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 (loss) (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 income. 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 income. As of June 30, 2022, we had net deferred gains of \$55 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, accounts payable and lease liabilities in Euro, Japanese Yen and 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 income. 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 income.

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

	Notional Amount	June 30, 2022	
		Fair Value	
		Asset ⁽¹⁾	Liability ⁽²⁾
Derivatives designated as cash flow hedging instruments:			
Foreign currency forward contracts	\$ 1,153	\$ 37	\$ —
Derivatives not designated as hedging instruments:			
Foreign currency forward contracts	957	21	2
Total derivatives	<u>\$ 2,110</u>	<u>\$ 58</u>	<u>\$ 2</u>

	December 31, 2021		
	Notional Amount	Fair Value	
		Asset ⁽¹⁾	Liability ⁽²⁾
Derivatives designated as cash flow hedging instruments:			
Foreign currency forward contracts	\$ 565	\$ 20	\$ —
Derivatives not designated as hedging instruments:			
Foreign currency forward contracts	\$ 1,370	\$ 1	\$ 7
Total derivatives	\$ 1,935	\$ 21	\$ 7

⁽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 for the three and six months ended June 30, 2022 and 2021 were as follows (in millions):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Derivatives in cash flow hedging relationships:				
Foreign currency forward contracts	\$ 46	\$ 21	\$ 71	\$ 21

The effect of our foreign currency derivatives in our condensed consolidated statements of income for the three and six months ended June 30, 2022 and 2021 was as follows (in millions):

	Statement of Income Classification	Three Months Ended June 30,		Six Months Ended June 30,	
		2022	2021	2022	2021
Derivatives in cash flow hedging relationships:					
Foreign currency forward contracts					
Net gain reclassified from AOCI into income	Product sales	\$ 30	\$ —	\$ 44	\$ —
Derivatives not designated as hedging instruments:					
Foreign currency forward contracts					
Net realized and unrealized gain (loss)	Other expense, net	\$ 41	\$ (54)	\$ 69	\$ (19)

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

8. Inventory

Inventory as of June 30, 2022 and December 31, 2021 consisted of the following (in millions):

	June 30, 2022	December 31, 2021
Raw materials	\$ 1,400	\$ 870
Work in progress	379	338
Finished goods	142	233
Total inventory	<u>\$ 1,921</u>	<u>\$ 1,441</u>

Inventory is recorded at the lower of cost or net realizable value. On a quarterly basis, we evaluate the composition of inventory to identify excess, obsolete, slow-moving or otherwise unsaleable items. We also assess whether we have any excess firm, non-cancelable, purchase commitment liabilities, resulting from our supply agreements with third-party vendors on a quarterly basis. The determination of net realizable value of inventory and firm purchase commitment liabilities requires judgment, including consideration of many factors, such as estimates of future product demand, current and future market conditions, potential product obsolescence, expiration and utilization of raw materials under firm purchase commitments and contractual minimums, among others.

Inventory write-downs as a result of excess, obsolescence, scrap or other reasons, and losses on firm purchase commitments are recorded as a component of cost of sales in our condensed consolidated statements of income. For the three and six months ended June 30, 2022, inventory write-downs were \$499 million and \$689 million, respectively. Inventory write-downs were immaterial for the three and six months ended June 30, 2021. For the three and six months ended June 30, 2022, losses on firm purchase commitments were \$184 million and \$342 million, respectively. As of June 30, 2022, the accrued liability for losses on firm future purchase commitments in our condensed consolidated balance sheets was \$342 million. There were no such charges in 2021 or accrued liabilities at December 31, 2021.

Pre-launch Inventory

Costs relating to raw materials and production of inventory in preparation for product launch prior to regulatory approval are capitalized when future commercialization is considered probable, the future economic benefit is expected to be realized, and we believe that material uncertainties related to the ultimate regulatory approval have been significantly reduced. For pre-launch inventory that is capitalized, we consider a number of factors based on the information available at the time, including the product candidate's current status in the drug development and regulatory approval process, results from the related clinical trials, results from meetings with relevant regulatory agencies prior to the filing of regulatory applications, potential impediments to the approval process such as product safety or efficacy, historical experience, viability of commercialization and market trends.

As of June 30, 2022, we had capitalized pre-launch inventory relating to our Omicron-containing booster candidate (mRNA-1273.214) of \$155 million in our condensed consolidated balance sheets.

9. Property and Equipment, Net

Property and equipment, net, as of June 30, 2022 and December 31, 2021 consisted of the following (in millions):

	June 30, 2022	December 31, 2021
Manufacturing and laboratory equipment	\$ 201	\$ 175
Leasehold improvements	365	313
Furniture, fixtures and other	17	11
Computer equipment and software	17	16
Internally developed software	8	9
Right-of-use asset, financing (Note 11)	898	857
Construction in progress	284	212
Total	1,790	1,593
Less: Accumulated depreciation	(466)	(352)
Property and equipment, net	<u>\$ 1,324</u>	<u>\$ 1,241</u>

Depreciation and amortization expense for the three and six months ended June 30, 2022 was \$76 million and \$155 million, respectively. Depreciation and amortization expense for the three and six months ended June 30, 2021 was \$69 million and \$84 million, respectively.

10. Other Balance Sheet Components

Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets, as of June 30, 2022 and December 31, 2021 consisted of the following (in millions):

	June 30, 2022	December 31, 2021
Down payments for materials and supplies	\$ 474	\$ 287
Down payments to manufacturing vendors	183	118
Prepaid services	110	126
Value added tax receivable	45	70
Tenant improvement allowance receivable	51	51
Interest receivable	57	27
Derivative assets	58	21
Other current assets	76	28
Prepaid expenses and other current assets	<u>\$ 1,054</u>	<u>\$ 728</u>

Accrued Liabilities

Accrued liabilities, as of June 30, 2022 and December 31, 2021 consisted of the following (in millions):

	June 30, 2022	December 31, 2021
Clinical trials	\$ 324	\$ 283
Raw materials	317	260
Royalties	158	241
Development operations	65	137
Manufacturing	244	227
Other external goods and services	100	79
Loss on future firm purchase commitments ⁽¹⁾	342	—
Compensation-related	128	126
Other	102	119
Accrued liabilities	<u>\$ 1,780</u>	<u>\$ 1,472</u>

⁽¹⁾ Related to losses that are expected to arise from firm, non-cancellable, commitments for future raw material purchases ([Note 8](#)).

Other Current Liabilities

Other current liabilities, as of June 30, 2022 and December 31, 2021 consisted of the following (in millions):

	June 30, 2022	December 31, 2021
Lease liabilities - financing (Note 11)	\$ 121	\$ 165
Lease liabilities - operating (Note 11)	38	46
Other	250	14
Other current liabilities	<u>\$ 409</u>	<u>\$ 225</u>

Deferred Revenue

The following table summarizes the activities in deferred revenue for the six months ended June 30, 2022 (in millions):

	December 31, 2021	Additions	Deductions	June 30, 2022
Product sales	\$ 6,658	\$ 1,834	\$ (4,166)	\$ 4,326
Grant revenue	6	—	(1)	5
Collaboration revenue	204	6	(43)	167
Total deferred revenue	<u>\$ 6,868</u>	<u>\$ 1,840</u>	<u>\$ (4,210)</u>	<u>\$ 4,498</u>

11. Leases

We have entered into various long-term non-cancelable lease arrangements for our facilities and equipment expiring at various times through 2042. 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 lease. We have two campuses in Massachusetts, our Cambridge campus and our Moderna Technology Center (MTC), an industrial technology center located in Norwood. We also lease other office and lab spaces globally for our business operations.

Operating Leases

Cambridge Campus

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 campus leases have expiry ranges from 2024 to 2029.

In addition, we are investing in a new Moderna Science Center (MSC) in Cambridge, to create a purpose-built space to support our next chapter of discovery (see [Note 12](#)). In connection with our MSC investment, in September 2021, we entered into amendments to our lease agreements to allow for an option for early termination of the leases, either in part or full. Notification of the intent to exercise the option must be provided by August 2023. We have not elected to exercise this option.

Finance Leases

Moderna Technology Center

Our MTC comprises three main buildings: MTC South, MTC North and MTC East. Each of MTC South and MTC North is approximately 200,000 square feet and provides office, laboratory and light manufacturing space, directly supporting improvement in our manufacturing capabilities. MTC East is approximately 240,000 square feet for commercial and clinical activities. The MTC campus is leased through 2042 and we have the option to extend the term for three extension periods of five years.

Embedded Leases

We have entered into multiple contract manufacturing service agreements with third parties which contain embedded leases within the scope of ASC 842. These leases expire from 2022 through 2023. As of June 30, 2022 and December 31, 2021, we had lease liabilities of \$129 million and \$166 million, respectively, related to the embedded leases. As of June 30, 2022 and December 31, 2021, we had right-of-use assets of \$101 million and \$173 million, respectively, related to the embedded leases.

Operating and financing lease right-of-use assets and lease liabilities as of June 30, 2022 and December 31, 2021 were as follows (in millions):

	June 30, 2022	December 31, 2021
Assets:		
Right-of-use assets, operating, net ^{(1) (2)}	\$ 122	\$ 142
Right-of-use assets, financing, net ^{(3) (4)}	619	665
Total	\$ 741	\$ 807
Liabilities:		
Current:		
Operating lease liabilities ⁽⁵⁾	\$ 38	\$ 46
Financing lease liabilities ⁽⁵⁾	121	165
Total current lease liabilities	159	211
Non-current:		
Operating lease liabilities, non-current	87	106
Financing lease liabilities, non-current	641	599
Total non-current lease liabilities	\$ 728	\$ 705
Total	\$ 887	\$ 916

⁽¹⁾ These assets are real estate related assets, which include land, office, and laboratory spaces.

⁽²⁾ Net of accumulated amortization.

⁽³⁾ These assets are real estate assets related to the MTC 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 as of June 30, 2022, were as follows (in millions):

Fiscal Year	Operating Leases	Financing Leases ⁽¹⁾
2022 (remainder of the year)	\$ 23	\$ 121
2023	39	38
2024	15	21
2025	16	22
2026	16	22
Thereafter	51	1,111
Total minimum lease payments	160	1,335
Less amounts representing interest or imputed interest	(35)	(573)
Present value of lease liabilities	\$ 125	\$ 762

⁽¹⁾ Includes certain optional lease term extensions, predominantly related to the MTC leases, which represent a total of \$662 million of undiscounted future lease payments.

12. Commitments and Contingencies

Legal Proceedings

We are involved in various claims and legal proceedings of a nature considered ordinary course in our business. The outcome of any such proceedings, regardless of the merits, is inherently uncertain; therefore, assessing the likelihood of loss and any estimated damages is difficult and subject to considerable judgment. We are not currently a party to any legal proceedings for which a material loss is probable, or for which a loss is reasonably estimable at this time.

Indemnification Obligations

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

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

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

Through the three and six months ended June 30, 2022 and the year ended December 31, 2021, we had not experienced any material 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 for raw materials and manufacturing services and with vendors for preclinical research studies, clinical trials and other goods or services. As of June 30, 2022, we had \$3.4 billion of non-cancelable purchase commitments related to raw materials and manufacturing agreements, which are expected to be paid through 2025. As of June 30, 2022, \$342 million of the purchase commitments related to raw materials was recorded as an accrued liability for loss on future firm purchase commitments. As of June 30, 2022, we had \$179 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 goods and services, including services related to clinical operations and support and contract manufacturing, for which we are not contractually able to terminate for convenience and avoid any and all future obligations to the vendors. Certain agreements provide for termination rights subject to termination fees or wind down costs. Under such agreements, we are contractually obligated to make certain payments to vendors, mainly, to reimburse them for their unrecoverable outlays incurred prior to cancellation. At June 30, 2022, we had cancelable open purchase orders of \$2.5 billion in total under such agreements for our significant clinical operations and support and contract manufacturing. These amounts represent only our estimate of those items for which we had a contractual commitment to pay at June 30, 2022, 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 and royalties based on annual net sales of licensed products for therapeutic and prophylactic products are accounted for as additional expense of the related product sales in the period in which the corresponding sales occur. For the three and six months ended June 30, 2022, we recognized \$157 million and \$364 million, respectively, of royalty expenses associated with our product sales, which was recorded to cost of sales in our condensed consolidated statements of income. For the three and six months ended June 30, 2021, we recognized \$148 million and \$232 million, respectively, of royalty expenses associated with our product sales, which was recorded to cost of sales in our condensed consolidated statements of income.

Additionally, we have other in-license agreements with third parties which require us to make future development, regulatory and commercial milestone payments and sales-based royalties for specified products associated with the agreements. The achievement of these milestones was not deemed probable as of June 30, 2022.

Moderna Science Center

In September 2021, we announced an investment in the MSC in Cambridge, Massachusetts. The MSC is expected to integrate scientific and non-scientific spaces, including our principal executive offices, and will be 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. We expect to begin the move-in process in 2023.

13. Stock-Based Compensation and Share Repurchase Program

Stock-Based Compensation

The following table presents the components and classification of stock-based compensation expense for the three and six months ended June 30, 2022 and 2021 as follows (in millions):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Options	\$ 27	\$ 24	\$ 52	\$ 46
Restricted Common Stock (RSUs) and Performance Stock Units (PSUs)	22	10	39	17
Employee Stock Purchase Plan (ESPP)	1	1	3	2
Total	<u>\$ 50</u>	<u>\$ 35</u>	<u>\$ 94</u>	<u>\$ 65</u>
Cost of sales	\$ 13	\$ 8	\$ 21	\$ 12
Research and development	19	15	39	29
Selling, general and administrative	18	12	34	24
Total	<u>\$ 50</u>	<u>\$ 35</u>	<u>\$ 94</u>	<u>\$ 65</u>

As of June 30, 2022, there was \$575 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 3.2 years at June 30, 2022.

