
**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, 2024

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission File Number: 001-38753



Moderna, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Delaware

81-3467528

(State or Other Jurisdiction of Incorporation or
Organization)

(IRS Employer
Identification No.)

325 Binney Street

Cambridge, Massachusetts

02142

(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 26, 2024, there were 384,396,030 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 that we may develop, including in response to variants of the SARS-CoV-2 virus, ongoing clinical development, manufacturing and supply, pricing, commercialization, regulatory matters (including authorization or approval for updated vaccines), demand for COVID-19 vaccines, our provisions for product returns, and third-party and governmental arrangements and potential arrangements;
- our expectations regarding the endemic and seasonal commercial market for COVID-19 vaccines and our preparations for and ability to effectively compete in such a market, as well as the impact that the evolving market will have on our financial returns;
- expected sales and delivery of our COVID-19 vaccine in future periods, and expected seasonality for sales;
- stability and storage conditions for our next-generation COVID-19 vaccine (mRNA-1283), and its potential as a component for a commercial combination vaccine;
- our expectations regarding commercialization of our respiratory syncytial virus (RSV) vaccine candidate (mRNA-1345), including anticipated demand, competition and further regulatory approvals for this product;
- financing and funding options we may consider as part of our research and development strategy;
- our ability to successfully contract with third-party suppliers, distributors and manufacturers;
- our ability and the ability of third parties with whom we contract to successfully manufacture, supply and distribute our COVID-19 vaccine and any future commercial products at scale, as well as drug substances, delivery vehicles, development candidates, and investigational medicines for preclinical and clinical use;
- internal and external costs associated with manufacturing our products, including our COVID-19 vaccine, and the impact on our cost of sales, and our anticipated 2024 cost of sales as a percentage of net product sales;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our commercial products, product candidates and technology, including our ability to enter into license agreements, and our expectations regarding pending legal proceedings related to our intellectual property;
- the potential of our individualized neoantigen therapy (INT) program and our plans for the program, including to expand to additional tumor types and plans for regulatory approval of INT;
- the timing of initiation, progress, completion, results and cost of our clinical trials, preclinical studies and research and development programs, as well as those of our collaborators;
- participant enrollment in our clinical trials, including enrollment demographics and timing;
- potential advantages of mRNA as compared to traditional medicine;
- our ability to obtain and maintain regulatory approval of our product candidates;
- the implementation of our business model and strategic plans for our business, products, product candidates and technology;
- potential product launches, including the timing of launches;
- our ability to successfully commercialize our products, if approved;
- the pricing and reimbursement of our medicines, if approved;
- the build out of our manufacturing and commercial operations;

- estimates of our future expenses, revenues and capital requirements;
- our operation and funding requirements, including our forecast of the period of time through which our financial resources will be adequate to support our operations;
- the potential benefits of strategic collaboration agreements and our ability to enter into strategic collaborations or other agreements with collaborators with development, regulatory and commercialization expertise;
- our financial performance;
- our tax provision and related tax liabilities;
- legal and regulatory developments in the United States and foreign countries;
- our ability to produce our products or product candidates with advantages in turnaround times or manufacturing cost; 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 and under Part I, Item 1A. "Risk Factors" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2023. 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, and our Statements and Perspectives webpage, <https://investors.modernatx.com/Statements--Perspectives/default.aspx>; as well as our social media channels: Facebook, www.facebook.com/modernatx; X, [@moderna_tx](http://www.twitter.com/moderna_tx); LinkedIn, www.linkedin.com/company/modernatx; Instagram ([@moderna_tx](http://www.instagram.com/moderna_tx)); and Threads ([@moderna_tx](http://www.threads.net/@moderna_tx)) 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.

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Item 1. Financial Statements

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

	June 30, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	\$ 2,478	\$ 2,907
Investments	6,010	5,697
Accounts receivable, net	163	892
Inventory	399	202
Prepaid expenses and other current assets	611	627
Total current assets	9,661	10,325
Investments, non-current	2,326	4,677
Property, plant and equipment, net	2,196	1,945
Right-of-use assets, operating leases	775	713
Deferred tax assets	81	81
Other non-current assets	641	685
Total assets	<u><u>\$ 15,680</u></u>	<u><u>\$ 18,426</u></u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 279	\$ 520
Accrued liabilities	1,333	1,798
Deferred revenue	702	568
Income taxes payable	7	63
Other current liabilities	42	66
Total current liabilities	2,363	3,015
Deferred revenue, non-current	95	83
Operating lease liabilities, non-current	668	643
Financing lease liabilities, non-current	576	575
Other non-current liabilities	266	256
Total liabilities	<u><u>3,968</u></u>	<u><u>4,572</u></u>
Commitments and contingencies (Note 11)		
Stockholders' equity:		
Preferred stock, par value \$ 0.0001 ; 162 shares authorized as of June 30, 2024 and December 31, 2023; no shares issued or outstanding at June 30, 2024 and December 31, 2023	—	—
Common stock, par value \$ 0.0001 ; 1,600 shares authorized as of June 30, 2024 and December 31, 2023; 384 and 382 shares issued and outstanding as of June 30, 2024 and December 31, 2023, respectively	—	—
Additional paid-in capital	631	371
Accumulated other comprehensive loss	(71)	(123)
Retained earnings	11,152	13,606
Total stockholders' equity	<u><u>11,712</u></u>	<u><u>13,854</u></u>
Total liabilities and stockholders' equity	<u><u>\$ 15,680</u></u>	<u><u>\$ 18,426</u></u>

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Revenue:				
Net product sales	\$ 184	\$ 293	\$ 351	\$ 2,121
Other revenue	57	51	57	85
Total revenue	241	344	408	2,206
Operating expenses:				
Cost of sales	115	731	211	1,523
Research and development	1,221	1,148	2,284	2,279
Selling, general and administrative	268	332	542	637
Total operating expenses	1,604	2,211	3,037	4,439
Loss from operations	(1,363)	(1,867)	(2,629)	(2,233)
Interest income	111	104	231	213
Other (expense) income, net	(27)	14	(46)	(34)
Loss before income taxes	(1,279)	(1,749)	(2,444)	(2,054)
Provision for (benefit from) income taxes	—	(369)	10	(753)
Net loss	\$ (1,279)	\$ (1,380)	\$ (2,454)	\$ (1,301)
Net loss per share:				
Basic and diluted	\$ (3.33)	\$ (3.62)	\$ (6.41)	\$ (3.39)
Weighted average common shares used in calculation of net loss per share:				
Basic and diluted	384	381	383	383

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Net loss	\$ (1,279)	\$ (1,380)	\$ (2,454)	\$ (1,301)
Other comprehensive income, net of tax:				
Available-for-sale securities:				
Unrealized gains (losses) on available-for-sale debt securities	29	(10)	49	69
Less: net realized losses on available-for-sale securities reclassified in net loss	1	14	3	30
Net increase from available-for-sale debt securities	30	4	52	99
Cash flow hedges:				
Less: net realized losses on derivative instruments reclassified in net loss	—	—	—	8
Net increase from derivatives designated as hedging instruments	—	—	—	8
Total other comprehensive income	30	4	52	107
Comprehensive loss	<u><u>\$ (1,249)</u></u>	<u><u>\$ (1,376)</u></u>	<u><u>\$ (2,402)</u></u>	<u><u>\$ (1,194)</u></u>

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

MODERNA, INC.
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(Uunaudited, in millions)

	Common Stock		Accumulated				Total Stockholders' Equity
	Shares	Amount	Additional Paid-In Capital	Other Comprehensive Loss	Retained Earnings		
Balance at March 31, 2024	383	\$ —	\$ 487	\$ (101)	\$ 12,431	\$ 12,817	
Exercise of options to purchase common stock	1	—	22	—	—	—	22
Issuance of common stock under employee stock purchase plan	—	—	10	—	—	—	10
Stock-based compensation	—	—	112	—	—	—	112
Other comprehensive income, net of tax	—	—	—	30	—	—	30
Net loss	—	—	—	—	(1,279)	(1,279)	
Balance at June 30, 2024	384	\$ —	\$ 631	\$ (71)	\$ 11,152	\$ 11,712	

	Common Stock		Accumulated				Total Stockholders' Equity
	Shares	Amount	Additional Paid-In Capital	Other Comprehensive Loss	Retained Earnings		
Balance at March 31, 2023	384	\$ —	\$ 731	\$ (267)	\$ 18,399	\$ 18,863	
Exercise of options to purchase common stock	1	—	4	—	—	—	4
Issuance of common stock under employee stock purchase plan	—	—	12	—	—	—	12
Stock-based compensation	—	—	74	—	—	—	74
Other comprehensive income, net of tax	—	—	—	4	—	—	4
Repurchase of common stock	(4)	—	(628)	—	—	—	(628)
Net loss	—	—	—	—	(1,380)	(1,380)	
Balance at June 30, 2023	381	\$ —	\$ 193	\$ (263)	\$ 17,019	\$ 16,949	

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	Common Stock		Accumulated				Total	
	Shares	Amount	Additional Paid-In Capital	Other Comprehensive Loss	Retained Earnings	Stockholders' Equity		
Balance at December 31, 2023	382	\$ —	\$ 371	\$ (123)	\$ 13,606	\$ 13,854		
Vesting of restricted common stock	1	—	—	—	—	—	—	—
Exercise of options to purchase common stock	1	—	37	—	—	—	37	
Issuance of common stock under employee stock purchase plan	—	—	10	—	—	—	10	
Stock-based compensation	—	—	213	—	—	—	213	
Other comprehensive income, net of tax	—	—	—	52	—	—	52	
Net loss	—	—	—	—	(2,454)	(2,454)		
Balance at June 30, 2024	384	\$ —	\$ 631	\$ (71)	\$ 11,152	\$ 11,712		
	384	\$ —	\$ 631	\$ (71)	\$ 11,152	\$ 11,712		

	Common Stock		Accumulated				Total	
	Shares	Amount	Additional Paid-In Capital	Other Comprehensive Loss	Retained Earnings	Stockholders' Equity		
Balance at December 31, 2022	385	\$ —	\$ 1,173	\$ (370)	\$ 18,320	\$ 19,123		
Vesting of restricted common stock	1	—	—	—	—	—	—	—
Exercise of options to purchase common stock	3	—	13	—	—	—	13	
Issuance of common stock under employee stock purchase plan	—	—	12	—	—	—	12	
Stock-based compensation	—	—	149	—	—	—	149	
Other comprehensive income, net of tax	—	—	—	107	—	—	107	
Repurchase of common stock	(8)	—	(1,154)	—	—	—	(1,154)	
Net loss	—	—	—	—	(1,301)	(1,301)		
Balance at June 30, 2023	381	\$ —	\$ 193	\$ (263)	\$ 17,019	\$ 16,949		
	381	\$ —	\$ 193	\$ (263)	\$ 17,019	\$ 16,949		

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

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

	Six Months Ended June 30,	
	2024	2023
Operating activities		
Net loss	\$ (2,454)	\$ (1,301)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	213	149
Depreciation and amortization	77	170
Amortization/accretion of investments	(55)	(29)
Loss (gain) on equity investments, net	35	(17)
Deferred income taxes	—	(530)
Other non-cash items	7	(12)
Changes in assets and liabilities, net of acquisition of business:		
Accounts receivable, net	729	1,153
Prepaid expenses and other assets	3	(142)
Inventory	(197)	234
Right-of-use assets, operating leases	(62)	(9)
Accounts payable	(199)	(187)
Accrued liabilities	(464)	(633)
Deferred revenue	146	(979)
Income taxes payable	(56)	(1)
Operating lease liabilities	25	12
Other liabilities	(11)	(18)
Net cash used in operating activities	<u>(2,263)</u>	<u>(2,140)</u>
Investing activities		
Purchases of marketable securities	(3,390)	(1,281)
Proceeds from maturities of marketable securities	3,536	3,264
Proceeds from sales of marketable securities	1,999	2,427
Purchases of property, plant and equipment	(378)	(347)
Acquisition of business, net of cash acquired	—	(85)
Investment in convertible notes and equity securities	—	(23)
Net cash provided by investing activities	<u>1,767</u>	<u>3,955</u>
Financing activities		
Proceeds from issuance of common stock through equity plans	47	25
Repurchase of common stock, including excise tax	—	(1,154)
Changes in financing lease liabilities	1	(81)
Net cash provided by (used in) financing activities	<u>48</u>	<u>(1,210)</u>
Net (decrease) increase in cash, cash equivalents and restricted cash	(448)	605
Cash, cash equivalents and restricted cash, beginning of year	2,928	3,217
Cash, cash equivalents and restricted cash, end of period	<u>\$ 2,480</u>	<u>\$ 3,822</u>
Non-cash investing and financing activities		
Purchases of property and equipment included in accounts payable and accrued liabilities	\$ 86	\$ 105
Right-of-use assets obtained through finance lease modifications and reassessments	\$ —	\$ 50

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

Our COVID-19 vaccine is our first commercial product and is marketed, where approved, under the name Spikevax®. Our original vaccine, mRNA-1273, targeted the SARS-CoV-2 ancestral strain, and we have leveraged our mRNA platform to rapidly adapt our vaccine to emerging SARS-CoV-2 strains to provide protection as the virus evolves and regulatory guidance is updated.

In May 2024, the U.S. Food and Drug Administration (FDA) approved mRESVIA® (mRNA-1345), our mRNA respiratory syncytial virus (RSV) vaccine, to protect adults aged 60 years and older from lower respiratory tract disease caused by RSV infection. The approval was granted under a breakthrough therapy designation and marks the second approved mRNA product from Moderna.

We have a diverse and extensive development pipeline of 40 development candidates across our 47 development programs, of which 43 are in clinical studies currently.

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, 2023 (2023 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 2023 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 the preparation of these condensed consolidated financial statements for the three and six months ended June 30, 2024 are consistent with those described in our 2023 Form 10-K. The only exception pertains to the policy related to research and development funding. We entered into a research and development funding arrangement in the first quarter of 2024. Please refer to [Note 5](#) for further details regarding this policy. The results of operations for the three and six months ended June 30, 2024 are not necessarily indicative of the operating results to be expected for the full fiscal year or future operating periods. We anticipate seasonal fluctuations in demand for our COVID-19 and recently approved RSV vaccines, with higher sales expected during the fall and winter seasons.

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. Changes in our estimates are recorded in the financial results of the period in which the new information becomes available. The actual results that we experience may differ materially from our estimates.

Comprehensive Income (Loss)

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

The components of accumulated other comprehensive loss for the three and six months ended June 30, 2024 were as follows (in millions):

	Unrealized Gains on Available-for-Sale Debt Securities	Pension and Postretirement Benefits	Total
Accumulated other comprehensive loss, balance at December 31, 2023	\$ (114)	\$ (9)	\$ (123)
Other comprehensive income	22	—	22
Accumulated other comprehensive loss, balance at March 31, 2024	(92)	(9)	(101)
Other comprehensive income	30	—	30
Accumulated other comprehensive loss, balance at June 30, 2024	\$ (62)	\$ (9)	\$ (71)

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,	
	2024	2023
Cash and cash equivalents	\$ 2,478	\$ 3,801
Restricted cash, non-current ⁽¹⁾	2	21
Total cash, cash equivalents and restricted cash shown in the condensed consolidated statements of cash flows	\$ 2,480	\$ 3,822

⁽¹⁾Included in other non-current assets in the condensed consolidated balance sheets.

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. Except as noted below, 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.

In November 2023, the FASB issued ASU No. 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures. This ASU broadens the disclosure requirements by requiring disclosures of significant segment expenses that are regularly provided to the chief operating decision maker (CODM) and included within each reported measure of segment profit or loss. The standard also requires entities to disclose, on an interim and annual basis, the amount and description, including the nature and type, of the other segment items. Additionally, entities are required to disclose the title and position of the individual identified as the CODM and an explanation of how the CODM uses the reported measures of a segment's profit or loss in assessing segment performance and deciding how to allocate resources. These enhanced disclosure obligations apply to entities that operate with one reportable segment as well. ASU 2023-07 is effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024 on a retrospective basis. Early adoption is permitted. We are currently assessing the impact that this new accounting standard will have on our consolidated financial statement disclosures.

In December 2023, the FASB issued ASU No. 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures. This ASU requires disaggregated information about a reporting entity's effective tax rate reconciliation as well as additional information on income taxes paid. The standard requires entities to disclose federal, state, and foreign income taxes in their rate reconciliation tables and elaborate on reconciling items that exceed a quantitative threshold. Additionally, it requires an annual disclosure of income taxes paid, net of refunds, categorized by jurisdiction based on a quantitative threshold. The ASU is effective on a prospective basis for annual periods beginning after December 15, 2024. Early adoption is permitted. This ASU will result in the required additional disclosures being included in our consolidated financial statements, once adopted. We are currently assessing the impact that this new accounting standard will have on our consolidated financial statement disclosures.

3. Net Product Sales

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
United States	\$ 162	\$ 2	\$ 262	\$ 3
Europe	—	60	—	636
Rest of world	22	231	89	1,482
Total	\$ 184	\$ 293	\$ 351	\$ 2,121

As of June 30, 2024, we have two commercial products authorized for use, our COVID-19 vaccine and our RSV vaccine. The RSV vaccine was approved by the FDA in May 2024 for adults aged 60 years and older. As of June 30, 2024, we had not commenced sales of our RSV vaccine.

Prior to the third quarter of 2023, we sold our COVID-19 vaccine to the U.S. Government, foreign governments and international organizations. The agreements and related amendments with these entities generally do not include variable consideration, such as discounts, rebates or returns. Certain of these agreements entitle us to upfront deposits for our COVID-19 vaccine supply, initially recorded as deferred revenue.

As of June 30, 2024 and December 31, 2023, we had deferred revenue of \$ 740 million and \$ 613 million, respectively, related to customer deposits for our COVID-19 vaccine. We expect \$ 645 million of our deferred revenue related to customer deposits as of June 30, 2024 to be realized in less than one year. Timing of product delivery and manufacturing, and receipt of marketing approval for the applicable COVID-19 vaccine will determine the period in which product sales are recognized.

In the third quarter of 2023, we commenced sales of our latest COVID-19 vaccine to the U.S. commercial market, in addition to continuing sales to foreign governments and international organizations. In the U.S., our COVID-19 vaccine is sold primarily to wholesalers and distributors, and to a lesser extent, directly to retailers and healthcare providers. Wholesalers and distributors typically do not make upfront payments to us.

Net product sales are recognized net of estimated wholesaler chargebacks, invoice discounts for prompt payments and pre-orders, provisions for sales returns, and other related deductions.

The following table summarizes product sales provision for the periods presented (in millions):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Gross product sales	\$ 191	\$ 293	\$ 413	\$ 2,121
Product sales provision:				
Wholesaler chargebacks, discounts and fees	22	—	—	—
Returns and other fees	(29)	—	(62)	—
Total product sales provision	\$ (7)	\$ —	\$ (62)	\$ —
Net product sales	\$ 184	\$ 293	\$ 351	\$ 2,121

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The following table summarizes the activities related to product sales provision recorded as accrued liabilities for the six months ended June 30, 2024 (in millions):

	Returns and other fees
Balance at December 31, 2023	\$ (556)
Provision related to sales made in 2024	(62)
Payments and returns related to sales made in current period	13
Payments and returns related to sales made in prior year	51
Balance at June 30, 2024	<u><u>\$ (554)</u></u>

4. Other Revenue

The following table summarizes other revenue for the periods presented (in millions):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Grant revenue	\$ 20	\$ 28	\$ 20	\$ 52
Collaboration revenue	7	23	7	33
Licensing and royalty revenue	30	—	30	—
Total other revenue	<u><u>\$ 57</u></u>	<u><u>\$ 51</u></u>	<u><u>\$ 57</u></u>	<u><u>\$ 85</u></u>

Grant Revenue

In April 2020, we entered into an agreement with the Biomedical Advanced Research and Development Authority (BARDA), a division of the Administration for Strategic Preparedness and Response (ASPR) within the U.S. Department of Health and Human Services (HHS), for an award of up to \$ 483 million to accelerate development of mRNA-1273. The agreement has been subsequently amended to provide for additional commitments to support various late-stage clinical development efforts of our original COVID-19 vaccine, mRNA-1273, including a 30,000 participant Phase 3 study, pediatric clinical trials, adolescent clinical trials and pharmacovigilance studies. The maximum award from BARDA, inclusive of all amendments, was approximately \$ 1.8 billion. All contract options have been exercised. As of June 30, 2024, the remaining available funding, net of revenue earned was \$ 77 million.