Share Repurchase Programs

On August 2, 2021, our Board of Directors authorized a Share Repurchase Program (2021 Repurchase Program) of our common stock. Pursuant to the 2021 Repurchase Program, we were authorized to repurchase up to \$1.0 billion of our outstanding common stock, with an expiration date no later than August 2, 2023. By the end of January 2022, we had repurchased the entire \$1.0 billion of common stock that was authorized under the 2021 Repurchase Program.

On February 22, 2022, our Board of Directors authorized a new Share Repurchase Program (2022 Repurchase Program) of our common stock, with no expiration date. Pursuant to the 2022 Repurchase Program, we may repurchase up to \$3.0 billion of our outstanding common stock. The timing and actual number of shares repurchased will 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 Securities Exchange Act of 1934, as amended.

During the six months ended June 30, 2022, we repurchased 13 million shares of our common stock under the 2021 and 2022 Repurchase Program for an aggregate of \$1.9 billion, including commissions and fees. As of June 30, 2022, there was a total of \$1.2 billion remaining for repurchases of our common stock under the 2022 Repurchase Program.

14. Income Taxes

The following table summarizes our income tax expense for the periods presented (in millions, except for percentages):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Income before income taxes	\$ 2,474	\$ 3,063	\$ 6,703	\$ 4,323
Provision for income taxes	\$ 277	\$ 283	\$ 849	\$ 322
Effective tax rate	11.2 %	9.2 %	12.7 %	7.5 %

The effective tax rate for the three and six months ended June 30, 2022 was lower than the U.S. statutory tax rate, primarily due to the benefit of the foreign derived intangible income deduction (FDII) and a discrete item for excess tax benefits related to stock-based compensation. The increased effective tax rate for the three and six months ended June 30, 2022 was mainly due to the tax benefit recorded in 2021 related to the release of the valuation allowance on the majority of our deferred tax assets, as well as a decrease in excess windfall benefits from stock-based compensation, partially offset by an increase in the FDII benefit in 2022.

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.

Effective January 1, 2022, research and development expenses are required to be capitalized and amortized for U.S. tax purposes. Unless modified or repealed, and based on current assumptions, the mandatory capitalization increases our cash tax liabilities, but also increases our FDII deduction resulting in a decrease to our effective tax rate.

15. Earnings per Share

The computation of basic earnings 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 during the period as determined by using the treasury stock method.

Basic and diluted EPS for the three and six months ended June 30, 2022 and 2021 were calculated as follows (in millions, except per share data):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
<i>Numerator:</i>				
Net income	\$ 2,197	\$ 2,780	\$ 5,854	\$ 4,001
<i>Denominator:</i>				
Basic weighted-average common shares outstanding	396	402	399	401
Effect of dilutive securities	23	29	24	29
Diluted weighted-average common shares outstanding	419	431	423	430
Basic EPS	\$ 5.55	\$ 6.93	\$ 14.66	\$ 9.98
Diluted EPS	\$ 5.24	\$ 6.46	\$ 13.85	\$ 9.30
Anti-dilutive potential common shares excluded from the EPS computation above	4	1	3	1

16. Subsequent Events

On July 28, 2022, we entered into a supply agreement with the U.S. government for an initial 66 million doses of our COVID-19 bivalent booster vaccine candidate (mRNA-1273.222) with options for the U.S. government to purchase up to an additional 234 million doses. On August 1, 2022, the U.S. government exercised an option to purchase 4 million pediatric doses of our COVID-19 bivalent booster vaccine candidate, bringing the total to 70 million doses purchased, with options to purchase an additional 230 million doses.

On August 1, 2022, our Board of Directors authorized a new Share Repurchase Program (2022 Second Repurchase Program) of our common stock, with no expiration date. Pursuant to the 2022 Second Repurchase Program, we may repurchase up to \$3.0 billion of our outstanding common stock. The timing and actual number of shares repurchased will 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 Securities Exchange Act of 1934 (the Exchange Act).

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

You should read the following discussion and analysis of our financial condition and results of operations together with our unaudited financial information and related notes included in this Form 10-Q and our consolidated financial statements and related notes and other financial information in our Annual Report on Form 10-K for the year ended December 31, 2021, which was filed with the Securities and Exchange Commission (the SEC) on February 25, 2022 (the 2021 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. 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.” 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.

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) as a two-dose, 100 µg primary series in individuals 18 years of age or older. In January 2022, we received full commercial approval for Spikevax as a two-dose, 100 µg primary series to prevent COVID-19 in individuals 18 years of age and older in the United States, and Spikevax is approved or authorized in individuals 18 years and older in more than 80 countries. In addition, we have received authorization from the FDA and global regulators in more than 40 countries for our COVID-19 vaccine as a two-dose 100 µg primary series in adolescents aged 12-17 years and as a two-dose 50 µg primary series in children ages 6 through 11 years old. Additionally, a two-dose, 25 µg primary series of our COVID-19 vaccine is authorized in young children ages 6 months through 5 years old in the United States, Canada, Australia, and other jurisdictions.

The FDA, European Medicines Agency (EMA), Swissmedic and other health agencies around the world have authorized a booster dose of our COVID-19 vaccine at the 50 µg dose level for adults ages 18 years and older. In March 2022, the FDA and other health agencies authorized a second booster dose at the 50 µg dose level for adults 50 years and older and adults over 18 years of age with certain kinds of immunocompromise.

Business Highlights and Recent Developments

Moderna COVID-19 Vaccine Clinical Studies

- **Omicron-specific booster candidates (mRNA-1273.529/214/222):** Our Omicron-containing vaccine candidates are being studied to evaluate the immunogenicity, safety and reactogenicity of mRNA-1273.529 and mRNA-1273.214 as a single booster dose in adults aged 18 years and older. mRNA-1273.529 is a vaccine candidate specific to the Omicron variant of concern (BA.1). mRNA-1273.214 is a bivalent candidate that combines our Omicron-specific (BA.1) candidate (mRNA-1273.529) and mRNA-1273. We are also developing a bivalent vaccine candidate (mRNA-1273.222) based upon the BA.4/5 Omicron variant strains and mRNA-1273. mRNA-1273.214 is being evaluated in an ongoing registrational, Phase 2/3 study in the U.S. and a Phase 3 study in the UK. We expect to begin dosing with mRNA-1273.222 in the U.S. Phase 2/3 study soon.

- Based on our June 2022 clinical data, a 50 µg booster dose of mRNA-1273.214 met all pre-specified endpoints including superior neutralizing antibody response (geometric mean ratio) against the Omicron variant one month after administration when compared to the original mRNA-1273 vaccine. The booster dose of mRNA-1273.214 was generally well-tolerated, with side effects comparable to a booster dose of mRNA-1273 at the 50 µg dose level. Additionally, one month after administration in previously vaccinated and boosted participants, a 50 µg booster dose of mRNA-1273.214 elicited potent neutralizing antibody responses against the Omicron subvariants BA.4 and BA.5 in all participants regardless of prior infection. We are working to complete regulatory submissions in the coming weeks requesting to update the composition of our booster vaccine to mRNA-1273.214.
- We are advancing both mRNA-1273.214 and mRNA-1273.222 for fall 2022 based on different market needs for Omicron subvariants. On July 28, 2022, we entered into a supply agreement with the U.S. government for an initial 66 million doses of mRNA-1273.222, with options for the U.S. government to purchase up to an additional 234 million doses. We also have supply agreements with other governments for the supply of mRNA-1273.214 for the fall booster season.
- **Beta-specific bivalent booster (mRNA-1273.211):** mRNA-1273.211 is a bivalent vaccine candidate that combines our Beta-specific candidate (mRNA-1273.351) and mRNA-1273. Several mutations found in the Beta variant of concern have been persistent in more recent variants of concern, including Omicron. A 50 µg booster dose of mRNA-1273.211 demonstrated superiority compared to a 50 µg booster dose of mRNA-1273 against Beta, Delta and Omicron variants of concern one month after administration. Superiority continued six months after administration for Beta and Omicron variants of concern as well. A 50 µg booster dose of mRNA-1273.211 was generally well tolerated with a reactogenicity profile comparable to a booster dose of mRNA-1273 at the 50 µg dose level.
- **Moderna COVID-19 Vaccine for adolescents and children:** In adolescents aged 12-17 years, the primary series (two doses of 100 µg) of our COVID-19 vaccine is authorized in more than 40 countries.

In children aged 6-11 years, the primary series (two doses of 50 µg) of our COVID-19 vaccine is authorized in more than 40 countries, including the U.S., the EU, Australia, and Canada.

In children aged 6 months to 5 years, the primary series (two doses of 25 µg) of our COVID-19 vaccine is authorized in the U.S., Canada, Australia, and other jurisdictions.

- **Next-generation vaccine candidate against COVID-19 (mRNA-1283):** mRNA-1283 is a next-generation vaccine candidate against COVID-19 and is being developed as a potential refrigerator-stable mRNA vaccine that will facilitate easier distribution and administration by healthcare providers. In a Phase 1 study of mRNA-1283, preliminary results indicate that when administered as primary series at lower dose levels (10 µg, 30 µg), mRNA-1283 elicits a robust anti-SARS-CoV-2 neutralizing antibody response comparable to the 100 µg mRNA-1273 primary series. The frequency of local and systemic solicited adverse reactions of the mRNA-1283 primary series administered at lower dose levels (10 µg, 30 µg) was overall comparable to mRNA-1273. Enrollment is complete in a Phase 2 study evaluating booster doses of mRNA-1283, mRNA-1283.211 (SARS-CoV-2/Beta bivalent), and mRNA-1283.529 (Omicron monovalent).
- For the second quarter of 2022, we recognized product sales of \$4.5 billion from sales of our COVID-19 vaccine, compared to \$4.2 billion in the second quarter of 2021.

Other Business Updates

In June 2022, we entered into an agreement in principle with the United Kingdom government to establish an mRNA Innovation and Technology Center in the United Kingdom. We expect this state-of-the-art mRNA vaccine manufacturing facility to provide access to rapid pandemic response capabilities and our respiratory virus vaccine candidates. Additionally, we plan to expand our presence in the United Kingdom through investments in research and development activities. The UK agreement follows previous agreements entered into with the Government of the Republic of Kenya, the Australian Federal Government and the Government of Canada to establish state-of-the-art mRNA vaccine manufacturing facilities in those countries.

Key Updates for our Other Development Candidates

- **Seasonal influenza (flu) (mRNA-1010, mRNA-1011, mRNA-1012, mRNA-1020 and mRNA-1030):** As part of our influenza vaccine development strategy, we are developing five different influenza vaccines. mRNA-1010 is a single investigational vaccine consisting of four distinct mRNA sequences that encode the A H1N1, H3N2 and influenza B Yamagata and Victoria lineages in our proprietary LNP. mRNA-1011 and mRNA-1012 are investigational vaccines that will include the four WHO-recommended strains and aim to add additional hemagglutinin (HA) antigens (e.g. H3N2, H1N1). mRNA-1020 and mRNA-1030 are investigational vaccines that will aim to add neuraminidase (NA) antigens.

In March 2022, an interim analysis of a Phase 2 study of mRNA-1010 identified no significant safety concerns, and the immunogenicity data is consistent with a potential for superiority to standard dose vaccine for influenza A strains (which drives the majority of disease in adults). The interim data is consistent with potential for non-inferiority to standard dose vaccine in influenza B strains (primarily a concern in pediatrics). In June 2022, the first participants were dosed in a Phase 3 safety and immunogenicity study of mRNA-1010. We expect to enroll approximately 6,000 adults in Southern Hemisphere countries. Further, we are preparing for a Phase 3 efficacy study in fall 2022 if needed.