In June 2024, we were awarded up to \$ 176 million through the Rapid Response Partnership Vehicle (RRPV), funded by BARDA, to accelerate the development of mRNA-based pandemic influenza vaccines. The project award will support the late-stage development of an mRNA-based vaccine to enable the licensure of a pre-pandemic vaccine against the H5 influenza virus. This subtype of the influenza virus causes a highly infectious and severe disease in birds known as avian influenza and poses a risk of spillover into the human population. The agreement also includes additional options to prepare for and accelerate responses to future public health threats. We had not recognized any revenue under this agreement as of June 30, 2024.

Licensing and Royalty Revenue

In April 2024, we entered a non-exclusive out-licensing agreement with a pharmaceutical company based in Japan for mRNA COVID-19-related intellectual property for the territory of Japan. Under the terms of the agreement, we received an upfront payment of \$ 50 million, which included a \$ 20 million prepayment creditable against future royalties. Additionally, we are entitled to receive low double-digit royalties on the net sales of the company's COVID-19 product.

Upon execution of the agreement, we recognized \$ 30 million of the upfront payment as other revenue in our condensed consolidated statements of operations. The remaining \$ 20 million was recorded as deferred revenue in our condensed consolidated balance sheets. Royalty revenue will be recognized when the underlying sales occur.

5. Collaboration Agreements and Research and Development Funding Arrangement

Merck

In June 2016, we entered into a Collaboration and License Agreement for the development and commercialization of personalized mRNA cancer vaccines (also known as individualized neoantigen therapy, or INT) with Merck. This agreement was subsequently amended and restated in 2018. Our role in this strategic alliance involves identifying genetic mutations in a particular patient's tumor cells, synthesizing mRNA for these mutations, encapsulating the mRNA in one of our proprietary lipid nanoparticles (LNPs), and administering a unique mRNA INT to each patient. Each INT is designed to specifically activate the patient's immune system against her or his own cancer cells.

In September 2022, Merck exercised its option for INT, including mRNA-4157, pursuant to the terms of the agreement and in October 2022 paid us an option exercise fee of \$ 250 million. Following this exercise, the Merck Participation Term commenced. Pursuant to the agreement, we and Merck have agreed to collaborate on further development and commercialization of INT, with costs and any profits or losses to be shared equally on a worldwide basis.

For the three and six months ended June 30, 2024, we recognized expenses, net of Merck's reimbursements, of \$ 95 million and \$ 171 million, respectively, related to the INT collaboration under the Merck Participation Term. For the three and six months ended June 30, 2023, these expenses were \$ 50 million and \$ 69 million, respectively.

Additionally, for the three and six months ended June 30, 2024, the net cost recovery for capital expenditures was \$ 33 million and \$ 57 million, respectively. For the three and six months ended June 30, 2023, the net cost recovery for capital expenditures was \$ 12 million and \$ 18 million, respectively. These amounts were applied to reduce the capitalized cost of the assets.

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 have occurred. In addition, we may be required to pay significant royalties on future sales if products related to these arrangements are commercialized.

Development and Commercialization Funding Arrangement with Blackstone Life Sciences (Blackstone)

In March 2024, we entered into a development and commercialization funding arrangement with Blackstone, under which Blackstone has committed to providing up to \$ 750 million in funding to us. This funding supports the development of our investigational mRNA-based influenza vaccine. Contingent upon regulatory approval in the U.S. and only if the approval is dependent on data from the funded activities, Blackstone will be entitled to receive low single-digit percentage royalties and up to \$ 750 million in sales milestone payments. These payments are based on net sales of our future influenza and combination vaccines, with sales milestone payments contingent upon achieving specified cumulative net sales targets.

Given the substantive transfer of financial risk to Blackstone, we account for this arrangement as an obligation to conduct research and development activities. The funding is recognized as a reduction to the expenses of our mRNA-based influenza program. This reduction is recognized proportionally as the related costs are incurred, based on an input method. We recorded immaterial research and development expense reductions for the three and six months ended June 30, 2024.

6. Financial Instruments

Cash and Cash Equivalents and Investments

The following tables summarize our cash, cash equivalents, and available-for-sale securities by significant investment category as of June 30, 2024 and December 31, 2023 (in millions):

June 30, 2024								
	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value	Cash and Cash Equivalents	Current Marketable Securities	Current Marketable Securities	Non-Current Marketable Securities
Cash and cash equivalents	\$ 2,478	\$ —	\$ —	\$ 2,478	\$ 2,478	\$ —	\$ —	\$ —
Available-for-sale:								
Certificates of deposit	29	—	—	29	—	29	—	—
U.S. treasury bills	588	—	—	588	—	588	—	—
U.S. treasury notes	3,593	—	(45)	3,548	—	2,642	906	—
Corporate debt securities	4,023	1	(47)	3,977	—	2,594	1,383	—
Government debt securities	196	—	(2)	194	—	157	37	—
Total	\$ 10,907	\$ 1	\$ (94)	\$ 10,814	\$ 2,478	\$ 6,010	\$ 2,326	—
December 31, 2023								
	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value	Cash and Cash Equivalents	Current Marketable Securities	Current Marketable Securities	Non-Current Marketable Securities
Cash and cash equivalents	\$ 2,907	\$ —	\$ —	\$ 2,907	\$ 2,907	\$ —	\$ —	\$ —
Available-for-sale:								
Certificates of deposit	27	—	—	27	—	27	—	—
U.S. treasury bills	807	—	—	807	—	807	—	—
U.S. treasury notes	4,407	3	(67)	4,343	—	2,664	1,679	—
Corporate debt securities	5,067	3	(81)	4,989	—	2,082	2,907	—
Government debt securities	211	—	(3)	208	—	117	91	—
Total	\$ 13,426	\$ 6	\$ (151)	\$ 13,281	\$ 2,907	\$ 5,697	\$ 4,677	—

The amortized cost and estimated fair value of available-for-sale securities by contractual maturity as of June 30, 2024 and December 31, 2023 were as follows (in millions):

June 30, 2024			
	Amortized Cost	Estimated Fair Value	
Due in one year or less	\$ 6,067	\$ 6,010	—
Due after one year through five years	2,362	2,326	—
Total	\$ 8,429	\$ 8,336	—

December 31, 2023			
	Amortized Cost	Estimated Fair Value	
Due in one year or less	\$ 5,751	\$ 5,697	—
Due after one year through five years	4,768	4,677	—
Total	\$ 10,519	\$ 10,374	—

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 income (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, 2024 and 2023. We did not record any credit-related allowance for available-for-sale securities as of June 30, 2024 and December 31, 2023.

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 as of June 30, 2024 and December 31, 2023 (in millions):

	Less than 12 Months		12 Months or More		Total	
	Gross		Gross		Gross	
	Unrealized Losses	Estimated Fair Value	Unrealized Losses	Estimated Fair Value	Unrealized Losses	Estimated Fair Value
As of June 30, 2024:						
U.S. treasury bills	\$ —	\$ 1,282	\$ —	\$ —	\$ —	\$ 1,282
U.S. treasury notes	(5)	1,175	(38)	2,164	(43)	3,339
Corporate debt securities	(4)	945	(45)	2,523	(49)	3,468
Government debt securities	—	52	(2)	116	(2)	168
Total	\$ (9)	\$ 3,454	\$ (85)	\$ 4,803	\$ (94)	\$ 8,257
As of December 31, 2023:						
U.S. treasury bills	\$ —	\$ 25	\$ —	\$ —	\$ —	\$ 25
U.S. treasury notes	(3)	774	(64)	2,983	(67)	3,757
Corporate debt securities	(1)	562	(79)	3,518	(80)	4,080
Government debt securities	—	8	(4)	143	(4)	151
Total	\$ (4)	\$ 1,369	\$ (147)	\$ 6,644	\$ (151)	\$ 8,013

As of June 30, 2024 and December 31, 2023, we held 341 and 392 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).

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The following tables summarize our financial assets and liabilities measured at fair value on a recurring basis as of June 30, 2024 and December 31, 2023 (in millions):

	Fair value at June 30, 2024	Fair Value Measurement Using	
		Level 1	Level 2
Assets:			
Money market funds	\$ 647	\$ 647	\$ —
Certificates of deposit	29	—	29
U.S. treasury bills	1,972	—	1,972
U.S. treasury notes	3,548	—	3,548
Corporate debt securities	4,286	—	4,286
Government debt securities	194	—	194
Equity investments ⁽¹⁾	31	31	—
Derivative instruments	2	—	2
Total	\$ 10,709	\$ 678	\$ 10,031
Liabilities:			
Derivative instruments	\$ 2	\$ —	\$ 2

	Fair value at December 31, 2023	Fair Value Measurement Using	
		Level 1	Level 2
Assets:			
Money market funds	\$ 1,572	\$ 1,572	\$ —
Certificates of deposit	27	—	27
U.S. treasury bills	1,246	—	1,246
U.S. treasury notes	4,343	—	4,343
Corporate debt securities	5,480	—	5,480
Government debt securities	208	—	208
Equity Investments ⁽¹⁾	24	24	—
Derivative instruments	4	—	4
Total	\$ 12,904	\$ 1,596	\$ 11,308
Liabilities:			
Derivative instruments	\$ 9	\$ —	\$ 9

⁽¹⁾ Investments in publicly traded equity securities with readily determinable fair values are recorded at quoted market prices for identical securities, with changes in fair value recorded in other income (expense), net, in our condensed consolidated statements of operations.

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As of June 30, 2024 and December 31, 2023, 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.

For the three and six months ended June 30, 2024, we recognized net losses of \$ 22 million and \$ 35 million, respectively, on equity investments from changes in fair value of the securities. For the three and six months ended June 30, 2023, we recognized net gains of \$ 36 million and \$ 17 million, respectively, on equity investments from changes in fair value of the securities.