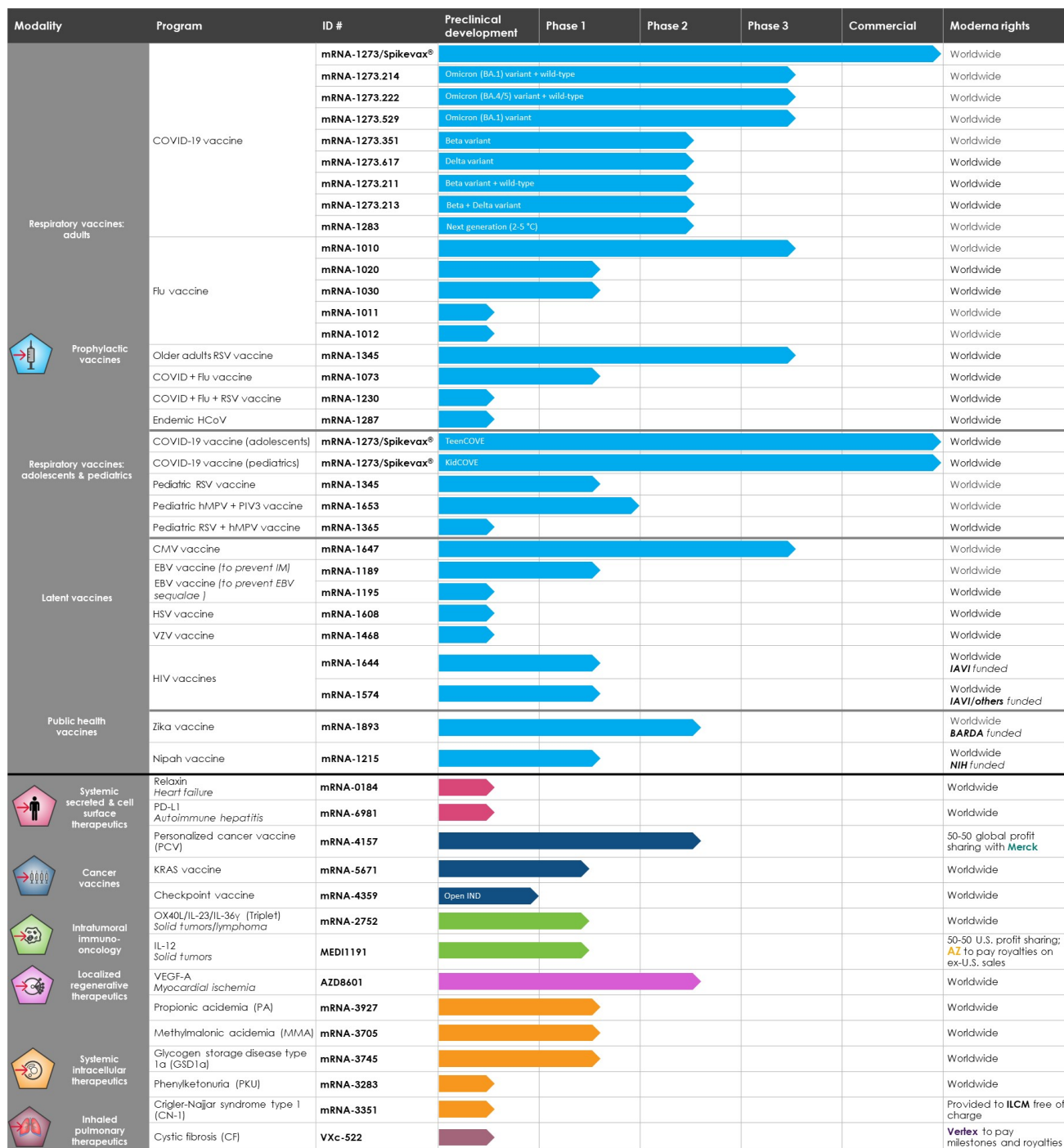
In April, we announced that the Phase 1/2 trial of mRNA-1020 and mRNA-1030 dosed its first participants, and the trial is now fully enrolled. The Phase 1/2 randomized, observer-blind, dose-ranging study will evaluate the safety, reactogenicity and immunogenicity of a single dose of mRNA-1020 or mRNA-1030 in healthy adults 18 years and older in the U.S. mRNA-1020 and mRNA-1030 candidates each include eight mRNAs, targeting both hemagglutinin and neuraminidase at different doses and ratios.

- **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, older adults of Japanese descent and children is ongoing. All cohorts are fully enrolled except the RSV seropositive children cohort, which 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. The Phase 3 portion of the pivotal global Phase 2/3 study of mRNA-1345 with approximately 34,000 participants is currently enrolling. Additionally, a Phase 3 study to evaluate the safety, tolerability and immunogenicity of mRNA-1345, when given alone or co-administered with a seasonal influenza vaccine, in adults 50 years of age or older is fully enrolled. The FDA has granted Fast Track designation for mRNA-1345 in adults older than 60 years of age.
- **Combined COVID and flu vaccine (mRNA-1073):** mRNA-1073 is a combination vaccine that encodes for the COVID spike protein and the influenza HA glycoproteins. A Phase 1/2 study comparing mRNA-1073 to co-administered mRNA-1010 and mRNA-1273, and to mRNA-1010 and mRNA-1273 alone is ongoing in approximately 1,050 participants aged 18-75 years, and the trial is fully enrolled.
- **HIV vaccines (mRNA-1644 & mRNA-1574):** We are currently advancing two HIV preventative vaccine strategies based on germline targeting and immune-focusing approaches. Our mRNA-1644 program is designed to test the hypothesis that sequential administration of priming and boosting HIV immunogens delivered by mRNA can induce specific classes of B-cell responses and guide their early maturation toward broadly neutralizing antibody (bnAb) development. The induction of bnAbs is widely considered to be a goal of HIV vaccination, and this is the first step in that process. The immunogens being tested in IAVI G002 were developed by scientific teams at IAVI and Scripps Research and will be delivered via Moderna's mRNA technology. The Phase 1 trial sponsored by IAVI and supported by the Gates Foundation is ongoing. In addition, we are also advancing an HIV trimer mRNA vaccine trial of mRNA-1574. The primary hypothesis is that the soluble and membrane-bound HIV envelope trimer mRNA vaccines will be safe and well-tolerated by HIV-uninfected individuals and will elicit autologous neutralizing antibodies. The Phase 1 trial is ongoing and is sponsored and funded by the Division of AIDS (DAIDS) of the National Institute of Allergy and Infectious Diseases (NIAID) within the National Institutes of Health (NIH).
- **Nipah vaccine (mRNA-1215):** The first participants in a Phase 1 study of mRNA-1215, our vaccine candidate against the Nipah virus (NiV), were dosed in July 2022. The trial is sponsored and funded by the NIAID. mRNA-1215 was co-developed along with the NIH's Vaccine Research Center, and the Phase 1 clinical testing is focused on pandemic preparedness.

- **Propionic acidemia (PA) (mRNA-3927):** The Phase 1/2 clinical trial for mRNA-3927, our therapy for the treatment of propionic acidemia, or PA, is ongoing, and the second cohort is fully enrolled. We are enrolling other patients into additional cohorts. 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):** The Phase 1/2 clinical trial for mRNA-3705, our therapy for the treatment of methylmalonic acidemia, or MMA, is ongoing and the first cohort has been fully enrolled. The study is now open in the UK, Canada and the U.S. Moderna is enrolling patients into additional cohorts. 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):** In June 2022, the first participant in the Phase 1 study of our GSD1a therapeutic candidate, mRNA-3745, was dosed. 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. The FDA has granted mRNA-3745 Orphan Drug Designation.
- **IL-12 (MEDI1191):** AstraZeneca is leading the early clinical development and an ongoing, open-label multicenter Phase 1 clinical trial of intratumoral injections of MEDI1191 alone and in combination with the checkpoint inhibitor, durvalumab. In April 2022, AstraZeneca presented updated Phase 1 data at the American Association for Cancer Research (AACR) conference. Intratumoral MEDI1191 combined with durvalumab was safe and the combination showed preliminary evidence of clinical benefit, with 29% of patients exhibiting partial responses or stable disease ≥ 12 weeks as best overall response.
- **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. Moderna shares worldwide commercial rights to mRNA-4157 with Merck.

Our Pipeline

The following chart shows our current pipeline of 46 development programs, grouped by respiratory vaccines, latent & public health vaccines and therapeutics.



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; ILCM, Institute for Life Changing Medicines; 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.

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

- **Prophylactic vaccines:** Our prophylactic vaccines modality currently includes 32 development programs, 23 of which have entered into clinical trials. We have ongoing Phase 1 trials for our RSV vaccine in pediatrics (mRNA-1345), flu vaccines (mRNA-1020 and mRNA-1030), combined COVID and flu vaccine (mRNA-1073), hMPV/PIV3 vaccine (mRNA-1653), EBV vaccine (mRNA-1189), HIV vaccines (mRNA-1644 and mRNA-1574) and Nipah vaccine (mRNA-1215). We have an ongoing Phase 2 study for our Zika vaccine (mRNA-1893). We have ongoing Phase 3 studies for our flu vaccine (mRNA-1010), RSV vaccine in older adults (mRNA-1345) and CMV vaccine (mRNA-1647). Our COVID-19 vaccine (mRNA-1273) is described in detail above. Our eight preclinical programs within our prophylactic vaccines modality are for a combined COVID-19, flu and RSV vaccine (mRNA-1230), combined pediatric RSV and hMPV vaccine (mRNA-1365), pan-HCoV vaccine (mRNA-1278), seasonal flu vaccines (mRNA-1011 and mRNA-1012), EBV vaccine to prevent long-term sequelae (mRNA-1195), VZV vaccine (mRNA-1468), and HSV vaccine (mRNA-1608). 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 two systemic secreted and cell surface therapeutics development candidates in our pipeline. Our secreted programs include Relaxin (mRNA-0184) for cardiac disorders and PD-L1 (mRNA-6981) for autoimmune hepatitis, which are currently in preclinical development. We are stopping our IL-2 program (mRNA-6231) after early clinical data and in response to the evolving competitive landscape. We previously announced positive data from our Chikungunya Antibody program (mRNA-1944) within this modality; however, we do not expect to advance our Chikungunya Antibody program without outside funding, and we are not currently pursuing further development of it at this time.
- **Cancer vaccines:** We are currently developing three 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 is a KRAS vaccine (mRNA-5671). We have retained all rights to our KRAS vaccine from Merck and we are evaluating next steps for the program. Our third program is our checkpoint vaccine (mRNA-4359), which has received safe to proceed from the FDA.
- **Intratumoral immuno-oncology:** We have two programs in this modality. Our first program, OX40L/IL-23/IL-36 γ (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 was developed in collaboration with 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. In 2021, the Phase 2 study met the primary endpoint of safety and tolerability of AZD8601 for the 3 mg dose. In the study of 11 patients, seven were treated with AZD8601 VEGF-A mRNA and four received placebo injections. Numerical trends were observed in endpoints in the heart failure efficacy domains compared with placebo, including increase in left ventricular ejection fraction (LVEF) and patient reported outcomes. In addition, all seven patients treated with AZD8601 had NT-proBNP (a biomarker that measures the level of a hormone that is elevated in patients with heart failure) levels below heart failure limit at 6 months follow-up compared to one of four patients treated with placebo. After a portfolio review, AstraZeneca has returned the rights to AZD8601 to us. We are evaluating next steps for the program.
- **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), glycogen storage disorder type 1a (GSD1a) (mRNA-3745), phenylketonuria (PKU) (mRNA-3283), and Crigler-Najjar Syndrome Type 1 (CN-1) (mRNA-3351). We have ongoing Phase 1 clinical trials for PA (mRNA-3927), MMA (mRNA-3705) and GSD1a (mRNA-3745). PKU (mRNA-3283) and CN-1 (mRNA-3351) are currently in preclinical development. 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 the periods presented (in millions):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Revenue:				
Product sales	\$ 4,531	\$ 4,197	\$ 10,456	\$ 5,930
Grant revenue	183	139	309	333
Collaboration revenue	35	18	50	28
Total revenue	<u>\$ 4,749</u>	<u>\$ 4,354</u>	<u>\$ 10,815</u>	<u>\$ 6,291</u>

For the three months ended June 30, 2022, we recognized \$4.5 billion of product sales from our COVID-19 vaccine, of which \$1.5 billion was generated in the United States and \$3.1 billion was generated from Europe and the rest of the world. For the three months ended June 30, 2021, we recognized \$4.2 billion of product sales from our COVID-19 vaccine, of which \$2.1 billion was generated in the United States and \$2.1 billion was generated from Europe and the rest of the world.

For the six months ended June 30, 2022, we recognized \$10.5 billion of product sales from our COVID-19 vaccine, of which \$2.4 billion was generated in the United States and \$8.1 billion was generated from Europe and the rest of the world. For the six months ended June 30, 2021, we recognized \$5.9 billion of product sales from our COVID-19 vaccine, of which \$3.4 billion was generated in the United States and \$2.5 billion was generated from Europe and the rest of the world.

As of June 30, 2022, we had deferred revenue of \$4.3 billion associated with customer deposits received or billable under supply agreements for delivery of our COVID-19 vaccine into 2023. Based upon currently signed supply agreements for delivery of our COVID-19 vaccine in 2022, we expect that our COVID-19 vaccine product sales will be generally consistent in the second half of 2022, as compared to the first half of the year. We also anticipate that product sales will be greater in the fourth quarter of 2022 than the third quarter of 2022, driven by the expected timing of potential marketing authorizations of our COVID-19 bivalent booster candidates.

Other than product sales, our revenue has been primarily derived from government-sponsored and private organizations including BARDA, DARPA and the Gates Foundation and from strategic alliances with AstraZeneca, Merck and Vertex to discover, develop, and commercialize potential mRNA medicines.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Grant revenue:				
BARDA ⁽¹⁾	\$ 179	\$ 134	\$ 301	\$ 326
Other	4	5	8	7
Total grant revenue	<u>\$ 183</u>	<u>\$ 139</u>	<u>\$ 309</u>	<u>\$ 333</u>

⁽¹⁾ For the three months ended June 30, 2022, \$175 million of BARDA grant revenue was related to our mRNA-1273 program and \$4 million was related to our Zika vaccine program. For the six months ended June 30, 2022, \$295 million of BARDA grant revenue was related to our mRNA-1273 program and \$6 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 June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Collaboration revenue:				
AstraZeneca	\$ 4	\$ 4	\$ 4	\$ 4
Merck	5	4	15	4
Vertex	25	9	29	18
Other	1	1	2	2
Total collaboration revenue	<u>\$ 35</u>	<u>\$ 18</u>	<u>\$ 50</u>	<u>\$ 28</u>

We expect to continue to receive funding from our contract with BARDA. As of June 30, 2022, the remaining available funding, net of revenue earned under our agreement with BARDA for the development of our mRNA-1273 vaccine was \$203 million. To the extent that existing or potential future products generate revenue, our revenue may vary due to many uncertainties in the future product demand, the development of our mRNA medicines and other factors.

Research and development expenses

We use our employee and infrastructure resources for the advancement of our platform, and for discovering and developing programs. Due to the number of ongoing programs and our ability to use resources across several projects, indirect or shared operating costs incurred for our research and development programs are generally not recorded or maintained on a program- or modality-specific basis. The following table reflects our research and development expenses, including direct program-specific expenses summarized by modality and indirect or shared operating costs summarized under other research and development expenses during the three and six months ended June 30, 2022 and 2021 (in millions):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Program expenses by modality:				
Prophylactic vaccines	\$ 336	\$ 241	\$ 526	\$ 489
Systemic secreted and cell surface therapeutics	2	1	3	2
Cancer vaccines	2	7	5	24
Intratumoral immuno-oncology	6	7	12	13
Systemic intracellular therapeutics	9	6	13	11
Inhaled pulmonary therapeutics ⁽¹⁾	3	—	5	—
Total program-specific expenses by modality ⁽²⁾	<u>\$ 358</u>	<u>\$ 262</u>	<u>\$ 564</u>	<u>\$ 539</u>
Other research and development expenses:				
Discovery programs	41	15	71	28
Platform research	31	27	65	52
Technical development and unallocated manufacturing expenses	195	53	329	86
Shared discovery and development expenses	66	49	196	88
Stock-based compensation	19	15	39	29
Total research and development expenses	<u>\$ 710</u>	<u>\$ 421</u>	<u>\$ 1,264</u>	<u>\$ 822</u>

⁽¹⁾ Inhaled pulmonary therapeutics modality was added in the fourth quarter of 2021.