In addition, as of December 31, 2023, we had \$ 42 million in equity investments without readily determinable fair values, which were recorded within other non-current assets in our consolidated balance sheets and excluded from the fair value measurement tables above. These investments became publicly traded during the first quarter of 2024 and were recorded at their quoted market price in our condensed consolidated balance sheets as of June 30, 2024.

7. Inventory

Inventory as of June 30, 2024 and December 31, 2023 consisted of the following (in millions):

	June 30,		December 31,	
	2024		2023	
Raw materials	\$ 199		\$ 163	
Work in progress		166		15
Finished goods		34		24
Total inventory	\$ 399		\$ 202	
Inventory, non-current ⁽¹⁾	\$ 161		\$ 170	

⁽¹⁾Consisted of raw materials with an anticipated consumption beyond one year. Inventory, non-current is included in other non-current assets in the condensed consolidated balance sheets.

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 operations. For the three and six months ended June 30, 2024, inventory write-downs were \$ 14 million and \$ 44 million, respectively. For the three and six months ended June 30, 2023, inventory write-downs were \$ 464 million and \$ 612 million, respectively. For the three and six months ended June 30, 2024, there were no losses on firm purchase commitments. For the three and six months ended June 30, 2023, losses on firm purchase commitments were \$ 75 million and \$ 141 million, respectively. Inventory write-downs were mainly related to obsolete inventory due to shelf-life expiration and inventory in excess of expected demand. Losses on firm purchase commitments were primarily related to excess raw material purchase commitments that will expire before the anticipated consumption of those raw materials. As of June 30, 2024 and December 31, 2023, the accrued liability for losses on firm future purchase commitments in our condensed consolidated balance sheets was \$ 1 million and \$ 79 million, respectively.

In May 2024, the FDA approved our RSV vaccine for adults aged 60 years and older, and we began to capitalize RSV vaccine inventory. As of June 30, 2024 and December 31, 2023, we had inventory on hand of \$ 560 million and \$ 372 million, respectively, inclusive of inventory for our COVID-19 and RSV vaccines. Our raw materials and work-in-progress inventory have variable shelf lives. We expect that the majority of this inventory will be consumed over the next three years. The shelf life of our COVID-19 vaccine product ranges from nine to twelve months. The shelf life of our RSV vaccine is 18 months.

Pre-launch Inventory

Consistent with guidance from regulators, we have updated our COVID-19 vaccine to target the KP.2 and JN.1 strains of the SARS-CoV-2 virus, and are prepared to meet the anticipated 2024-2025 season demand. We anticipate supplying our vaccine targeting the KP.2 strain to the U.S. and Canadian markets, consistent with guidance from U.S. and Canadian regulators, respectively. Our vaccine targeting the JN.1 strain will be available to support other markets where regulators are targeting JN.1, subject to regulatory approvals. We have submitted data to regulators worldwide to support registration and supply of the Spikevax 2024-2025 formula in time for the upcoming vaccination season, which will commence in the third quarter.

We commenced manufacturing and capitalizing pre-launch inventory costs related to both KP.2 and JN.1 strains in the first half of 2024, prior to regulatory approval. As of June 30, 2024, we had capitalized pre-launch COVID-19 vaccine inventory of \$ 165 million in our condensed consolidated balance sheets.

8. Property, Plant and Equipment, Net

Property, plant and equipment, net, as of June 30, 2024 and December 31, 2023 consisted of the following (in millions):

	June 30, 2024	December 31, 2023
Land and land improvements	\$ 22	\$ 22
Manufacturing and laboratory equipment	355	345
Leasehold improvements	664	522
Furniture, fixtures and other	33	26
Computer equipment and software	136	74
Construction in progress	961	860
Right-of-use assets, financing (Note 10)	529	529
Total	2,700	2,378
Less: Accumulated depreciation	(504)	(433)
Property, plant and equipment, net	\$ 2,196	\$ 1,945

Depreciation and amortization expense for three and six months ended June 30, 2024 was \$ 40 million and \$ 75 million, respectively. Depreciation and amortization expense for the three and six months ended June 30, 2023 was \$ 90 million and \$ 168 million, respectively.

9. Other Balance Sheet Components

Accounts Receivable, net

Accounts receivable, net, as of June 30, 2024 and December 31, 2023 consisted of the following (in millions):

	June 30, 2024	December 31, 2023
Accounts receivable	\$ 492	\$ 1,584
Less: Wholesalers chargebacks, discounts and fees	(329)	(692)
Accounts receivable, net	\$ 163	\$ 892

Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets, as of June 30, 2024 and December 31, 2023 consisted of the following (in millions):

	June 30, 2024	December 31, 2023
	2024	2023
Prepaid services	\$ 184	\$ 182
Down payments and prepayments related to manufacturing and materials	111	168
Income tax receivable	105	19
Collaboration receivable	73	61
Interest receivable	56	59
Value added tax receivable	26	50
Prepaid income tax	25	—
Other current assets	31	88
Prepaid expenses and other current assets	\$ 611	\$ 627

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Other Non-Current Assets

Other non-current assets, as of June 30, 2024 and December 31, 2023 consisted of the following (in millions):

	June 30, 2024	December 31, 2023
Down payments and prepayments, non-current	\$ 321	\$ 342
Inventory, non-current ⁽¹⁾	161	170
Goodwill	52	52
Finite-lived intangible asset	42	44
Equity investments	31	66
Other	34	11
Other non-current assets	\$ 641	\$ 685

⁽¹⁾ Consisted of raw materials with an anticipated consumption beyond one year.

Accrued Liabilities

Accrued liabilities, as of June 30, 2024 and December 31, 2023 consisted of the following (in millions):

	June 30, 2024	December 31, 2023
Provisions related to product sales (Note 3)	\$ 554	\$ 556
Compensation-related	187	245
Manufacturing	119	167
Other external goods and services	109	137
Clinical trials	96	175
Property, plant and equipment	93	94
Development operations	90	140
Raw materials	42	27
Commercial	32	56
Royalties	10	122
Loss on future firm purchase commitments ⁽¹⁾	1	79
Accrued liabilities	\$ 1,333	\$ 1,798

⁽¹⁾Related to losses that are expected to arise from firm, non-cancellable, commitments for future raw material purchases ([Note 7](#)).

Other Current Liabilities

Other current liabilities, as of June 30, 2024 and December 31, 2023 consisted of the following (in millions):

	June 30, 2024	December 31, 2023
Lease liabilities - operating (Note 10)	\$ 25	\$ 25
Other	17	41
Other current liabilities	\$ 42	\$ 66

Deferred Revenue

The following table summarizes the activities in deferred revenue for the six months ended June 30, 2024 (in millions):

	December 31, 2023	Additions	Deductions	June 30, 2024
Product sales	\$ 613	\$ 196	\$ (69)	\$ 740
Grant revenue	4	—	—	4
Collaboration revenue	34	6	(7)	33
Licensing and royalty revenue	—	20	—	20
Total deferred revenue	<u>\$ 651</u>	<u>\$ 222</u>	<u>\$ (76)</u>	<u>\$ 797</u>

10. 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 costs under such arrangements on a straight-line basis over the life of the lease. We have two main campuses in Massachusetts, our Cambridge campus and our Moderna Technology Center (MTC), an industrial technology center located in Norwood. We also lease various parcels of land, and office and lab spaces across the globe for our business operations.

Cambridge Campus

Our Cambridge campus consists of multiple leased properties, including office and research laboratory spaces totaling approximately 667,000 square feet, including the Moderna Science Center.

Moderna Science Center

In September 2021, we entered into a lease agreement for a building in Cambridge, Massachusetts, comprising approximately 462,000 square feet. This facility, which includes our principal executive offices along with additional office and laboratory spaces, is referred to as the Moderna Science Center (MSC). After an approximately two-year building project, the lease term is 15 years, with options for two additional seven-year extensions. During the third quarter of 2023, we commenced the lease and recognized the related right-of-use asset and lease liability on our condensed consolidated balance sheets.

Following the commencement of the MSC lease, we amended the expiration dates of our existing leases at Technology Square in the fourth quarter of 2023. Originally scheduled to expire ranging from 2024 to 2029, these leases have been adjusted to conclude by early 2025. All our Cambridge leases are classified as operating leases.

Moderna Technology Center

Our Moderna Technology Center is composed of three buildings, MTC South, MTC North and MTC East, totaling approximately 686,000 square feet. Our MTC leases expire in 2042 and we have the option to extend the term for three extension periods of five years each. All of our MTC leases are classified as finance leases.

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Operating and financing lease right-of-use assets and lease liabilities as of June 30, 2024 and December 31, 2023 were as follows (in millions):

	June 30, 2024	December 31, 2023
Assets:		
Right-of-use assets, operating, net ⁽¹⁾ ⁽²⁾	\$ 775	\$ 713
Right-of-use assets, financing, net ⁽³⁾ ⁽⁴⁾	430	436
Total	\$ 1,205	\$ 1,149
Liabilities:		
Current:		
Operating lease liabilities ⁽⁵⁾	\$ 25	\$ 25
Total current lease liabilities	25	25
Non-current:		
Operating lease liabilities, non-current	668	643
Financing lease liabilities, non-current	576	575
Total non-current lease liabilities	1,244	1,218
Total	\$ 1,269	\$ 1,243

⁽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.

⁽⁴⁾Included in property, plant 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, 2024, were as follows (in millions):

Fiscal Year	Operating Leases	Financing Leases ⁽¹⁾
2024 (remainder of the year)	\$ 38	\$ 9
2025	69	22
2026	70	22
2027	75	23
2028	76	23
Thereafter	833	1,074
Total minimum lease payments	1,161	1,173
Less amounts representing interest or imputed interest	(468)	(597)
Present value of lease liabilities	\$ 693	\$ 576

⁽¹⁾Includes certain optional lease term extensions, predominantly related to the MTC leases, which represent a total of \$ 668 million of undiscounted future lease payments.