⁽²⁾ Includes a total of 43 and 30 development candidates at June 30, 2022 and 2021, 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 contract research organizations (CROs) in connection with our preclinical studies and clinical trials, contract manufacturing organizations, and allocated manufacturing costs of pre-launch inventory, mRNA supply and consumables. Costs to acquire and manufacture pre-launch inventory, mRNA supply for preclinical studies and clinical trials are recognized and included in unallocated manufacturing expenses when incurred, and subsequently allocated to program-specific manufacturing costs after completion of the program-specific production. The timing of allocating manufacturing costs to the specific program varies depending on the program development and production schedule. We generally do not allocate personnel-related costs, including stock-based compensation, costs associated with our general platform research, technical development, and other shared costs on a program-specific basis. These costs were therefore excluded from the summary of program-specific expenses by modality.

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

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

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

The largest component of our total operating expenses has historically been our investment in research and development activities, including preclinical and clinical development of our product candidates, development of our platform, mRNA technologies, and manufacturing technologies.

As we continue to pursue our indication expansion of mRNA-1273, and continue to develop variant-specific COVID-19 vaccine candidates and our next-generation COVID-19 vaccine candidate, we expect to continue to incur significant additional expenses. In connection with the BARDA agreement to accelerate development of mRNA-1273, grant revenue and expenses within the committed funding scope are expected to continue in 2022. BARDA’s funding is expected to offset those expenses that are covered under the BARDA agreement, subject to our obtaining reimbursement from BARDA. As of June 30, 2022, the remaining available funding, net of revenue earned was \$203 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, RSV vaccine, flu vaccine 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.

Critical accounting policies and significant judgments and estimates

There have been no material changes in our critical accounting policies and estimates in the preparation of our condensed consolidated financial statements during the three months ended June 30, 2022 compared to those disclosed in our 2021 Form 10-K.

Results of operations

The following table summarizes our condensed consolidated statements of income for each period presented (in millions):

	Three Months Ended June 30,		Change 2022 vs. 2021	
	2022	2021	\$	%
Revenue:				
Product revenue	\$ 4,531	\$ 4,197	\$ 334	8%
Grant revenue	183	139	44	32%
Collaboration revenue	35	18	17	94%
Total revenue	4,749	4,354	395	9%
Operating Expenses:				
Cost of sales	1,381	750	631	84%
Research and development	710	421	289	69%
Selling, general and administrative	211	121	90	74%
Total operating expenses	2,302	1,292	1,010	78%
Income from operations	2,447	3,062	(615)	(20)%
Interest income	40	3	37	1,233%
Other expense, net	(13)	(2)	(11)	550%
Income before income taxes	2,474	3,063	(589)	(19)%
Provision for income taxes	277	283	(6)	(2)%
Net income	\$ 2,197	\$ 2,780	\$ (583)	(21)%
	Six Months Ended June 30,		Change 2022 vs. 2021	
	2022	2021	\$	%
Revenue:				
Product revenue	\$ 10,456	\$ 5,930	\$ 4,526	76%
Grant revenue	309	333	(24)	(7)%
Collaboration revenue	50	28	22	79%
Total revenue	10,815	6,291	4,524	72%
Operating Expenses:				
Cost of sales	2,398	943	1,455	154%
Research and development	1,264	822	442	54%
Selling, general and administrative	479	198	281	142%
Total operating expenses	4,141	1,963	2,178	111%
Income from operations	6,674	4,328	2,346	54%
Interest income	55	7	48	686%
Other expense, net	(26)	(12)	(14)	117%
Income before income taxes	6,703	4,323	2,380	55%
Provision for income taxes	849	322	527	164%
Net income	\$ 5,854	\$ 4,001	\$ 1,853	46%

Revenue

Total revenue increased by \$395 million, or 9%, for the three months ended June 30, 2022, compared to the same period in 2021, mainly due to an increase in product sales from sales of our COVID-19 vaccine. Product revenue increased by \$334 million, or 8%, for the three months ended June 30, 2022, compared to the same period in 2021, largely driven by a higher average selling price due to favorable customer mix. Grant revenue increased by \$44 million, or 32%, for the three months ended June 30, 2022, compared to the same period in 2021, primarily driven by an increase in revenue from BARDA related to our mRNA-1273 vaccine development.

Total revenue increased by \$4.5 billion, or 72%, for the six months ended June 30, 2022, compared to the same period in 2021, mainly due to an increase in product sales from sales of our COVID-19 vaccine. Product revenue increased by \$4.5 billion, or 76%, for the six months ended June 30, 2022, compared to the same period in 2021, largely driven by our manufacturing capacity ramp-up. Grant revenue decreased by \$24 million, or 7%, for the six months ended June 30, 2022, compared to the same period in 2021, primarily driven by a decrease in revenue from BARDA related to our mRNA-1273 vaccine development.

Operating expenses

Cost of sales

Cost of sales for the three months ended June 30, 2022 was \$1.4 billion, including third-party royalties of \$157 million. Cost of sales for the three months ended June 30, 2022 increased by \$631 million, or 84%, compared to the same period in 2021. Cost of sales as a percentage of product sales for the three months ended June 30, 2022 was 30%, compared to 18% for the same period in 2021. These increases were primarily attributable to write-downs for excess and obsolete inventory related to our COVID-19 vaccine, losses on firm purchase commitments of raw materials, and unutilized manufacturing capacity driven by a shift in product demand.

Cost of sales for the six months ended June 30, 2022 was \$2.4 billion, including third-party royalties of \$364 million. Cost of sales for the six months ended June 30, 2022 increased by \$1.5 billion, or 154%, compared to the same period in 2021, primarily due to higher sales volume, as well as inventory write-downs and losses on firm purchase commitments of raw materials. Cost of sales as a percentage of product sales for the six months ended June 30, 2022 was 23%, compared to 16% for the same period in 2021. The increase was mainly due to write-downs for excess and obsolete inventory related to our COVID-19 vaccine and losses on firm purchase commitments of raw materials, and to a lesser extent, unutilized manufacturing capacity, and the lack of the pre-launch inventory benefit that positively impacted the first quarter of 2021. If inventory sold for the six months ended June 30, 2021 was valued at cost, our cost of sales for the period would have been \$1.1 billion, or 19%, of our product sales.

We expect our manufacturing costs to increase as we move from a pandemic to a seasonal market environment for our COVID-19 vaccine. We expect that this shift will cause our cost of sales for the full year of 2022 to represent a higher percentage of our product sales than the percentage experienced in 2021.

Research and development expenses

Research and development expenses increased by \$289 million, or 69%, for the three months ended June 30, 2022, compared to the same period in 2021. The increase was primarily attributable to increases in clinical trial expenses of \$162 million, personnel-related costs of \$57 million, and consulting and outside services of \$39 million.

Research and development expenses increased by \$442 million, or 54%, for the six months ended June 30, 2022, compared to the same period in 2021. The increase was primarily attributable to increases in clinical trial expenses of \$200 million, personnel-related costs of \$96 million, consulting and outside services of \$62 million, technology and facility-related costs of \$32 million, and manufacturing costs for clinical trial materials of \$27 million. These increases for the three and six month periods in 2022 were largely driven by increased clinical development, particularly our COVID-19 vaccine and RSV programs, and headcount.

We expect that research and development expenses will increase in 2022 as we continue to progress our indication expansion of mRNA-1273, and continue to develop our pipeline and advance our product candidates into later-stage development, in particular our RSV, flu and CMV vaccine programs. In addition, we also expect to incur significant costs related to the development of variant-specific COVID-19 candidates and our next-generation COVID-19 vaccine candidate.

Selling, general and administrative expenses

Selling, general and administrative expenses increased by \$90 million, or 74%, for the three months ended June 30, 2022, compared to the same period in 2021. The increase was mainly due to an increase in distributor fees and marketing expenses of \$31 million and an increase in personnel-related costs of \$27 million. These increases for the three month period in 2022 were primarily driven by our COVID-19 vaccine commercialization-related activities and increased headcount.

Selling, general and administrative expenses increased by \$281 million, or 142%, for the six months ended June 30, 2022, compared to the same period in 2021. The increase was mainly due to an increase in distributor fees of \$66 million, an increase in personnel-related costs of \$58 million, an endowment to the Moderna Charitable Foundation (the Foundation) of \$50 million, an increase in consulting and outside services of \$37 million, and an increase in marketing expenses of \$27 million. These increases for the six month period in 2022 were primarily driven by our COVID-19 vaccine commercialization-related activities, increased headcount, and the launch of the Foundation.

We expect that selling, general and administrative expenses will increase in 2022, as we continue to build out our global commercial, regulatory, sales and marketing infrastructure to support the commercialization of our COVID-19 vaccine, and continue to expand the number of programs and our business operations.

Interest income

Interest income increased by \$37 million for the three months ended June 30, 2022, compared to the same period in 2021. Interest income increased by \$48 million for the six months ended June 30, 2022, compared to the same period in 2021. The increases in interest income from our investments in marketable securities for the three and six month periods in 2022 were mainly driven by increased investment balances and an overall higher interest rate environment.

Other expense, net

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

	Three Months Ended June 30,		Change 2022 vs. 2021	
	2022	2021	\$	%
(Loss) gain on investments	\$ (8)	\$ 2	\$ (10)	(500)%
Interest expense	(5)	(5)	—	—%
Other income, net	—	1	(1)	(100)%
Total other expense, net	<u>\$ (13)</u>	<u>\$ (2)</u>	<u>\$ (11)</u>	<u>550%</u>
	Six Months Ended June 30,		Change 2022 vs. 2021	
	2022	2021	\$	%
(Loss) gain on investments	\$ (14)	\$ 2	\$ (16)	(800)%
Interest expense	(11)	(8)	(3)	38%
Other expense, net	(1)	(6)	5	(83)%
Total other expense, net	<u>\$ (26)</u>	<u>\$ (12)</u>	<u>\$ (14)</u>	<u>117%</u>

Total other expense, net increased by \$11 million for the three months ended June 30, 2022, compared to the same period in 2021. Total other expense, net increased by \$14 million for the six months ended June 30, 2022, compared to the same period in 2021. The increases in other expense, net for the three and six month periods in 2022 were primarily due to realized losses on available-for-sale debt securities. Our interest expense is primarily related to our finance leases. Please refer to [Note 11](#) to our condensed consolidated financial statements.

Income taxes

Provision for income taxes decreased by \$6 million for the three months ended June 30, 2022, compared to the same period in 2021, primarily due to a decrease in pre-tax income, partially offset by a higher effective tax rate. Provision for income taxes increased by \$527 million for the six months ended June 30, 2022, compared to the same period in 2021, primarily due to an increase in pre-tax income and a higher effective tax rate. The increase in effective tax rate for the three and six months ended June 30, 2022 was mainly due to the tax benefit recorded in 2021 related to the release of the valuation allowance on the majority of our deferred tax assets, as well as a decrease in excess windfall benefits from stock-based compensation, partially offset by an increase in foreign derived intangible income benefit in 2022. We expect that our effective tax rate will increase for the full year 2022 compared to 2021, mainly driven by the release of the valuation allowance on the majority of the deferred tax assets in 2021.

Liquidity and capital resources

The following table summarizes our cash, cash equivalents, investments and working capital for each period presented (in millions):

	June 30, 2022	December 31, 2021
Financial assets:		
Cash and cash equivalents	\$ 2,873	\$ 6,848
Investments	5,024	3,879
Investments, non-current	10,162	6,843
Total	<u>\$ 18,059</u>	<u>\$ 17,570</u>
Working capital:		
Current assets	\$ 13,563	\$ 16,071
Current liabilities	6,812	9,128
Total	<u>\$ 6,751</u>	<u>\$ 6,943</u>

Our 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. Cash, cash equivalents and investments as of June 30, 2022 increased by \$489 million, or 3%, compared to December 31, 2021. During the six months ended June 30, 2022, we generated cash from operations of \$3.1 billion, partially offset by repurchases of our common stock of \$1.9 billion, purchases of property and equipment of \$219 million, and unrealized losses on available-for-sale debt securities of \$326 million.

Working capital, which is current assets less current liabilities, as of June 30, 2022 decreased by \$192 million, or 3%, compared to December 31, 2021, primarily due to a decrease in deferred revenue of \$2.2 billion, mainly driven by revenue recognized from deferred revenue in excess of customer deposits received, and a decrease in income taxes payable of \$527 million. This was offset by a decrease in cash, cash equivalents and short-term investments of \$2.8 billion, primarily due to purchases of long-term marketable securities, repurchases of our common stock, and income tax payments.

As of June 30, 2022, we did not have any off-balance sheet arrangements.

Cash flow

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

	Six Months Ended June 30,	
	2022	2021
Net cash provided by (used in):		
Operating activities	\$ 3,067	\$ 7,034
Investing activities	(5,073)	(4,058)
Financing activities	(1,969)	2
Net (decrease) increase in cash, cash equivalents and restricted cash	<u>\$ (3,975)</u>	<u>\$ 2,978</u>

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.

Beginning in the third quarter of 2020, we entered into supply agreements with the U.S. Government, other international governments, and Gavi for the supply of our COVID-19 vaccine and received upfront deposits. As of June 30, 2022, we had \$4.3 billion in deferred revenue related to customer deposits received or billable. In addition, we expect to continue to receive funding from our contract with BARDA related to our mRNA-1273 program. As of June 30, 2022, the remaining available funding from BARDA, net of revenue earned was \$203 million.

Net cash provided by operating activities for the six months ended June 30, 2022 was \$3.1 billion and consisted of net income of \$5.9 billion and non-cash adjustments of \$83 million, partially offset by a net change in assets and liabilities of \$2.7 billion. Non-cash items primarily included deferred income taxes of \$376 million, depreciation and amortization of \$155 million, and stock-based compensation of \$94 million. The net change in assets and liabilities was mainly due to a decrease in deferred revenue of \$2.4 billion, a decrease in income taxes payable of \$527 million, an increase in inventory of \$480 million, and an increase in prepaid expenses and other assets of \$324 million, partially offset by a decrease in accounts receivable of \$484 million, an increase in accrued liabilities of \$305 million, and an increase in other liabilities of \$263 million.

Net cash provided by operating activities decreased by \$4.0 billion, or 56%, during the six months ended June 30, 2022, compared to the same period in 2021, primarily attributable to revenue recognized from deferred revenue in excess of customer deposits received and increased income tax payments, partially offset by increased product sales and higher collection of receivables.

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 six months ended June 30, 2022 was \$5.1 billion, which primarily included purchases of marketable securities of \$8.7 billion and purchases of property and equipment of \$219 million, partially offset by proceeds from sales of marketable securities of \$2.5 billion and proceeds from maturities of marketable securities of \$1.4 billion.

Net cash used in investing activities increased by \$1.0 billion, or 25%, during the six months ended June 30, 2022, compared to the same period in 2021, primarily reflecting timing differences related to purchases, sales, and maturities of marketable debt securities and changes in our investment portfolio mix.

Financing activities

Net cash used in financing activities for the six months ended June 30, 2022 was \$2.0 billion, primarily due to repurchase of common stock of \$1.9 billion.

Net cash used in financing activities increased by \$2.0 billion during the six months ended June 30, 2022, compared to the same period in 2021, mainly due to repurchase of common stock.

Operation and funding requirements

Our principal sources of funding as of June 30, 2022 consisted of cash and cash equivalents, investments, and cash we expect to generate from operations. We generated net income of \$12.2 billion for the year ended 2021, following the authorization of our first commercial product in December 2020. From our inception to the end of 2020, we incurred significant losses from operations due to our significant research and development expenses. We have retained earnings of \$15.8 billion as of June 30, 2022.

We have significant future capital requirements including expected operating expenses to conduct research and development activities, operate our organization, meet capital expenditure needs, and fund our share repurchase program (refer to [Note 13](#) to our condensed consolidated financial statements). 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 our COVID-19 vaccine, including development of any new generations of boosters and vaccines against variants of SARS-CoV-2, and buildout of global commercial, regulatory, sales and marketing infrastructure to support the commercialization of our COVID-19 vaccine will require significant cash outflows during 2022, most of which may not be reimbursed or otherwise paid for by our partners or collaborators. In addition, we have substantial facility, lease and purchase obligations (refer to [Note 11](#) and [Note 12](#) to our condensed consolidated financial statements). We have entered into certain collaboration and licensing agreements with third parties that include the funding of certain research and development activities and potential future milestone and royalty payments by us.

We believe that our cash, cash equivalents, and investments as of June 30, 2022, 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 included in this Form 10-Q. 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, 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.

Contractual Obligations

As of June 30, 2022, 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 2021 Form 10-K.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Our market risks, and the way we manage them, are summarized in Part II, Item 7A, “Quantitative and Qualitative Disclosures About Market Risk” of our 2021 Form 10-K. There have been no material changes to our market risk or to our management of such risks for the three and six months ended June 30, 2022.

Item 4. Controls and Procedures

Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2022. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of June 30, 2022, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the three months ended June 30, 2022, 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

We are involved in various claims and legal proceedings of a nature considered ordinary course in our business, including the intellectual property litigation described below. Most of the issues raised by these claims are highly complex and subject to substantial uncertainties. For a description of risks relating to these and other legal proceedings we face, see Part I, Item 1A, “Risk Factors,” of our 2021 Form 10-K, including the discussion under the headings entitled “Risks related to our intellectual property,” and “Risks related to the manufacturing of our commercial products, development candidates, investigational medicines and our future pipeline.”

The outcome of any such proceedings, regardless of the merits, is inherently uncertain; therefore, assessing the likelihood of loss and any estimated damages is difficult and subject to considerable judgment. We describe below those legal matters for which a material loss is either (i) possible but not probable, and/or (ii) not reasonably estimable at this time.

Proceedings Related to Patents Owned by Arbutus

On February 28, 2022, Arbutus Biopharma Corporation (Arbutus) and Genevant Sciences GmbH (Genevant) filed a complaint against Moderna in the U.S. District Court for the District of Delaware asserting that Moderna’s manufacture, use, offer to sell, or sales within the United States (as well as importation into the United States) of its COVID-19 vaccine, or active inducement of the same, willfully infringes U.S. Patent Nos. 8,058,069, 8,492,359, 8,822,668, 9,364,435, 9,504,651, and 11,141,378, which concern lipid nanoparticles. The action is *Arbutus Biopharma Corp. et al. v. Moderna Inc. et al.*, Case No. 1:22-cv-00252-MN (D. Del.). Arbutus and Genevant are not seeking to prevent or stop the marketing or sales of Moderna’s COVID-19 vaccine. The complaint seeks a judgment of infringement of the asserted patents, monetary damages (together with interest), costs and expenses of the lawsuit, and attorneys’ fees.

Proceedings Related to Patents Owned by Alnylam

On March 17, 2022 and July 12, 2022, Alnylam Pharmaceuticals, Inc. (Alnylam) filed complaints against Moderna in the U.S. District Court for the District of Delaware asserting that Moderna’s manufacture, use, offer to sell, or sales within the United States (as well as import into the United States) of its COVID-19 vaccine, or active inducement of the same, infringes U.S. Patent No. 11,246,933, which issued on February 15, 2022, and concerns cationic lipids, and U.S. Patent No. 11,382,979, which issued on July 12, 2022 and concerns lipid nanoparticles. The actions are *Alnylam Pharmaceuticals, Inc. v. Moderna, Inc. et al.*, Case No. 1:22-cv-00335-CFC (D. Del.) and *Alnylam Pharmaceuticals, Inc. v. Moderna, Inc. et al.*, Case No. 1:22-cv-00925-CFC (D. Del.). Alnylam is not seeking to prevent or stop the marketing or sales of Moderna’s COVID-19 vaccine. The complaints seek a judgment of infringement of the asserted patents, monetary damages (together with interest), costs and expenses of the lawsuits, and attorneys’ fees.

Item 1A. Risk Factors

Information regarding risk and uncertainties related to our business appears in Part I, Item 1A. “Risk Factors” of our 2021 Form 10-K. There have been no material changes from the risk factors previously disclosed in the 2021 Form 10-K other than those set forth in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2022 and filed with the SEC on May 4, 2022.

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

Issuer Purchases of Equity Securities

The following table provides information with respect to the shares of common stock repurchased by us during the three months ended June 30, 2022:

Period	Total Number of Shares Purchased	Average Price Paid per Share ⁽¹⁾	Total Number of Shares Purchased as Part of Publicly Announced Program	Approximate Dollar Value of Shares that May Yet Be Purchased Under the Program (in millions)
April 1 - April 30, 2022	2,491,413	\$ 155.34	5,702,838	\$ 2,133
May 1 - May 31, 2022	3,459,344	\$ 137.64	9,162,182	\$ 1,657
June 1 - June 30, 2022	3,221,557	\$ 135.03	12,383,739	\$ 1,222
Total	9,172,314			

⁽¹⁾ Average price paid per share includes related expenses.

Refer to [Note 13](#) to condensed consolidated financial statements for information regarding our share repurchase programs.

Item 6. Exhibits

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

<u>Exhibit No.</u>	<u>Exhibit Index</u>
10.1*#	Amended and Restated Non-Employee Director Compensation Policy, effective April 28, 2022.
10.2#	Updated Executive Retirement and Strategic Consulting Agreement, dated May 27, 2022, between ModernaTX, Inc. and David Meline (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K/A filed on June 1, 2022).
10.3#	Executive Separation Agreement and Release, dated May 13, 2022, between ModernaTX, Inc. and Jorge Gomez (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K/A filed on May 13, 2022).
10.4*†	Amendment No. 13 to Agreement No. HHSO100201600029C, by and between ModernaTX, Inc. and the Biomedical Advanced Research and Development Authority, dated as of March 23, 2022.
10.5†	Amendment Nos. P00022 and P00023 to Award Contract No. W911QY20C0100, by and between Moderna US Inc. and the Army Contracting Command of the U.S. Department of Defense, dated August 9, 2020 (incorporated by reference to Exhibit 10.5 to the Company's Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2022).
10.6*†	Amendment No. P00024 to Award Contract No. W911QY20C0100, by and between Moderna US Inc. and the Army Contracting Command of the U.S. Department of Defense, dated August 9, 2020.
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.
- # Indicates a management contract or any compensatory plan, contract or arrangement.
- + The certification furnished in Exhibit 32.1 hereto is deemed to accompany this Form 10-Q and will not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended. Such certification will not be deemed to be incorporated by reference into any filings under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, except to the extent that the Registrant specifically incorporates it by reference.

SIGNATURES

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

MODERNA, INC.

Date:
August 3, 2022

By: /s/ Stéphane Bancel

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

Date:
August 3, 2022

By: /s/ David W. Meline

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

Moderna, Inc.

Amended and Restated Non-Employee Director Compensation Policy

The purpose of this Amended and Restated Non-Employee Director Compensation Policy (the “Policy”) of Moderna, Inc., a Delaware corporation (the “Company”), is to provide a total compensation package that enables the Company to attract and retain, on a long-term basis, high-caliber directors who are not employees or officers of the Company or its subsidiaries (“Outside Directors”). In furtherance of the purpose stated above, all Outside Directors shall be paid compensation for services provided to the Company as set forth below:

I. Cash Retainers

- (a) Annual Retainer for Board Membership: \$60,000 for general availability and participation in meetings and on conference calls of our Board of Directors (the “Board of Directors”). No additional compensation for attending individual Board of Director meetings.
- (b) Additional Annual Retainer for Non-Executive Chairman of the Board of Directors: \$65,000
- (c) Additional Annual Retainers for Committee Membership:

Audit Committee Chairperson:	\$25,000
Audit Committee non-Chairperson member:	\$12,000
Compensation & Talent Committee Chairperson:	\$20,000
Compensation & Talent Committee non-Chairperson member:	\$10,000
Nominating and Corporate Governance Committee Chairperson:	\$15,000
Nominating and Corporate Governance Committee non-Chairperson member:	\$7,500
Product Development Committee Chairperson:	\$15,000
Product Development non-Chairperson member:	\$10,000

No additional compensation for attending individual committee meetings. All cash retainers will be paid quarterly, in arrears, or upon the earlier resignation or removal of the Outside Director. Cash retainers owing to Outsider Directors shall be annualized, meaning that with respect to Outside Directors who join the Board of Directors during the calendar year, such amounts shall be pro-rated based on the number of calendar days served by such director.

II. Equity Retainers

All grants of equity retainer awards to Outside Directors pursuant to this Policy will be automatic and nondiscretionary and will be made in accordance with the following provisions:

(a) Value. For purposes of this Policy, “Value” means with respect to (i) any award of stock options the grant date fair value of the option (i.e., Black-Scholes Value) determined in accordance with the reasonable assumptions and methodologies employed by the Company for calculating the fair value of options under ASC 718 and which shall generally reflect, when calculating the fair value, the average closing market price on the Nasdaq Global Market (or such other market on which the Company’s common stock is then principally listed) (the “NASDAQ”) of one share of the Company’s common stock over the preceding 20 trading days, up to and including the last trading day immediately preceding the grant date; and (ii) any award of restricted stock and restricted stock units (“RSUs”) the product of (A) the average closing market price on the NASDAQ over the preceding 20 trading days, up to and including the last trading day immediately preceding the grant date of one share of the Company’s common stock on the grant date and (B) the aggregate number of shares pursuant to such award.

(b) Revisions. The Compensation & Talent Committee (the “Compensation Committee”) in its discretion may change and otherwise revise the terms of awards to be granted under this Policy, including, without limitation, the number of shares subject thereto, for awards of the same or different type granted on or after the date the Compensation Committee determines to make any such change or revision.

(c) Sale Event Acceleration. In the event of a Sale Event (as defined in the Company’s 2018 Stock Option and Incentive Plan (as amended from time to time, the “Stock Plan”)), the equity retainer awards granted to Outside Directors pursuant to this Policy shall become 100% vested and exercisable.

(d) Initial Grant. Upon initial election to the Board of Directors, each new Outside Director will receive an initial, one-time equity grant (the “Initial Grant”) with a Value of \$400,000, of which 75% of the Value shall be delivered in the form of a non-statutory stock option and 25% of the Value shall be delivered in the form of RSUs. The portion of the Initial Grant delivered as a stock option shall have an exercise price per share equal to the closing price of a share of the Company’s common stock on the date of grant and a term of ten years, and shall vest in full on the one-year anniversary of the grant date. The portion of the Initial Grant delivered as RSUs shall vest in full on the one-year anniversary of the grant date. All vesting of the Initial Grant shall cease if the director resigns from our Board of Directors or otherwise ceases to serve as a director, unless the Board of Directors determines that the circumstances warrant continuation of vesting.