11. 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, 2024 and the year ended December 31, 2023, 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, 2024, we had \$ 1.5 billion of non-cancelable purchase commitments related to raw materials and manufacturing agreements, which are expected to be paid through 2029. As of June 30, 2024, we had \$ 157 million of non-cancelable purchase commitments related to clinical services and other goods and services which are expected to be paid through 2030. 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 winddown 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. As of June 30, 2024, we had cancelable open purchase orders of \$ 3.1 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 as of June 30, 2024, 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

We have patent license agreements with Cellscript, LLC and its affiliate, mRNA RiboTherapeutics, Inc., and the National Institute of Allergy and Infectious Diseases. Under these agreements, we are required to pay royalties and certain milestone payments. For further information on our licensing and royalty payments, please refer to our 2023 Form 10-K under the heading "Business—Intellectual Property—In-licensed intellectual property" and Note 11 to our consolidated financial statements contained therein.

For the three and six months ended June 30, 2024, we recognized \$ 10 million and \$ 18 million, respectively, of royalty expenses associated with our product sales. For the three and six months ended June 30, 2023, we recognized \$ 12 million and \$ 98 million, respectively, of royalty expenses associated with our product sales. These royalty expenses were recorded to cost of sales in our condensed consolidated statements of operations.

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 have not yet occurred as of June 30, 2024.

12. Stock-Based Compensation and Share Repurchase Programs

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, 2024 and 2023 as follows (in millions):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Options	\$ 40	\$ 34	\$ 80	\$ 70
Restricted Stock Units (RSUs) and Performance Stock Units (PSUs)	70	37	128	74
Employee Stock Purchase Plan (ESPP)	2	3	5	5
Total	\$ 112	\$ 74	\$ 213	\$ 149
Cost of sales	\$ 6	\$ 16	\$ 13	\$ 21
Research and development	67	33	127	75
Selling, general and administrative	39	25	73	53
Total	\$ 112	\$ 74	\$ 213	\$ 149

As of June 30, 2024, there was \$ 1.0 billion 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 2.8 years as of June 30, 2024.

Share Repurchase Programs

As of June 30, 2024, \$ 1.7 billion of our Board of Directors' authorization for repurchases of our common stock (the 2022 Repurchase Programs) remains outstanding, with no expiration date. The timing and actual number of shares repurchased under the 2022 Repurchase Programs 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 three and six months ended June 30, 2024, there were no shares repurchased.

13. 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,	
	2024	2023	2024	2023
Loss before income taxes	\$ (1,279)	\$ (1,749)	\$ (2,444)	\$ (2,054)
Provision for (benefit from) income taxes	\$ —	\$ (369)	\$ 10	\$ (753)
Effective tax rate	— %	21.1 %	(0.4)%	36.7 %

The effective tax rate for the three and six months ended June 30, 2024 was higher than the statutory rate, due to certain of our foreign subsidiaries that have taxable income, while we incurred a net loss before income taxes on a consolidated basis. We cannot recognize tax benefits from the loss due to our global valuation allowance, which we continue to maintain against the majority of our global deferred tax assets. The changes in our effective tax rate, compared to the same periods in 2023, primarily result from the continued application of our valuation allowance and adjustments of our valuation allowance, which was initially established in the third quarter of 2023. For additional details regarding our deferred tax assets and the policies governing our valuation allowance, please refer to Note 13 to our consolidated financial statements in our 2023 Form 10-K.

We periodically reassess the need for valuation allowances on our deferred tax assets, considering both positive and negative evidence to evaluate whether it is more likely than not that all or a portion of such assets will not be realized. Significant management judgment is required in assessing the realizability of our deferred tax assets. In the event that actual results differ from our estimates, we adjust our estimates in future periods and we may need to modify our valuation allowance, which could materially impact our financial position and results of operations.

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 U.S. or any other major taxing jurisdiction.

14. Net Loss per Share

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

Basic and diluted EPS for the three and six months ended June 30, 2024 and 2023 were calculated as follows (in millions, except per share data):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Numerator:				
Net loss	\$ (1,279)	\$ (1,380)	\$ (2,454)	\$ (1,301)
Denominator:				
Basic and diluted weighted-average common shares outstanding	384	381	383	383
Basic and Diluted EPS	\$ (3.33)	\$ (3.62)	\$ (6.41)	\$ (3.39)
Common stock equivalents excluded from the EPS computation above because their inclusion would have been anti-dilutive	34	28	34	28

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 fiscal year ended December 31, 2023, which was filed with the Securities and Exchange Commission (the SEC) on February 23, 2024 (the 2023 Form 10-K).

Overview

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

Since our founding in 2010, we have transformed from a research-stage company advancing programs in the field of mRNA to a commercial enterprise with a diverse clinical portfolio of vaccines and therapeutics across six modalities, a broad intellectual property portfolio and integrated manufacturing capabilities that allow for rapid clinical and commercial production at scale. We have a diverse and extensive development pipeline of 40 development candidates across our 47 development programs, of which 43 are in clinical studies currently.

Our COVID-19 vaccine is our first commercial product and is marketed, where approved, under the name Spikevax®. Our original vaccine, mRNA-1273, targeted the SARS-CoV-2 ancestral strain, and we have leveraged our mRNA platform to rapidly adapt our vaccine to emerging SARS-CoV-2 strains to provide protection as the virus evolves and regulatory guidance is updated. In May 2024, the U.S. Food and Drug Administration (FDA) granted approval for mRESVIA® (mRNA-1345), our mRNA vaccine against respiratory syncytial virus (RSV), to protect adults aged 60 and older from lower respiratory tract disease caused by RSV infection. This marks our second approved mRNA product and underscores our ongoing commitment to delivering solutions for patients by addressing global public health threats related to infectious diseases.

Business Highlights

RSV

In May 2024, the FDA approved mRESVIA to protect adults aged 60 years and older from lower respiratory tract disease caused by RSV infection. The approval was granted under a breakthrough therapy designation and marks our second approved mRNA product. Subsequently, the Advisory Committee on Immunization Practices (ACIP) issued a recommendation for all unvaccinated people 75 years of age and older and unvaccinated people ages 60-74 who are at increased risk for RSV to receive the vaccine for the prevention of RSV-associated lower respiratory tract disease (RSV-LRTD) and acute respiratory disease (ARD).

In June 2024, the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending marketing authorization for mRESVIA in the European Union. We have filed for mRNA-1345 approval with regulators in multiple markets around the world.

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The FDA's approval of mRESVIA was based on positive data from the Phase 3 clinical trial ConquerRSV, a global study conducted in approximately 37,000 adults ages 60 years or older in 22 countries. The primary analysis with 3.7 months of median follow-up found mRNA-1345 had a vaccine efficacy against RSV lower respiratory tract disease (LRTD) of 83.7% (95.88% CI 66.0%, 92.2%). A follow-up analysis of the primary endpoint was performed during FDA review, including cases that started before the primary analysis cut-off date but were not confirmed until afterward. The results were consistent with the primary analysis [VE 78.7% (CI 62.9%, 87.8%)] and were included in the U.S. package insert. An additional longer-term analysis showed mRNA-1345 had continued protection against RSV LRTD over 8.6 months median follow-up.

COVID-19

Consistent with guidance from regulators, we have updated our COVID-19 vaccine to target the KP.2 and JN.1 strains of the SARS-CoV-2 virus, and are prepared to meet the anticipated 2024-2025 season demand. We anticipate supplying our vaccine targeting the KP.2 strain to the U.S. and Canadian markets, consistent with guidance from U.S. and Canadian regulators, respectively. Our vaccine targeting the JN.1 strain will be available to support other markets where regulators are targeting JN.1, subject to regulatory approvals. We have submitted data to regulators worldwide to support registration and supply of the Spikevax 2024-2025 formula in time for the upcoming vaccination season, which will commence in the third quarter.

Pandemic influenza

In June 2024, we were awarded up to \$176 million through the Rapid Response Partnership Vehicle (RRPV) to accelerate the development of mRNA-based pandemic influenza vaccines. The RRPV is a consortium funded by the Biomedical Advanced Research and Development Authority (BARDA), part of the Administration for Strategic Preparedness and Response (ASPR) within the U.S. Department of Health and Human Services (HHS). The project award will support the late-stage development of an mRNA-based vaccine to enable the licensure of a pre-pandemic vaccine against the H5 influenza virus. This subtype of the influenza virus causes a highly infectious and severe disease in birds known as avian influenza and poses a risk of spillover into the human population. The agreement also includes additional options to prepare for and accelerate responses to future public health threats.

In 2023, we initiated a Phase 1/2 study to generate safety and immunogenicity data for our investigational pandemic influenza vaccine (mRNA-1018) in healthy adults aged 18 years and older. The study includes vaccine candidates against the H5 and H7 avian influenza viruses.

Japan

In July 2024, we entered into a joint agreement with Mitsubishi Tanabe Pharma Corporation regarding the co-promotion of our mRNA respiratory vaccine portfolio in Japan, including Spikevax. Under the agreement, we will handle the manufacturing, sales, medical education and distribution of our mRNA respiratory vaccines. Both companies will engage in activities to enable broad access to our mRNA respiratory portfolio to have the maximum impact on public health in Japan.

In April 2024, we entered a non-exclusive out-licensing agreement with a pharmaceutical company based in Japan for mRNA COVID-19-related intellectual property for the territory of Japan. We received an upfront payment of \$50 million, which included a \$20 million prepayment creditable against future royalties. Additionally, we are entitled to low double-digit royalties on the net sales of the company's COVID-19 product.

Net product sales and Net loss per share

For the second quarter of 2024, we recognized net product sales of \$184 million from sales of our COVID-19 vaccine, compared to \$293 million for the second quarter of 2023. Net loss per share was \$(3.33) for the second quarter of 2024, compared to \$(3.62) for the second quarter of 2023.

Recent Program Developments

Next-generation COVID-19 vaccine

- In June 2024, we announced that our next-generation COVID-19 vaccine candidate (mRNA-1283) met its primary vaccine efficacy endpoint in a Phase 3 trial, demonstrating non-inferior vaccine efficacy against COVID-19 compared to Spikevax in participants 12 years of age and older. Higher efficacy was observed in adults 18 years of age and older compared to Spikevax (mRNA-1273), with a consistent trend observed in the subset of adults age 65 and older.