(e) Annual Grant. On the date of the Company’s Annual Meeting of Stockholders, each Outside Director who will continue as a member of the Board of Directors following such Annual Meeting of Stockholders will receive an equity grant on the date of such Annual Meeting of Stockholders (the “Annual Grant”) with a Value of \$425,000, which may be in the form of a mix of RSUs and stock options as chosen by the Outside Director; provided that there shall not be more than 25% of such value delivered in the form of RSUs. The portion of the Annual Grant delivered as a stock option shall have an exercise price per share equal to the closing price of a share of the Company’s common stock on the date of grant and a term of ten years, and shall vest in full on the earlier of (i) the one-year anniversary of the grant date or (ii) the next Annual Meeting of Stockholders. The portion of the Annual Grant delivered as RSUs shall vest in full on the earlier of (i) the one-year anniversary of the grant date or (ii) the next Annual Meeting of Stockholders. All vesting of the Annual Grant shall cease if the director resigns from our Board of Directors or otherwise ceases to serve as a director, unless the Board of Directors determines

that the circumstances warrant continuation of vesting. If a new Outside Director joins our Board of Directors on a date other than the date of the Company's Annual Meeting of Stockholders, then such Outside Director will be granted a pro-rata portion of the Annual Grant based on the time between such Outside Director's appointment and the next Annual Meeting of Stockholders, on the first eligible grant date following such Outside Director's appointment to our Board of Directors.

III. Expenses

The Company will reimburse all reasonable out-of-pocket expenses incurred by Outside Directors in attending meetings of the Board of Directors or any committee thereof.

IV. Maximum Annual Compensation

The aggregate amount of compensation, including both equity compensation and cash compensation, paid to any Outside Director in a calendar year period shall not exceed \$1,500,000 for the first year of service and \$1,000,000 for each year of service thereafter (or such other limits as may be set forth in Section 3(b) of the Stock Plan or any similar provision of a successor plan). For this purpose, the "amount" of equity compensation paid in a calendar year shall be determined based on the grant date fair value thereof, as determined in accordance with ASC 718 or its successor provision, but excluding the impact of estimated forfeitures related to service-based vesting conditions.

Date Amended and Restated Policy Approved: March 21, 2019, as amended March 27, 2020, April 28, 2021, and as further amended April 28, 2022.

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. P00013		3. EFFECTIVE DATE See Block 16c		4. REQUISITION/PURCHASE REQ. NO.	
6. ISSUED BY ASPR-BARDA 200 Independence Ave., S.W. Room 640-G Washington DC 20201		7. ADMINISTERED BY (If other than item 6) CODE US DEPT OF HEALTH & HUMAN SERVICES ASST SEC OF PREPAREDNESS & RESPONSE ACQ MANAGEMENT, CONTRACTS, & GRANTS O'NEILL HOUSE OFFICE BUILDING Washington DC 20515		5. PROJECT NO.(If applicable) ASPR-BARDA02	
8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code) MODERNATX, INC 1492235 Attn: [***] MODERNATX, INC. 200 TECHNOLOGY 200 TECHNOLOGY SQ CODE 1492235		(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 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) See Schedule					
13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACT S/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.					
A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.					
B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(B).					
C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:					
D. OTHER (Specify type of modification and authority) X FAR43.103(a) Mutual Agreement of both Parties					
E. IMPORTANT: Contractor is not, X is required to sign this document and return 1 copies to the issuing office.					
14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.) Tax ID Number: 27-0226313 DUNS Number: 069723520 1. The purpose of this no cost modification is to incorporate HHSAR Clause 352.232-71 -Electronic Submission of Payment Requests (FEB 2022), into Section I of the contract and to update invoice instructions in Section G.4 of the contract. The total amount, scope, period of performance and all other terms and conditions of the contract remain unchanged. By signing this modification, Modernatx hereby releases the Government from any and all liability under this contract for further equitable adjustments attributable to such fact or circumstance giving rise to this modification. Continued ... Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.					
15A. NAME AND TITLE OF SIGNER (Type or print) [***]		16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print) [***]			
15B. CONTRACTOR/OFFEROR [***] (Signature of person authorized to sign)		15C. DATE SIGNED 5/24/2022		16B. UNITED STATES OF AMERICA (Signature of Contracting Officer)	
				16C. DATE SIGNED	

CONTINUATION SHEET	REFERENCE NO. OF DOCUMENT BEING CONTINUED 75A50120C00034/P00013	PAGE OF 2 5
---------------------------	--	------------------

NAME OF OFFEROR OR CONTRACTOR
MODERNATX, INC 1492235

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	Period of Performance: 04/03/2020 to 08/31/2023				

--	--	--	--

OPTIONAL FORM 336 (4-86)
Sponsored by GSA
FAR (48 CFR) 53.110

The following is hereby inserted into Section G Contract Administration Data of the contract as an additional clause or as a modification to an existing clause for Invoice Instructions:

Section G – Contract Administration:

G. 4 – Invoice Submission is replaced by the following:

Electronic Invoicing and Payment Requirements - Invoice Processing Platform (IPP)

- All Invoice submissions for goods and or services delivered to facilitate payments must be made electronically through the U.S. Department of Treasury's Invoice Processing Platform System (IPP).
- Invoice Submission for Payment means any request for contract financing payment or invoice payment by the Contractor. To constitute a proper invoice, the payment request must comply with the requirements identified in the applicable Prompt Payment clause included in the contract, or the clause 52.212-4 Contract Terms and Conditions – Commercial Items included in commercial items contracts. The IPP website address is: <https://www.ipp.gov>.
- The Agency will enroll the Contractors new to IPP. The Contractor must follow the IPP registration email instructions for enrollment to register the Collector Account for submitting invoice requests for payment. The Contractor Government Business Point of Contact (as listed in SAM) will receive Registration email from the Federal Reserve Bank of St. Louis (FRBSTL) within 3 – 5 business days of the contract award for new contracts or date of modification for existing contracts.
- Registration emails are sent via email from ipp.noreply@mail.eroc.twai.gov. Contractor assistance with enrollment can be obtained by contacting the IPP Production Helpdesk via email to IPPCustomerSupport@fiscal.treasury.gov or phone (866) 973-3131.
- The Contractor POC will receive two emails from **IPP Customer Support**, the first email contains the initial administrative IPP User ID. The second email, sent within 24 hours of receipt of the first email, contains a temporary password. You must log in with the temporary password within 30 days.
- If your company is already registered to use IPP, you will not be required to reregister.
- If the Contractor is unable to comply with the requirement to use IPP for submitting invoices for payment as authorized by HHSAR 332.7002, a written request must be submitted to the Contracting Officer to explain the circumstances that require the authorization of alternate payment procedures.

Additional Office of the Assistant Secretary for Preparedness and Response (ASPR) requirements:

- (i) The contractor shall submit invoices under this contract once per month. For indefinite delivery vehicles, separate invoices must be submitted for each order.

(ii) Invoices must break-out price/cost by contract line item number (CLIN) as specified in the pricing section of the contract.

(iii) Invoices must include the Dun & Bradstreet Number (DUNS) of the Contractor.

(iv) Invoices that include time and materials or labor hours CLINS must include supporting documentation to (1) substantiate the number of labor hours invoiced for each labor category, and (2) substantiate material costs incurred (when applicable).

(v) Invoices that include cost-reimbursement CLINs must be submitted in a format showing expenditures for that month, as well as contract cumulative amounts.

At a minimum the following cost information shall be included, in addition to supporting documentation to substantiate costs incurred.

- Direct Labor - include all persons, listing the person's name, title, number of hours worked, hourly rate, the total cost per person and a total amount for this category;
 - Indirect Costs (i.e., Fringe Benefits, Overhead, General and Administrative, Other Indirects)- show rate, base and total amount;
 - Consultants (if applicable) - include the name, number of days or hours worked, daily or hourly rate, and a total amount per consultant;
 - Travel - include for each airplane or train trip taken the name of the traveler, date of travel, destination, the transportation costs including ground transportation shown separately and the per diem costs. Other travel costs shall also be listed;
 - Subcontractors (if applicable) - include, for each subcontractor, the same data as required for the prime Contractor;
 - Other Direct Costs - include a listing of all other direct charges to the contract, i.e., office supplies, telephone, duplication, postage; and
 - Fee – amount as allowable in accordance with the Schedule and FAR 52.216-8 if applicable.
- (End)

SECTION I – CONTRACT CLAUSES

a. The following is hereby incorporated by full text, at no additional cost to the Government, into Section I:

SECTION I – Contract Clauses

HHSAR 352.232-71 Electronic Submission of Payment Requests (FEB 2022)

(a) Definitions. As used in this clause—

Payment request means a bill, voucher, invoice, or request for contract financing payment with associated supporting documentation. The payment request must comply with the requirements identified in FAR 32.905(b), “Content of Invoices” and the applicable Payment clause included in this contract.

(b) Except as provided in paragraph (c) of this clause, the Contractor shall submit payment requests electronically using the Department of Treasury Invoice Processing Platform (IPP) or successor system. Information regarding IPP, including IPP Customer Support contact

information, is available at www.ipp.gov or any successor site.

(c) The Contractor may submit payment requests using other than IPP only when the Contracting Officer authorizes alternate procedures in writing in accordance with HHS procedures.

(d) If alternate payment procedures are authorized, the Contractor shall include a copy of the Contracting Officer's written authorization with each payment request.

(end)

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 and confidential.

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT			1. CONTRACT ID CODE	PAGE OF PAGES 1 14	
2. AMENDMENT/MODIFICATION NO. P00024		3. EFFECTIVE DATE 30-JUN-2022	4. REQUISITION/PURCHASE REQ. NO. SEE SCHEDULE		5. PROJECT NO.(If applicable)
6. ISSUED BY CODE ACC-APG - COVID RESPONSE - W58P05 6472 INTEGRITY COURT (BUILDING 4401) ABERDEEN PROVING GROUND MD 21005-3013		W58P05	7. ADMINISTERED BY (If other than item 6) CODE 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) See Schedule					
13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT /ORDER NO. AS DESCRIBED IN ITEM 14.					
	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.				
	B. THE ABOVE NUMBERED CONTRACT /ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(B).				
X	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF: FAR 43.103(a)(3), Mutual Agreement of the Parties				
	D. OTHER (Specify type of modification and authority)				
E. IMPORTANT: Contractor is not, X is required to sign this document and return 1 copies to the issuing office.					
14. DESCRIPTION OF AMENDMENT /MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.) Modification Control Number: [***] 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 6/30/2022	16B. UNITED STATES OF AMERICA By: [***] (Signature of Contracting Officer)		16C. DATE SIGNED 30-JUN-2022	

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:

P00024

OBLIGATION AMOUNT: \$4,846,475.52

a. The purpose of this modification (P00024) is to:

(1) Create and fund CLIN 0007 for the extension of VMI storage and distribution

(2) Update the Statement of Work (SOW) to reflect an extension to Vendor Managed Inventory (VMI) storage and the organization change from Operation Warp Speed (OWS) to HHS Coordination Operations and Response Element (HCORE). Government acknowledges product expiry is currently being evaluated and agree fee for destruction of expired product will be negotiated prior to disposal.

(3) Update FAR 52.217-9(c): contract not to exceed [***]

b. This modification was requested by the program office to meet the Government's COVID-19 National Response Strategy.

c. The total value contract has increased by \$4,846,475.52 from \$8,218,794,804.60 to \$8,223,641,280.12. The total funded amount has increased by \$4,846,475.52 from \$8,182,294,804.60 to \$8,187,141,280.12.

All other terms and conditions remain unchanged.

SECTION A - SOLICITATION/CONTRACT FORM

The total cost of this contract was increased by \$4,846,475.52 from \$8,218,794,804.60 to \$8,223,641,280.12.

SECTION B - SUPPLIES OR SERVICES AND PRICES

CLIN 0007 is added as follows:

ITEM NO	SUPPLIES/SERVICES	QUANTITY	UNIT	UNIT PRICE	AMOUNT
0007		12	Months	\$403,872.96	\$4,846,475.52
	VMI and Distribution Extension FFP a. The contractor shall secure, manage and maintain storage for up to 100M doses of mRNA-1273 vaccine and deliver to the designated government facility in accordance with Section F. FOB: Destination PURCHASE REQUEST NUMBER: 0011814533 PSC CD: 6505				
				NET AMT	\$4,846,475.52
					\$4,846,475.52
	ACRN AP CIN: GFEB001181453300001				

SECTION C - DESCRIPTIONS AND SPECIFICATIONS

The following have been modified:

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

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

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

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

USG supports large scale manufacturing so that vaccine doses or therapeutic treatment courses are immediately available for nationwide access as soon as a positive efficacy signal is obtained and the medical countermeasures are authorized for widespread use.

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

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

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

C.1.3 Consistent with the Updated EUA Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) dated 01 April 2021, up to 15 doses may be extracted from Moderna's newly authorized multidose vials with 8.0mL fill volume (1600mcg). The Government and Moderna agree that 15 doses per vial are only attainable using premium low dead volume (LDV) syringes, which are in short supply globally. Utilizing initial ancillary equipment, vaccine administration personnel can reliably extract 13 doses from these vials; however, the Government has identified needle/syringe combinations that can be used to extract 14 doses.

C.1.3.1 Given the two parties' shared interest in reducing vaccine waste and accelerating the availability of Moderna's SARS-CoV-2 vaccine doses, the Government and Moderna intend that the Moderna vaccines doses be administered with needles and syringes compatible with extraction of 14 doses when possible. Toward this end, the Government shall maintain a list of syringe and/or needle combinations which will allow extraction of 14 doses per 8.0mL vial, which list shall be updated jointly by the Government and Moderna as any additional syringe and/or needle combinations compatible with extraction of 14 doses/vial are identified. Furthermore, the Government will, to the extent that appropriate needles and syringes are available, assemble and ship kits containing sufficient quantities of syringes and needles compatible with extraction of 14 doses per vial (Kit Moderna 140) with Moderna's SARS-CoV-2 vaccine. The Government expects that these kits will be available beginning 01 May 2021 for a significant portion of Moderna's remaining deliveries. If, however, appropriate syringes and needles are not available, the Government will revert to shipping the Kit Moderna 130 with Moderna's SARS-CoV-2 vaccine.

C.2 **APPLICABLE DOCUMENTS.**

C.2.1 Federal Documents:

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

C.3 **REQUIREMENTS.** Independently, and not as an agent of the USG, in accordance with the Proposal submitted by Moderna US, Inc. in response to Solicitation Number W911QY20R0043, Titled, "Advanced Procurement of mRNA-1273 Vaccine for Prevention of SARS-CoV-2 Coronavirus (COVID-19)", dated July 10, 2020 (and any subsequent USG-approved revisions thereto), the contractor shall provide all necessary services, qualified personnel, material, equipment and facilities (not otherwise provided by the USG under the terms of this contract) to perform the specific tasks set forth below.

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

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

C.3.1.1.1 Storage of FDP doses prior to delivery consistent with all FDA requirements to ensure that the product remains available for use in target populations. Storage and maintenance of the vaccine prior to delivery shall be under conditions and at temperatures necessary to retain stability for use as prescribed in this contract for a period of 12 months. (Based on FDP stability data that supports a 120month shelf-life, subject to FDA confirmation of the assigned shelf-life.) Ensure requirements of 21CFR207, Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution are met prior to distribution to the CDC. Documents shall be provided under CDRL A002, FDA Interactions and Inspections Documentation.

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

C.3.1.1.3 Ensuring that vial labeling and packaging is consistent with FDA guidance for use in target populations and that labeling is updated as appropriate.

C.3.1.1.4 Coordinating with FDA to establish an approved commercial vial label, carton and packaging insert (printed or electronic).

C.3.1.1.5 Ensuring the product complies with the Drug Supply Chain Security Act (DSCSA), Sections 581-585 of PL 113-54 (Nov. 27, 2013), including product verification, serialization, traceability and detection and response requirements, subject to any exceptions established by or the enforcement discretion of the FDA, including "Exemption from Certain Product Tracing and Product Identification Requirements Under Section 582 of the FD&C Act" (April 2020).

C.3.1.1.6 In coordination with the USG, the contractor shall conduct a demonstration of the vaccine shipping process prior to the first delivery of FDP doses at a time mutually agreed to by the contractor and the USG. Moderna shall provide specifications and details associated with the shipping process and containers (IAW CDRL A005) to enable the USG to adequately plan and prepare for potential distribution of the vaccine.

C.3.1.1.7 Following release of product the contractor shall, promptly deliver product to the designated delivery site via a qualified distribution vendor in accordance with Section F and paragraph C.7 below. In the unforeseen event that a designated delivery site cannot receive product and the contractor provides storage beyond 20 days of product release, the contract will be subject to modification for acceptance purposes.

C.3.1.2 Site Visits and Audits. The contractor shall accommodate periodic or ad hoc site visits by BARDA and FDA representatives for required site visits and audits at facilities used to support this contract throughout the period of performance of the contract.

C.3.1.2.1 BARDA Audits. If issues are identified during an audit, the contractor shall submit a report detailing the finding and corrective action(s) in accordance with CDRL A001.

C.3.1.2.2 FDA Audits. The Contractor shall notify the Contracting Officer and Contracting Officer's Representative (COR) within [***] of a scheduled FDA audit or within [***] of an ad hoc site visit or audit if the FDA does not provide advance notice. The contractor shall provide copies of any FDA Audit Report received from subcontractors that occur as a result of this contract or for this product within [***] of receiving correspondence from the FDA or third party in accordance with CDRL A002. The Contractor shall provide

the Contracting Officer with a plan for addressing areas of nonconformance, if any are identified, within [***] of submittal of the audit report in accordance with CDRL A002.

C.3.1.2.3 FDA Interactions. The contractor shall provide copies of the plan and processes that will ensure the USG has visibility and input on all FDA communications regarding the drugs and biologics for the following, but not limited to: FDA interactions, FDA meetings, communications, submissions, inspections, and enforcement documentation in accordance with CDRL A002.

C.3.2 CLIN 1001 - Option Period 1: Large Scale Manufacturing of 100 Million Vaccine Doses.

C.3.2.1 The contractor shall complete all scope required for the production, release and delivery use of 100 million FDP doses of a SARS-CoV-2 mRNA-1273 vaccine. This shall include the following tasks and other activities reasonably contemplated by such tasks:

C.3.2.1.1 Storage of FDP doses prior to delivery consistent with all FDA requirements to ensure that the product remains available for use in target populations. Storage and maintenance of the vaccine prior to delivery shall be under conditions and at temperatures necessary to retain stability for use as prescribed in this contract for a period of 12 months. (Based on FDP stability data that supports a 12-month shelf-life, subject to FDA confirmation of the assigned shelf-life.) Ensure requirements of 21CFR207, Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution are met prior to distribution to the CDC. Documents shall be provided under CDRL A002, FDA Interactions and Inspections Documentation.

C.3.2.1.2 cGMP manufacturing of 100 million doses, subject to any exceptions established by or the enforcement discretion of the FDA.

C.3.2.1.3 Ensuring that vial labeling and packaging is consistent with FDA guidance for use in target populations and that labeling is updated.

C.3.2.1.4 Ensuring the product complies with the Drug Supply Chain Security Act (DSCSA), Sections 581-585 of PL 113-54 (Nov. 27, 2013), including product verification, serialization, traceability and detection and response requirements subject to any exceptions established by or the enforcement discretion of the FDA.

C.3.2.1.5 Following release of the product the contractor shall deliver the product to the designated distribution site via a qualified distribution vendor in accordance with Section F and paragraph C.7 below. To the extent a natural disaster or other emergency affecting a designated delivery site restricts such site's ability to receive product, the Contractor and the USG will promptly agree on an alternate USG delivery location, or storage as Vendor Managed Inventory (VMI) at the contractor site.

C.3.2.2 Site Visits and Audits. The contractor shall accommodate periodic or ad hoc site visits by BARDA and FDA representatives for required site visits and audits at facilities used to support this contract throughout the period of performance of the contract.

C.3.2.2.1 BARDA Audits. If issues are identified during an audit, the contractor shall submit a report detailing the finding and corrective action(s) in accordance with CDRL A001.

C.3.2.2.2 FDA Audits. The Contractor shall notify the Contracting Officer and COR within [***] of a scheduled FDA audit or within [***] of an ad hoc site visit or audit if the FDA does not provide advance notice. The contractor shall provide copies of any FDA Audit Report received from subcontractors that occur as a result of this contract or for this product within [***] of receiving correspondence from the FDA or third party in accordance with CDRL A015. The Contractor shall provide the Contracting Officer with a plan for addressing areas of nonconformance, if any are identified, within [***] of submittal of the audit report in accordance with CDRL A002.

C.3.2.2.3 FDA Interactions. The contractor shall provide copies of the plan and processes that will ensure the USG has visibility and input on all FDA communications regarding the drugs and biologics for the following, but not limited to: FDA interactions, FDA meetings, communications, submissions, inspections, and enforcement documentation in accordance with CDRL A002.

C.3.3 CLIN 2001 - Option Period 2: Large Scale Manufacturing of 100 Million Vaccine Doses.

C.3.3.1 The contractor shall complete all scope required for the production, release and delivery use of 100 million FDP doses of a SARS-CoV-2 mRNA-1273 vaccine. This shall include the following tasks and other activities reasonably contemplated by such tasks:

C.3.3.1.1 Storage of FDP doses prior to delivery consistent with all FDA requirements to ensure that the product remains available for use in target populations. Storage and maintenance of the vaccine prior to delivery shall be under conditions and at temperatures necessary to retain stability for use as prescribed in this contract for a period of 12 months. (Based on FDP stability data that supports a 12-month shelf-life, subject to FDA confirmation of the assigned shelf-life.) Ensure requirements of 21CFR207, Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution are met prior to distribution to the CDC. Documents shall be provided under CDRL A002, FDA Interactions and Inspections Documentation.

C.3.3.1.2 cGMP manufacturing of 100 million doses, subject to any exceptions established by or the enforcement discretion of the FDA.

C.3.3.1.3 Ensuring that vial labeling and packaging is consistent with FDA guidance for use in target populations and that labeling is updated as appropriate.

C.3.3.1.4 Ensuring that the product complies with the Drug Supply Chain Security Act (DSCSA), Sections 581-585 of PL 113-54 (Nov. 27, 2013), including product verification, serialization, traceability and detection and response requirements, subject to any exceptions established by or the enforcement discretion of the FDA.

C.3.3.1.5 Following release the contractor shall deliver product to the nearest designated distribution site via a qualified distribution vendor in accordance with Section F and paragraph C.7 below. To the extent a natural disaster or other emergency affecting a designated delivery site restricts such site's ability to receive product, the Contractor and the USG will promptly agree on an alternate USG delivery location, or storage as Vendor Managed Inventory (VMI) at the contractor site.

C.3.3.2 Site Visits and Audits. The contractor shall accommodate periodic or ad hoc site visits by BARDA and FDA representatives for required site visits and audits at facilities used to support this contract throughout the period of performance of the contract.

C.3.3.2.1 BARDA Audits. If issues are identified during an audit, the contractor shall submit a report detailing the finding and corrective action(s) in accordance with CDRL A001.

C.3.3.2.2 FDA Audits. The Contractor shall notify the Contracting Officer and COR within [***] of a scheduled FDA audit or within [***] of an ad hoc site visit or audit if the FDA does not provide advance notice. The contractor shall provide copies of any FDA Audit Report received from subcontractors that occur as a result of this contract or for this product within [***] of receiving correspondence from the FDA or third party in accordance with CDRL A002. The Contractor shall provide the Contracting Officer with a plan for addressing areas of nonconformance, if any are identified, within [***] of submittal of the audit report in accordance with CDRL A002.

C.3.3.2.3 FDA Interactions. The contractor shall provide copies of the plan and processes that will ensure the USG has visibility and input on all FDA communications regarding the drugs and biologics for the following, but not limited to: FDA interactions, FDA meetings, communications, submissions, inspections, and enforcement documentation in accordance with CDRL A002.

C.3.4 **CLIN 3001 - Option Period 3: Large Scale Manufacturing of 100 Million Vaccine Doses.**

C.3.4.1 The contractor shall complete all scope required for the production, release and delivery use of 100 million FDP doses of a SARS-CoV-2 mRNA-1273 vaccine. This shall include the following tasks and other activities reasonably contemplated by such tasks:

C.3.4.1.1 Storage of FDP doses prior to delivery consistent with all FDA requirements to ensure that the product remains available for use in target populations. Storage and maintenance of the vaccine prior to delivery shall be under conditions and at temperatures necessary to retain stability for use as prescribed in this contract per C.7 for a period of 12 months. (Based on FDP stability data that supports a 12-month shelf-life, subject to FDA confirmation of the assigned shelf-life.) Ensure requirements of 21CFR207, Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution are met prior to distribution to the CDC. Documents shall be provided under CDRL A002, FDA Interactions and Inspections Documentation.

C.3.4.1.2 cGMP manufacturing of 100 million doses, subject to any exceptions established by or the enforcement discretion of the FDA.

C.3.4.1.3 Ensuring that vial labeling and packaging is consistent with FDA guidance for use in target populations and that labeling is updated.

C.3.4.1.4 Ensuring the product complies with the Drug Supply Chain Security Act (DSCSA), Sections 581-585 of PL 113-54 (Nov. 27, 2013), including product verification, serialization, traceability and detection and response requirements subject to any exceptions established by or the enforcement discretion of the FDA.

C.3.4.1.5 Following release of the product the contractor shall deliver the product to the designated distribution site via a qualified distribution vendor in accordance with Section F and paragraph C.7 below. To the extent a natural disaster or other emergency affecting a designated delivery site restricts such site's ability to receive product, the Contractor and the USG will promptly agree on an alternate USG delivery location, or storage as Vendor Managed Inventory (VMI) at the contractor site.

C.3.4.2 Site Visits and Audits. The contractor shall accommodate periodic or ad hoc site visits by BARDA and FDA representatives for required site visits and audits at facilities used to support this contract throughout the period of performance of the contract.

C.3.4.2.1 BARDA Audits. If issues are identified during an audit, the contractor shall submit a report detailing the finding and corrective action(s) in accordance with CDRL A001.

C.3.4.2.2 FDA Audits. The Contractor shall notify the Contracting Officer and COR within [***] of a scheduled FDA audit or within [***] of an ad hoc site visit or audit if the FDA does not provide advance notice. The contractor shall provide copies of any FDA Audit Report received from subcontractors that occur as a result of this contract or for this product within [***] of receiving correspondence from the FDA or third party in accordance with CDRL A015. The Contractor shall provide the Contracting Officer with a plan for addressing areas of nonconformance, if any are identified, within [***] of submittal of the audit report in accordance with CDRL A002.

C.3.4.2.3 FDA Interactions. The contractor shall provide copies of the plan and processes that will ensure the USG has visibility and input on all FDA communications regarding mRNA-1273 for the following, but not limited to:

FDA interactions, FDA meetings, communications, submissions, inspections, and enforcement documentation in accordance with CDRL A002.

C.3.5 CLIN 4001 - Option Period 4: Large Scale Manufacturing of 100 Million Vaccine Doses.