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Combination vaccine against influenza and COVID-19

- In June 2024, we announced that our combination vaccine candidate against influenza and COVID-19 (mRNA-1083) met its primary endpoints, eliciting higher immune responses against influenza virus and SARS-CoV-2 than licensed flu and COVID vaccines in adults 50 years and older, including an enhanced influenza vaccine in adults 65 years and older. mRNA-1083 comprises components of mRNA-1010, our vaccine candidate for seasonal influenza, and mRNA-1283, our next-generation COVID-19 vaccine candidate. Each investigational vaccine has independently demonstrated positive Phase 3 clinical trial results.

Individualized neoantigen therapy (INT)

- In June 2024, we and our collaborator, Merck, announced additional 3-year data showing that our investigational INT mRNA-4157 (V940) in combination with KEYTRUDA® demonstrated sustained improvement in recurrence-free survival and distant metastasis-free survival versus KEYTRUDA alone in patients with high-risk stage III/IV melanoma following complete resection. In the Phase 2b KEYNOTE-942/mRNA-4157-P201 study, at a median planned follow-up of 34.9 months, the combination therapy reduced the risk of recurrence or death by 49% and the risk of distant metastasis or death by 62% compared to KEYTRUDA alone. The 2.5-year recurrence-free survival rate was 74.8% for the combination therapy versus 55.6% for KEYTRUDA alone, with the benefit observed across exploratory subgroups.
- We and Merck have initiated Phase 3 randomized clinical trials evaluating mRNA-4157 (V940) in combination with KEYTRUDA as an adjuvant treatment in patients with resected high-risk (Stage IIB-IV) melanoma and non-small cell lung cancer. Both trials are actively enrolling. In 2024, we and Merck also initiated three new randomized clinical studies in additional tumor types, including: a Phase 2 adjuvant treatment in patients with renal cell carcinoma, or kidney cancer; a Phase 2 adjuvant treatment in patients with high-risk muscle-invasive bladder cancer; and a Phase 2/3 neoadjuvant and adjuvant treatment in patients with cutaneous squamous cell carcinoma, the second most common form of skin cancer.

Rare Disease and Other Therapeutics

- *Methylmalonic Acidemia (MMA):* In June 2024, the FDA selected our investigational therapeutic for MMA (mRNA-3705) for the Support for Clinical Trials Advancing Rare Disease Therapeutics (START) pilot program. The START pilot program was initiated by the FDA in September 2023 to accelerate the development of novel treatments addressing unmet medical needs in rare diseases, with an initial selection of up to seven novel treatments, three by the Center for Drug Evaluation and Research (CDER) and four by the Center for Biologics Evaluation and Research (CBER). The milestone-driven initiative is intended to help the progression to pivotal clinical studies or pre-BLA/NDA meeting stages by enhancing communications between manufacturers and the FDA. Selected manufacturers are expected to benefit from rapid, ad hoc FDA interactions to support clinical development, such as study design, patient population, and statistical methods, beyond standard formal meetings. The program is designed to generate high-quality, reliable data to support marketing approvals, ensuring promising treatments advance efficiently through regulatory milestones.

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Our Pipeline

The following chart shows our current pipeline of 47 development programs across our six modalities.

Modality	Program	ID #	Preclinical development	Phase 1	Phase 2	Phase 3	Commercial	Moderna rights
Respiratory vaccines: adults	COVID-19 vaccine	Spikevax®						Worldwide
	COVID-19 vaccine [next generation]	mRNA-1283						Worldwide
		mRNA-1010						Worldwide
		mRNA-1020						Worldwide
	Flu vaccine	mRNA-1030						Worldwide
		mRNA-1011						Worldwide
		mRNA-1012						Worldwide
		mRESVIA®						Worldwide
	RSV vaccine (older adults)	mRNA-1083						Worldwide
	Flu + COVID vaccine	mRNA-1230						Worldwide
Infectious disease vaccines	Flu + RSV vaccine	mRNA-1045						Worldwide
	Endemic HCoV vaccine	mRNA-1287						Worldwide
	Pandemic Flu	mRNA-1018						Worldwide
	RSV + hMPV vaccine	mRNA-1365						Worldwide
	COVID-19 vaccine (adolescents)	mRNA-1273						Worldwide
	COVID-19 vaccine [pediatrics]	mRNA-1273						Worldwide
Respiratory vaccines: adolescents & pediatrics	RSV vaccine (pediatric)	mRNA-1345						Worldwide
	CMV vaccine	mRNA-1647						Worldwide
	EBV vaccine [to prevent IM]	mRNA-1189						Worldwide
	EBV vaccine [to prevent EBV sequelae]	mRNA-1195						Worldwide
	HSV vaccine	mRNA-1608						Worldwide
	VZV vaccine	mRNA-1468						Worldwide
		mRNA-1644						Worldwide IAVI funded
		mRNA-1574						Worldwide IAVI/others funded
		mRNA-1403						Worldwide
	Norovirus vaccines	mRNA-1405						Worldwide
Bacterial		mRNA-1975						Worldwide
		mRNA-1982						Worldwide
								Worldwide BARDA funded
								Worldwide NIH funded
Public health vaccines	Zika vaccine	mRNA-1893						Worldwide BARDA funded
	Nipah vaccine	mRNA-1215						Worldwide NIH funded
	Mpox vaccine	mRNA-1769						Worldwide
	Relaxin	mRNA-0184						Worldwide
	Individualized neoantigen therapy (INT) – adjuvant melanoma	mRNA-4157						50-50 global profit sharing with Merck
Cardiovascular therapeutics	Individualized neoantigen therapy (INT) – adjuvant NSCLC	mRNA-4157						50-50 global profit sharing with Merck
	Individualized neoantigen therapy (INT) – cSCC	mRNA-4157						50-50 global profit sharing with Merck
	Individualized neoantigen therapy (INT) – RCC	mRNA-4157						50-50 global profit sharing with Merck
	Individualized neoantigen therapy (INT) – bladder cancer	mRNA-4157						50-50 global profit sharing with Merck
	KRAS therapy	mRNA-5671						Worldwide
	Checkpoint therapy	mRNA-4359						Worldwide
Intratumoral immunotherapy	OX40L/IL-23/IL-36γ (Triplet) Solid tumors/lymphoma	mRNA-2752						Worldwide
	Proprionic acidemia (PA)	mRNA-3927						Worldwide
	Methylmalonic acidemia (MMA)	mRNA-3705						Worldwide
Rare disease intracellular therapeutics	Glycogen storage disease type 1a (GSD1a)	mRNA-3745						Worldwide
	Omithine transcarbamylase deficiency (OTC)	mRNA-3139						Worldwide
	Phenylketonuria (PKU)	mRNA-3210						Worldwide
	Crigler-Najjar syndrome type 1 (CN-1)	mRNA-3351						Provided to ILCM free of charge
Inhaled pulmonary therapeutics	Cystic fibrosis (CF)	mRNA-3692 / VX-522						Vertex to pay milestones and royalties

Abbreviations: BARDA, Biomedical Advanced Research and Development Authority; CMV, cytomegalovirus; cSCC, cutaneous squamous cell carcinoma; EBV, Epstein-Barr virus; HCoV, human coronaviruses; HIV, human immunodeficiency virus; hMPV, human metapneumovirus; HSV, herpes simplex virus; IAVI, International AIDS Vaccine Initiative; ILCM, Institute for Life Changing Medicines; IL-23, interleukin 23; IL-36γ, interleukin-36 gamma; IM, infectious mononucleosis; NIH, National Institutes of Health; NSCLC, non-small cell lung cancer; OX40L, wildtype OX40 ligand; RCC, renal cell carcinoma; RSV, respiratory syncytial virus; VZV, varicella-zoster virus.

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Results of operations

The following table summarizes our condensed consolidated statements of operations for the periods presented (in millions):

	Three Months Ended June 30,		Change 2024 vs. 2023	
	2024	2023	\$	%
Revenue:				
Net product sales	\$ 184	\$ 293	\$ (109)	(37)%
Other revenue	57	51	6	12%
Total revenue	241	344	(103)	(30)%
Operating expenses:				
Cost of sales	115	731	(616)	(84)%
Research and development	1,221	1,148	73	6%
Selling, general and administrative	268	332	(64)	(19)%
Total operating expenses	1,604	2,211	(607)	(27)%
Loss from operations	(1,363)	(1,867)	504	(27)%
Interest income	111	104	7	7%
Other (expense) income, net	(27)	14	(41)	293%
Loss before income taxes	(1,279)	(1,749)	470	(27)%
Provision for (benefit from) income taxes	—	(369)	369	(100)%
Net loss	\$ (1,279)	\$ (1,380)	\$ 101	(7)%
Six Months Ended June 30,		Change 2024 vs. 2023		
		2024	2023	\$ %
Revenue:				
Net product sales	\$ 351	\$ 2,121	\$ (1,770)	(83)%
Other revenue	57	85	(28)	(33)%
Total revenue	408	2,206	(1,798)	(82)%
Operating expenses:				
Cost of sales	211	1,523	(1,312)	(86)%
Research and development	2,284	2,279	5	—%
Selling, general and administrative	542	637	(95)	(15)%
Total operating expenses	3,037	4,439	(1,402)	(32)%
Loss from operations	(2,629)	(2,233)	(396)	18%
Interest income	231	213	18	8%
Other expense, net	(46)	(34)	(12)	35%
Loss before income taxes	(2,444)	(2,054)	(390)	19%
Provision for (benefit from) income taxes	10	(753)	763	(101)%
Net loss	\$ (2,454)	\$ (1,301)	\$ (1,153)	89%

Revenue

Net product sales

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
United States	\$ 162	\$ 2	\$ 262	\$ 3
Europe	—	60	—	636
Rest of world	22	231	89	1,482
Total	\$ 184	\$ 293	\$ 351	\$ 2,121

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In the third quarter of 2023, we commenced sales of our COVID-19 vaccine to the U.S. commercial market, in addition to continuing sales to foreign governments and international organizations. In the U.S., our COVID-19 vaccine is now sold primarily to wholesalers and distributors, and to a lesser extent, directly to retailers and healthcare providers. Net product sales are recognized net of estimated wholesaler chargebacks, invoice discounts for prompt payments and pre-orders, provisions for sales returns, and other related deductions.