C.3.5.1 The contractor shall complete all scope required for the production, release and delivery use of 100 million FDP doses of a SARS-CoV-2 mRNA-1273 vaccine. This shall include the following tasks and other activities reasonably contemplated by such tasks:

C.3.5.1.1 Storage of FDP doses prior to delivery consistent with all FDA requirements to ensure that the product remains available for use in target populations. Storage and maintenance of the vaccine prior to delivery shall be under conditions and at temperatures necessary to retain stability for use as prescribed in this contract per C.7 for a period of 12 months. (Based on FDP stability data that supports a 12-month shelf-life, subject to FDA confirmation of the assigned shelf-life.) Ensure requirements of 21CFR207, Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution are met prior to distribution to the CDC. Documents shall be provided under CDRL A002, FDA Interactions and Inspections Documentation.

C.3.5.1.2 cGMP manufacturing of 100 million doses, subject to any exceptions established by or the enforcement discretion of the FDA.

C.3.5.1.3 Ensuring that vial labeling and packaging is consistent with FDA guidance for use in target populations and that labeling is updated.

C.3.5.1.4 Ensuring the product complies with the Drug Supply Chain Security Act (DSCSA), Sections 581-585 of PL 113-54 (Nov. 27, 2013), including product verification, serialization, traceability and detection and response requirements subject to any exceptions established by or the enforcement discretion of the FDA.

C.3.5.1.5 Following release of the product the contractor shall deliver the product to the designated distribution site via a qualified distribution vendor in accordance with Section F and paragraph C.7 below. To the extent a natural disaster or other emergency affecting a designated delivery site restricts such site's ability to receive product, the Contractor and the USG will promptly agree on an alternate USG delivery location, or storage as Vendor Managed Inventory (VMI) at the contractor site.

C.3.5.2 Site Visits and Audits. The contractor shall accommodate periodic or ad hoc site visits by BARDA and FDA representatives for required site visits and audits at facilities used to support this contract throughout the period of performance of the contract.

C.3.5.2.1 BARDA Audits. If issues are identified during an audit, the contractor shall submit a report detailing the finding and corrective action(s) in accordance with CDRL A001.

C.3.5.2.2 FDA Audits. The Contractor shall notify the Contracting Officer and COR within [***] of a scheduled FDA audit or within [***] of an ad hoc site visit or audit if the FDA does not provide advance notice. The contractor shall provide copies of any FDA Audit Report received from subcontractors that occur as a result of this contract or for this product within [***] of receiving correspondence from the FDA or third party in accordance with CDRL A015. The Contractor shall provide the Contracting Officer with a plan for addressing areas of nonconformance, if any are identified, within [***] of submittal of the audit report in accordance with CDRL A002.

C.3.5.2.3 FDA Interactions. The contractor shall provide copies of the plan and processes that will ensure the USG has visibility and input on all FDA communications regarding the drugs and biologics for the following, but not limited to: FDA interactions, FDA meetings, communications, submissions, inspections, and enforcement documentation in accordance with CDRL A002.

C.4 **CLIN 0002: Data Deliverables.** The contractor shall provide the following in accordance with the Contract Data Requirements List (CDRL), DD Forms 1423, provided at Appendix A.

C.4.1 Monthly Inventory Report (CDRL A003), detailing at a minimum, raw materials, formulated LNPs, and the fill, finish, and released product.

C.4.2 Quality Management Plan. The contractor shall provide a Quality Management Plan, in accordance with CDRL A004, describing the quality policy and objectives, management review, competencies and training, process document control, feedback, evaluation, corrective action and preventive action, process improvement, measurement, and data analysis processes. The framework is normally divided into infrastructure, senior management responsibility, resource management, lifecycle management, and quality management system evaluation.

C.4.3 Shipping Documentation (CDRL A005) for all Finished Drug Product (FDP) transferring from the contractor's fill/finish facility to a USG facility. The contractor shall obtain concurrence on planned shipment protocols prior to transport.

C.4.4 Expiring Items Report (CDRL A006) for all FDP in the USG's possession.

C.4.5 Key Personnel Listing (CDRL A007).

C.4.6 Monthly Technical Progress Report (CDRL A008), to include an Integrated Master Schedule, identifying key activities and contract status.

C.4.7 Final Technical Report (CDRL A009), documenting the work performed and results obtained for the entire contract period of performance.

C.4.8 Supply Chain Resiliency Plan (SCRp). The contractor shall provide, in accordance with CDRL A010 and CDRL Attachment 0001, a comprehensive SCRp that provides for identification and reporting of critical components associated with the secure supply of drug substance, drug product, and work-in-process through to finished goods, and key equipment suppliers and their locations, including addresses, points of contact, and work performed per location, to include subcontractors.

C.4.9 Risk Management Plan (RMP). The Contractor shall provide an RMP in accordance with CDRL A011 that outlines the impacts of each risk in relation to the cost, schedule, and performance objectives. The plan shall include risk mitigation strategies. Each risk mitigation strategy shall capture how the corrective action will reduce impacts on cost, schedule and performance. The following RMP information shall be included in the Monthly Technical Progress Report (CDRL A008).

Risk Register content:

- a. Manuf/FF-risks or possible delays. If none N/A
- b. Supply chain – same as above
- c. Distribution challenges – same as above
- d. Regulatory – same as above

C.4.10 Manufacturing Reports and Dose Tracking. The Contractor shall provide, in accordance with CDRL A013, manufacturing reports and manufacturing dose tracking projections and actuals utilizing the USG-provided "COVID-19 Dose Tracking Template" (CDRL Attachment 0003).

C.4.11 Product Acceptance Report (for each lot of Drug Product). The contractor shall provide, in accordance with CDRL A014, pictures of the drug product with lot number, drug product lot tree, list of associated deviations (from drug substance and product), and a Certificate of Analysis.

C.4.12 Incident Report. The contractor shall communicate to BARDA and document all critical programmatic concerns, issues, or probable risks that have or are likely to significantly impact project schedule and/or cost and/or performance in accordance with CDRL A016. "Significant" is frequently defined as a 10% or greater cost or schedule variance within a control account, but should be confirmed in consultation with the COR. Incidents that present liability to the project even without cost/schedule impact, such as breach of GCP during a clinical study, shall also be reported.

C.4.13 FDA Correspondence. The contractor shall provide any correspondence between Contractor and FDA relevant to the scope of this contract and submit in accordance with CDRL A017.

C.4.14 Press Releases. The contractor shall accurately and factually represent the work conducted under this contract in all press releases. The contractor shall provide an advance copy of any press release in accordance with CDRL A018.

C.4.15 Manufacturing Development Plan. The contractor shall provide a Manufacturing Development Plan, in accordance with CDRL A025, describing the manufacturing process for the drug/biologic product to ensure conformity with §501(a)(2)(B) of the Food, Drug, and Cosmetics Act (FD&C Act, Title 21 United States Code (USC) §351 (a)(2)(B)), regarding good manufacturing practices (GMP).

C.5 Administration.

C.5.1 Post Award Teleconference. The contractor shall host a Post Award Teleconference within 15 calendar days after contract award.

C.5.1.1 The contractor shall provide an Agenda, IAW CDRL A020, detailing the planned activities for the subsequent 30 calendar days and shall discuss agenda items for the Post Award Kickoff Meeting.

C.5.1.2 The contractor shall provide Meeting Minutes IAW CDRL A021.

C.5.2 Post Award Kickoff Meeting. The contracting officer may request the contractor host a contract Kick-Off Meeting within 30 calendar days after contract award via teleconference. The contracting officer shall establish the date and time of the conference and prepare the agenda to include discussion on contract activities and schedule.

C.5.3 Bi-Weekly Teleconference. The contractor shall participate in bi-weekly teleconferences (or more frequent meetings required by the USG if warranted based on contract activities) to discuss performance on the contract.

C.5.4 The contractor shall provide an Agenda, IAW CDRL A020; Meeting Minutes in accordance with CDRL A021; and, Presentation Material in accordance with CDRL A022 for each of the aforementioned teleconferences or meetings throughout the contract period of performance.

C.5.5 Daily "Check-In". The contractor shall participate in a daily "check-in" (via teleconference or email) to address key cost, schedule and technical updates. Daily updates may be shared with senior USG leaders during the COVID- 19 response and should be provided on a non-confidential basis, unless the update includes confidential information in which case, the contractor shall provide the update in both confidential and non-confidential formats. Daily check-ins may occur on weekdays, excluding federal holidays. Upon request of the USG, check-ins may also occur on weekends and on federal holidays, provided at least 24 hours' notice.

C.6 Security.

C.6.1 Access and General Protection/Security Policy and Procedures. The contractor shall provide all information required for background checks necessary to access critical information related to HCore, and to meet USG installation access requirements to be accomplished by the installation Director of Emergency Services or Security Office. The contractor employees shall comply with all personnel identity verification requirements as directed by the USG and/or local policy. In addition to the changes otherwise authorized by the changes clause of this contract, should the security status of HCore change the USG may require changes in the contractor's security matters or processes. In addition to the industry standards for employment background checks, the contractor shall be willing to have key individuals, in exceptionally sensitive positions, identified for additional vetting by the United States USG.

C.6.2 Security Program and Plan. The contractor shall implement a comprehensive security program that provides overall protection of personnel, information, data, and facilities associated with fulfilling the USG's requirement. The contractor's security practices and procedures shall be detailed in a Security Plan, in accordance with CDRL A019, and shall demonstrate how the contractor shall meet and adhere to the security requirements outlined in CDRL Attachment 0002. This plan shall be delivered to the USG within 45 days of award, and the USG will review in detail and submit comments within ten (10) business days to the Contracting Officer (CO) to be forwarded to the Contractor. The Contractor shall review the Security Plan comments, and submit a final Security Plan to the U.S. USG within thirty (30) calendar days after receipt of the comments. The Security Plan shall include a timeline for compliance of all the required security measures outlined in CDRL Attachment 0002.

C.6.3 Operational Security (OPSEC). The contractor shall develop and submit an OPSEC Standard Operating Procedure (SOP)/Plan IAW CDRL A024. The contractor shall identify in the SOP/Plan critical information related to this contract, why it needs to be protected, where it is located, who is responsible for it, and how to protect it.

C.7 Vendor Managed Inventory (VMI). The Contractor shall provide the capability to store the vaccine until 30 June 2023 to support storage for product delivered for Options 3 and 4. This request for up to 100M doses, will require up to [***] pallets of storage of [***] and [***]. The requirement is up to 100M doses of mRNA- 1273 vaccine, in accordance with product labeling and requirements for each product type. The contractor shall, in accordance with paragraph C.3.1.1.6, ensure the product storage of FDP doses for up to 12 months prior to delivery consistent with all FDA requirements to ensure that the product remains available for use in target populations. [***]. The contractor shall store the product to ensure product quality with audible alarms and contacting. The contractor shall notify the USG within [***] of detection of an incident with the potential to impact product quality and implement corrective actions to mitigate the incident. BARDA/JPEO- CBRND personnel may conduct Quality Audits of the storage facility, when deemed necessary. The contractor shall notify the USG of Corrective/Preventive actions within [***] of detection of an incident with potential to impacts product quality. BARDA/JPEO-CBRND personnel may conduct Quality Audits of the storage facility, when deemed necessary.

C.7.1 The USG will provide the contractor advance notice of the required delivery locations for the vaccine. The contractor shall ship mRNA-1273 vaccines to designated locations [***] in the United States. The contractor shall be responsible for shipment of all vaccine product whether acceptance is conducted at origin or destination. [***].

C.7.2 The vaccine product shall be shipped and tracked by the distribution vendor's shipping tracking number, to the USG-designated sites within the continental United States.

C.7.3 [***]. Implementation of a Vendor Managed Inventory Plan/SOP

(CDRL A012) shall be provided to the USG. [***]. Notwithstanding either of the foregoing sentences, the contractor shall not be liable for loss of or damage to supplies caused by the negligence of officers, agents, or employees of the USG acting within the scope of their employment.

SECTION E - INSPECTION AND ACCEPTANCE

The following Acceptance/Inspection Schedule was added for CLIN 0007:

INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
Destination	Government	Destination	Government

SECTION F - DELIVERIES OR PERFORMANCE

The following Delivery Schedule for CLIN 0007 has been added:

DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	ODAAC / CAGE
POP 01-JUL-2022 TO 30-JUN-2023	N/A	N/A FOB: Destination	

SECTION G - CONTRACT ADMINISTRATION DATA

Accounting and Appropriation Summary for the Payment

Office

As a result of this modification, the total funded amount for this document was increased by \$4,846,475.52 from \$8,182,294,804.60 to \$8,187,141,280.12.

CLIN 0007:

Funding on CLIN 0007 is initiated as follows:

ACRN: AP

CIN: GFEB001181453300001

Acctng Data: 0212021202220400000665654260 S.0074658.5.44 6100.0152021001

Increase: \$4,846,475.52

Total: \$4,846,475.52

Cost Code: A5XAH

SECTION I - CONTRACT CLAUSES

The following have been modified:

52.217-9 OPTION TO EXTEND THE TERM OF THE CONTRACT (MAR 2000)

(a) The Government may extend the term of this contract by written notice to the Contractor within [***] for; provided that the Government gives the Contractor a preliminary written notice of its intent to extend at least [***] for Options 1 and 2, [***] for Option 3 and 4 before the contract expires. The preliminary notice does not commit the Government to an extension.

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

(c) The total duration of this contract, including the exercise of any options under this clause, shall not exceed [***].

(End of clause)

(End of Summary of Changes)

**CERTIFICATION PURSUANT TO RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

CERTIFICATIONS

I, Stéphane Bancel, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Moderna, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 3, 2022

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

**CERTIFICATION PURSUANT TO RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

CERTIFICATIONS

I, David W. Meline, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Moderna, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 3, 2022

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

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350
AS ADOPTED PURSUANT TO SECTION 906
OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report on Form 10-Q of Moderna, Inc. (the “Company”) for the period ended June 30, 2022 as filed with the Securities and Exchange Commission on the date hereof (the “Report”), we, Stéphane Bancel, Chief Executive Officer of the Company, and David W. Meline, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of our knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 3, 2022

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

Date: August 3, 2022

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