The following table summarizes product sales provision for the periods presented (in millions):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Gross product sales	\$ 191	\$ 293	\$ 413	\$ 2,121
Product sales provision:				
Wholesaler chargebacks, discounts and fees	22	—	—	—
Returns and other fees	(29)	—	(62)	—
Total product sales provision	\$ (7)	\$ —	\$ (62)	\$ —
Net product sales	\$ 184	\$ 293	\$ 351	\$ 2,121

As of June 30, 2024, we have two commercial products authorized for use: our COVID-19 vaccine and our RSV vaccine. Our RSV vaccine was approved by the FDA in May 2024 for adults aged 60 years and older. As of June 30, 2024, we had not commenced sales of our RSV vaccine.

As of June 30, 2024, we had deferred revenue of \$740 million associated with customer deposits received or billable under supply agreements, with the majority of our COVID-19 vaccine deliveries scheduled in 2024.

Our net product sales for the first quarter and first half of 2024 declined significantly as compared to the same periods in 2023. This decline is indicative of the evolving nature of the endemic COVID-19 vaccine market, which has transitioned toward a seasonal commercial pattern. The sales in these periods reflect this greater seasonality, with reduced demand observed during the first half of the year. We anticipate that the demand for our COVID-19 vaccine will be higher in the fall and winter seasons across both hemispheres, as countries prepare for seasonal vaccination campaigns. For the full year of 2024, we expect the progression toward a seasonal commercial market to persist, resulting in further projected reductions in net product sales for our COVID-19 vaccine relative to 2023.

Other revenue

Other revenue comprises grant revenue, collaboration revenue, and licensing and royalty revenue.

Total revenue decreased by \$103 million and \$1.8 billion, or 30% and 82%, for the three and six months ended June 30, 2024, respectively, compared to the same periods in 2023, mainly due to a reduction in net product sales of our COVID-19 vaccine.

Net product sales decreased by \$109 million and \$1.8 billion, or 37% and 83%, for the three and six months ended June 30, 2024, respectively, compared to the same periods in 2023. This was primarily due to lower sales volumes in regions outside the United States, coupled with the market's transition to a seasonal commercial pattern for the COVID-19 vaccine market. Additionally, the decrease in sales volume was attributed to the fact that in the prior year period, we primarily delivered doses that had been deferred from 2022. This decline was partially offset by a higher average selling price in the United States, where commercial market sales commenced in the third quarter of 2023.

Other revenue increased by \$6 million, or 12%, and decreased by \$28 million, or 33%, for the three and six months ended June 30, 2024, respectively, compared to the same periods in 2023. The increase for the three months ended was driven by the licensing and royalty revenue in the current period. The decrease for the six months ended was mainly due to a reduction in grant revenue under our agreement with BARDA for the development of our COVID-19 vaccine, partially offset by an increase in licensing and royalty revenue.

Operating expenses

Cost of sales

Cost of sales for the three months ended June 30, 2024 was \$115 million, which included third-party royalties of \$10 million, unutilized manufacturing capacity and wind-down costs of \$55 million, and inventory write-downs of \$14 million. Cost of sales for the six months ended June 30, 2024 was \$211 million, which included third-party royalties of \$18 million, unutilized manufacturing capacity and wind-down costs of \$82 million, and inventory write-downs of \$44 million, primarily related to our finished and semi-finished COVID-19 vaccine inventory. Cost of sales for the three months ended June 30, 2023 was \$731 million, including third-party royalties of \$12 million, inventory write-downs of \$464 million, unutilized manufacturing capacity of \$135 million, and losses on firm purchase commitments of \$75 million. Cost of sales for the six months ended June 30, 2023 was \$1.5 billion, including third-party royalties of \$98 million, inventory write-downs of \$612 million, unutilized manufacturing capacity of \$270 million, and losses on firm purchase commitments and related cancellation fees of \$117 million. Please refer to [Note 7](#) to our condensed consolidated financial statements for inventory related charges. These charges in 2024, other than royalties, were largely attributable to end-of-season demand adjustments and commitments related to manufacturing capacity.

Cost of sales for the three months ended June 30, 2024 decreased by \$616 million, or 84%, compared to the same period in 2023. Cost of sales as a percentage of net product sales for the three months ended June 30, 2024 was 62%, compared to 249% for the same period in 2023. Cost of sales for the six months ended June 30, 2024 decreased by \$1.3 billion, or 86%, compared to the same period in 2023. Cost of sales as a percentage of net product sales for the six months ended June 30, 2024 was 60%, compared to 72% for the same period in 2023. The decrease in cost of sales for both the three and six month periods in 2024 was primarily driven by a lower sales volume, coupled with reduced inventory write-downs, unutilized manufacturing capacity, and losses on firm purchase commitments and related cancellation fees. The decrease in cost of sales as a percentage of net product sales for both the three and six month periods in 2024 was mainly driven by reduced costs, partially offset by the decreased sales volume, reflecting a decline in product demand and increased product seasonality.

We anticipate that the full year cost of sales as a percentage of net product sales for 2024 will be lower than the 70% experienced in 2023. This expectation is based on projected improvements in our manufacturing efficiency and expected reductions in inventory write-downs. However, due to the strong seasonality of our business, we expect this percentage to be higher in the first half of the year than the second half of the year.

Research and development expenses

Research and development expenses increased by \$73 million, or 6%, for the three months ended June 30, 2024, compared to the same period in 2023. The increase was primarily attributable to the purchase of a priority review voucher, and an increase in personnel-related costs and stock-based compensation of \$101 million. The increase was partially offset by a decrease in clinical trial expenses of \$159 million. Research and development expenses for the six months ended June 30, 2024 remained consistent with the same period in 2023. This reflects a \$155 million increase in personnel-related costs and stock-based compensation, and the purchase of a priority review voucher, offset by a \$194 million reduction in clinical trial expenses and an \$85 million reduction in upfront license payments. The increase in personnel-related costs and stock-based compensation for both periods was driven by higher headcount to support our continued research and development efforts. The decrease in clinical trial expenses for both periods was due to reduced spending on our COVID-19 and seasonal flu programs, aligning with our planned trial schedules.

We anticipate a modest reduction in research and development expenses in 2024 compared to 2023 levels. We continue to develop our pipeline and advance our product candidates into later-stage development, particularly our ongoing Phase 3 studies. These include our next-generation COVID-19, seasonal flu, CMV and combination vaccine programs, as well as our INT program.

Selling, general and administrative expenses

Selling, general and administrative expenses decreased by \$64 million, or 19%, for the three months ended June 30, 2024, compared to the same period in 2023, mainly due to a decrease in consulting and outside services across all functions of \$65 million. Selling, general and administrative expenses decreased by \$95 million, or 15%, for the six months ended June 30, 2024, compared to the same period in 2023. The decrease for the six months ended June 30, 2024 was mainly due to a \$145 million reduction in consulting and outside services across all functions, partially offset by an increase in personnel-related costs and stock-based compensation of \$54 million, primarily driven by an expanded headcount in digital, medical affairs and commercial functions to support our digital and artificial intelligence initiatives and marketed products. The decrease in both periods reflects cost discipline and efficiencies gained by reducing reliance on external consultants and bringing functions in-house.

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We anticipate that selling, general and administrative expenses in 2024 will be slightly lower than the levels experienced in 2023. This reflects our ongoing commitment to efficiency as we expand our global commercial, regulatory, sales and marketing infrastructure. Moreover, it aligns with our strategic focus on advancing our program development and enhancing our overall business processes.

Interest income

For the three and six months ended June 30, 2024, interest income increased by \$7 million and \$18 million, or 7% and 8%, respectively, compared to the same periods in 2023. The increase in interest income from our investments in marketable securities for the three and six month periods in 2024 was mainly attributable to an overall higher interest rate environment, partially offset by lower average investment balances.

Other (expense) income, net

The following tables summarize other (expense) income, net for the periods presented (in millions):

	Three Months Ended June 30,		Change 2024 vs. 2023	
	2024	2023	\$	%
(Loss) gain on investments	\$ (23)	\$ 22	\$ (45)	205%
Interest expense	(6)	(13)	7	(54)%
Other income, net	2	5	(3)	(60)%
Total other (expense) income, net	\$ (27)	\$ 14	\$ (41)	293%

	Six Months Ended June 30,		Change 2024 vs. 2023	
	2024	2023	\$	%
Loss on investments	\$ (38)	\$ (13)	\$ (25)	192%
Interest expense	(12)	(22)	10	(45)%
Other income, net	4	1	3	300%
Total other expense, net	\$ (46)	\$ (34)	\$ (12)	35%

For the three and six months ended June 30, 2024, total other expense, net increased by \$41 million and \$12 million, or 293% and 35%, respectively, compared to the same periods in 2023. The increase in other expense, net for the three and six months ended June 30, 2024 was primarily due to the increases in losses on equity investments and available-for-sale debt securities. Our interest expense is primarily related to our finance leases. Please refer to [Note 10](#) to our condensed consolidated financial statements.

Income taxes

Provision for income taxes increased by \$369 million and \$763 million, or 100% and 101%, for the three and six months ended June 30, 2024, compared to the same periods in 2023. The increase in both periods was primarily due to certain of our foreign subsidiaries that have taxable income, while we incurred a net loss before income taxes on a consolidated basis. We cannot recognize tax benefits from the loss due to our global valuation allowance, which we continue to maintain against the majority of our global deferred tax assets. As a result of the valuation allowance, the effective tax rates for the three and six months ended June 30, 2024 are not comparable to the same periods in the prior year. Please refer to [Note 13](#) to our condensed consolidated financial statements.

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Liquidity and capital resources

The following table summarizes our cash, cash equivalents, investments and working capital as of June 30, 2024 and December 31, 2023 (in millions):

	June 30, 2024	December 31, 2023
Financial assets:		
Cash and cash equivalents	\$ 2,478	\$ 2,907
Investments	6,010	5,697
Investments, non-current	2,326	4,677
Total	\$ 10,814	\$ 13,281
Working capital:		
Current assets	\$ 9,661	\$ 10,325
Current liabilities	2,363	3,015
Total	\$ 7,298	\$ 7,310

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, 2024 decreased by \$2.5 billion, or 19%, compared to December 31, 2023. The decrease in cash, cash equivalents and investments was primarily due to a net cash outflow from operating activities of \$2.3 billion and purchases of property and equipment of \$378 million during the six months ended June 30, 2024.

Working capital, which is current assets less current liabilities, as of June 30, 2024 decreased by \$12 million, compared to December 31, 2023, primarily due to a decrease in accounts receivable of \$729 million, mainly due to timing of collections and decline in product sales. This was partially offset by a decrease in accrued liabilities of \$465 million and a decrease in accounts payable of \$241 million, both of which were driven by lower spend during the period.

As of June 30, 2024, we did not have any off-balance sheet arrangements, other than those obligations and commitments disclosed herein.

Cash flow

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

	Six Months Ended June 30,	
	2024	2023
Net cash (used in) provided by:		
Operating activities	\$ (2,263)	\$ (2,140)
Investing activities	1,767	3,955
Financing activities	48	(1,210)
Net (decrease) increase in cash, cash equivalents and restricted cash	\$ (448)	\$ 605

Operating activities

We derive cash flows from operations primarily from cash collected from customer deposits and accounts receivable related to our COVID-19 vaccine product sales, as well as certain government-sponsored and private organizations, strategic alliances and funding arrangements. 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, foreign governments and international organizations for the supply of our COVID-19 vaccine and received upfront deposits. In the third quarter of 2023, we commenced sales of our COVID-19 vaccine to the U.S. commercial market, in addition to continuing sales to foreign governments and international organizations. In the U.S., our COVID-19 vaccine is sold primarily to wholesalers and distributors, and to a lesser extent, directly to retailers and healthcare providers. Wholesalers and distributors typically do not make upfront payments to us. As of June 30, 2024, we had \$740 million in deferred revenue related to customer deposits received or billable.

Net cash used in operating activities for the six months ended June 30, 2024 was \$2.3 billion and consisted of net loss of \$2.5 billion, non-cash adjustments of \$277 million and a net change in assets and liabilities of \$86 million. Non-cash items primarily included stock-based compensation of \$213 million, and depreciation and amortization of \$77 million. The net change in assets and liabilities was mainly due to an increase in inventory of \$197 million, driven by increased raw material purchases and manufacturing of COVID products, and decreases in accrued liabilities of \$464 million and accounts payable of \$199 million, driven by overall lower spend in the period. This was partially offset by a decrease in accounts receivable of \$729 million driven by timing of collections and decline in product sales, and an increase in deferred revenue of \$146 million due to customer deposits received in excess of revenue recognized.

Net cash used in operating activities increased by \$123 million, or 6%, during the six months ended June 30, 2024, compared to the same period in 2023, primarily attributable to an increase in net loss of \$1.2 billion, a change in inventory of \$431 million, driven by less inventory write-downs, and a decrease in accounts receivable of \$424 million related to timing of collections and decline in product sales, partially offset by a change in deferred revenue of \$1.1 billion due to customer deposits received in excess of revenue recognized, and deferred income taxes of \$530 million driven by an increase in valuation allowance.

Investing activities

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

Net cash provided by investing activities for the six months ended June 30, 2024 was \$1.8 billion, which primarily included proceeds from maturities and sales of marketable securities of \$5.5 billion, partially offset by purchases of marketable securities of \$3.4 billion, and purchases of property and equipment of \$378 million.

Net investing cash flows decreased by \$2.2 billion, or 55%, during the six months ended June 30, 2024, compared to the same period in 2023, primarily due to an increase in purchases of marketable securities of \$2.1 billion.

Financing activities

Net cash provided by financing activities for the six months ended June 30, 2024 was \$48 million, primarily due to proceeds from issuance of common stock through equity plans of \$47 million.

Net cash provided by financing activities increased by \$1.3 billion, or 104%, during the six months ended June 30, 2024, compared to the same period in 2023, mainly due to a decrease in repurchases of common stock of \$1.2 billion.

Operation and funding requirements

Our principal sources of funding as of June 30, 2024 consisted of cash and cash equivalents, investments, and cash we may generate from operations. We generated net income of \$8.4 billion and \$12.2 billion for the years ended in 2022 and 2021, respectively, 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 also incurred a net loss of \$2.5 billion for the six months ended June 30, 2024 and a net loss of \$4.7 billion for the year ended 2023. We have retained earnings of \$11.2 billion as of June 30, 2024.

We have significant future capital requirements including expected operating expenses to conduct research and development activities, operate our organization, and meet capital expenditure needs. We anticipate maintaining substantial expenses across all areas of our ongoing activities, particularly as we continue research and development of our development candidates and clinical activities for our investigational medicines. This also extends to our manufacturing costs, including our arrangements with our supply and manufacturing partners. Our ongoing work on our RSV, seasonal flu and CMV vaccine candidates, individualized neoantigen therapy, next generation COVID-19 vaccine, combination vaccines, late-stage clinical development, and buildout of global commercial, regulatory, sales and marketing infrastructure and manufacturing facilities will require significant cash outflows in future periods, most of which will 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 10](#) and [Note 11](#) to our condensed consolidated financial statements). We have entered into various collaboration and licensing agreements, as well as a research and development funding arrangement with third parties. These arrangements collectively encompass the funding of specific research and development activities, with the distinction that under the research and development funding arrangement, we receive funding. However, for all these arrangements, we may be obligated to make potential future milestone and royalty payments.

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We believe that our cash, cash equivalents, and investments as of June 30, 2024, together with cash expected to be generated from product sales, will be sufficient to enable us to fund our projected operations and capital expenditures 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. For example, we experienced a decline in customer demand for our COVID-19 vaccine in 2023, and this trend continued into the first half of 2024, reflecting the market's ongoing transition to a seasonal commercial pattern in the endemic COVID-19 vaccine market. We foresee that our commitment to investing in our business for future product launches may lead to continued negative cash flows from operations in upcoming periods. 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.

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, 2024 compared to those disclosed in our 2023 Form 10-K.

Contractual Obligations

As of June 30, 2024, other than disclosed within [Note 5](#), [Note 10](#) and [Note 11](#) 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 2023 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 2023 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, 2024.

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, 2024. 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, 2024, 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

We deployed a new Enterprise Resource Planning (ERP) system to align with our current operating models, which went live in the second quarter of 2024. In conjunction with this ERP implementation, we revised relevant internal controls, processes, and procedures. Given the inherent risks in implementing an ERP system, we will continue to evaluate the design and operational effectiveness of these controls. Aside from those associated with the ERP implementation, 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, 2024, 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 in our 2023 Form 10-K under the heading "Legal Proceedings." 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 2023 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 and product candidates." 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.

Pfizer/BioNTech Patent Litigation

As more fully described in our 2023 Form 10-K, we have initiated patent infringement proceedings against Pfizer and BioNTech (and affiliated entities) in the U.S. and Europe. Pfizer and BioNTech have also filed actions seeking revocation of certain of our patents.

There are two patents at issue in the European patent infringement proceedings—EP3590949 (the '949 patent), which relates to chemically-modified mRNA and EP3718565 (the '565 patent), which relates to coronavirus mRNA vaccines.

In July 2024, the High Court of Justice of England & Wales issued a judgment confirming the validity of the '949 patent and finding that Pfizer and BioNTech had infringed the patent. The court further determined that the '565 patent was invalid. These decisions are first instance decisions subject to appeal.

In December 2023, the District Court of The Hague issued a first instance decision determining that the '949 patent was invalid in the Netherlands. Moderna has appealed this decision to the Court of Appeal of The Hague, with a second instance decision expected in 2025.

In addition, there remain ongoing Opposition Proceedings at the European Patent Office by a number of opponents, including Pfizer and BioNTech related to these two patents.

Item 1A. Risk Factors

Information regarding risk and uncertainties related to our business appears in Part I, Item 1A. "Risk Factors" of our 2023 Form 10-K. There have been no material changes from the risk factors previously disclosed in the 2023 Form 10-K.

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

Issuer Purchases of Equity Securities

On August 1, 2022, our Board of Directors authorized a share repurchase program for our common stock of up to \$3.0 billion, with no expiration date. During the three months ended June 30, 2024, there were no shares repurchased. As of June 30, 2024, \$1.7 billion of our Board of Directors' authorization for repurchases of our common stock remains outstanding, with no expiration date.

For details about our share repurchase programs, please refer to Note 12 to our consolidated financial statements, as set forth in our 2023 Form 10-K.

Item 5. Other Information

During the three months ended June 30, 2024, the following officers (as defined in Rule 16a-1(f) of the Securities Exchange Act of 1934, as amended) of the Company took the following actions regarding trading arrangements with respect to our securities:

On June 10, 2024, Stephane Bancel, our Chief Executive Officer, adopted a trading arrangement that is intended to satisfy the affirmative defense of Rule 10b5-1(c) (the Bancel 10b5-1 Plan). Between September 25, 2024 and February 27, 2025, the Bancel 10b5-1 Plan provides for the potential sale of up to 150,000 shares of the Company's common stock. The Bancel 10b5-1 Plan expires on February 27, 2025, or upon the earlier completion of all authorized transactions under the Bancel 10b5-1 Plan.

On June 10, 2024, Shannon Klinger, our Chief Legal Officer, adopted a trading arrangement that is intended to satisfy the affirmative defense of Rule 10b5-1(c) (the Klinger 10b5-1 Plan). Between September 12, 2024 and August 15, 2025, the Klinger 10b5-1 Plan provides for the potential exercise of vested stock options and the associated sale of up to 73,086 shares of the Company's common stock. The Klinger 10b5-1 Plan expires on August 15, 2025, or upon the earlier completion of all authorized transactions under the Klinger 10b5-1 Plan.

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>
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

+ 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 1, 2024 By: /s/ Stéphane Bancel
Stéphane Bancel
Chief Executive Officer and Director
(*Principal Executive Officer*)

Date: August 1, 2024 By: /s/ James M. Mock
James M. Mock
Chief Financial Officer
(*Principal Financial 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, 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 1, 2024

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, James M. Mock, 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 1, 2024

By: /s/ James M. Mock

James M. Mock

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, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), we, Stéphane Bancel, Chief Executive Officer of the Company, and James M. Mock, 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 1, 2024

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

Date: August 1, 2024

By: /s/ James M. Mock
James M. Mock
Chief Financial Officer
(Principal Financial Officer)