

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

(Mark One)

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

325 Binney Street
Cambridge, Massachusetts 02142
(Address of Principal Executive (Zip Code)
Offices)

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

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

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

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

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

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

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

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

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

As of October 31, 2024, there were 384,817,811 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 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;
- commercialization of our respiratory syncytial virus (RSV) vaccine (mRNA-1345), including anticipated demand, competition and further regulatory approvals for this product;
- our ability to obtain and maintain regulatory approval of our product candidates;
- our ability to successfully launch and commercialize our products and the timing of launches;
- 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;
- our ability and the ability of third parties with whom we contract to successfully manufacture, supply and distribute our COVID-19 or RSV vaccines and any future commercial products at scale, as well as drug substances, delivery vehicles, development candidates, and investigational medicines for preclinical and clinical use;
- 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;
- internal and external costs associated with manufacturing our products, including our COVID-19 or RSV vaccines, and the impact on our cost of sales, and our anticipated 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 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;
- the implementation of our business model and strategic plans for our business, products, product candidates and technology;
- 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.x.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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MODERNA, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited, in millions, except per share data)

	September 30, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	\$ 1,644	\$ 2,907
Investments	5,223	5,697
Accounts receivable, net	1,564	892
Inventory	412	202
Prepaid expenses and other current assets	823	627
Total current assets	9,666	10,325
Investments, non-current	2,335	4,677
Property, plant and equipment, net	2,381	1,945
Right-of-use assets, operating leases	784	713
Deferred tax assets	81	81
Other non-current assets	556	685
Total assets	<u>\$ 15,803</u>	<u>\$ 18,426</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 373	\$ 520
Accrued liabilities	1,376	1,798
Deferred revenue	379	568
Income taxes payable	4	63
Other current liabilities	69	66
Total current liabilities	2,201	3,015
Deferred revenue, non-current	95	83
Operating lease liabilities, non-current	679	643
Financing lease liabilities, non-current	625	575
Other non-current liabilities	276	256
Total liabilities	3,876	4,572
Commitments and contingencies (Note 11)		
Stockholders' equity:		
Preferred stock, par value \$0.0001; 162 shares authorized as of September 30, 2024 and December 31, 2023; no shares issued or outstanding at September 30, 2024 and December 31, 2023	—	—
Common stock, par value \$0.0001; 1,600 shares authorized as of September 30, 2024 and December 31, 2023; 385 and 382 shares issued and outstanding as of September 30, 2024 and December 31, 2023, respectively	—	—
Additional paid-in capital	751	371
Accumulated other comprehensive income (loss)	11	(123)
Retained earnings	11,165	13,606
Total stockholders' equity	11,927	13,854
Total liabilities and stockholders' equity	<u>\$ 15,803</u>	<u>\$ 18,426</u>

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Revenue:				
Net product sales	\$ 1,820	\$ 1,757	\$ 2,171	\$ 3,878
Other revenue	42	74	99	159
Total revenue	1,862	1,831	2,270	4,037
Operating expenses:				
Cost of sales	514	2,241	725	3,764
Research and development	1,137	1,160	3,421	3,439
Selling, general and administrative	281	442	823	1,079
Total operating expenses	1,932	3,843	4,969	8,282
Loss from operations	(70)	(2,012)	(2,699)	(4,245)
Interest income	103	105	334	318
Other expense, net	(12)	(51)	(58)	(85)
Income (loss) before income taxes	21	(1,958)	(2,423)	(4,012)
Provision for income taxes	8	1,672	18	919
Net income (loss)	\$ 13	\$ (3,630)	\$ (2,441)	\$ (4,931)
Earnings (loss) per share:				
Basic	\$ 0.03	\$ (9.53)	\$ (6.37)	\$ (12.89)
Diluted	\$ 0.03	\$ (9.53)	\$ (6.37)	\$ (12.89)
Weighted average common shares used in calculation of earnings (loss) per share:				
Basic	385	381	383	382
Diluted	399	381	383	382

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Net income (loss)	\$ 13	\$ (3,630)	\$ (2,441)	\$ (4,931)
Other comprehensive income, net of tax:				
Available-for-sale securities:				
Unrealized gains on available-for-sale securities	73	46	122	115
Less: net realized losses on available-for-sale securities reclassified in net income (loss)	1	6	4	36
Net increase from available-for-sale securities	74	52	126	151
Cash flow hedges:				
Less: net realized losses on derivative instruments reclassified in net income (loss)	—	—	—	8
Net increase from derivatives designated as hedging instruments	—	—	—	8
Gains on foreign currency translation	8	—	8	—
Total other comprehensive income	82	52	134	159
Comprehensive income (loss)	<u>\$ 95</u>	<u>\$ (3,578)</u>	<u>\$ (2,307)</u>	<u>\$ (4,772)</u>

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

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

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Retained Earnings	Total Stockholders' Equity
	Shares	Amount				
Balance at June 30, 2024	384	\$ —	\$ 631	\$ (71)	\$ 11,152	\$ 11,712
Exercise of options to purchase common stock	—	—	2	—	—	2
Issuance of common stock under employee stock purchase plan	1	—	6	—	—	6
Stock-based compensation	—	—	112	—	—	112
Other comprehensive income, net of tax	—	—	—	82	—	82
Net income	—	—	—	—	13	13
Balance at September 30, 2024	385	\$ —	\$ 751	\$ 11	\$ 11,165	\$ 11,927

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Retained Earnings	Total Stockholders' Equity
	Shares	Amount				
Balance at June 30, 2023	381	\$ —	\$ 193	\$ (263)	\$ 17,019	\$ 16,949
Exercise of options to purchase common stock	—	—	6	—	—	6
Stock-based compensation	—	—	77	—	—	77
Other comprehensive income, net of tax	—	—	—	52	—	52
Repurchase of common stock, including excise tax	—	—	1	—	—	1
Net loss	—	—	—	—	(3,630)	(3,630)
Balance at September 30, 2023	381	\$ —	\$ 277	\$ (211)	\$ 13,389	\$ 13,455

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	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Retained Earnings	Total Stockholders' Equity
	Shares	Amount				
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	—	39	—	—	39
Issuance of common stock under employee stock purchase plan	1	—	16	—	—	16
Stock-based compensation	—	—	325	—	—	325
Other comprehensive income, net of tax	—	—	—	134	—	134
Net loss	—	—	—	—	(2,441)	(2,441)
Balance at September 30, 2024	385	\$ —	\$ 751	\$ 11	\$ 11,165	\$ 11,927

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Retained Earnings	Total Stockholders' Equity
	Shares	Amount				
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	—	19	—	—	19
Issuance of common stock under employee stock purchase plan	—	—	12	—	—	12
Stock-based compensation	—	—	226	—	—	226
Other comprehensive income, net of tax	—	—	—	159	—	159
Repurchase of common stock, including excise tax	(8)	—	(1,153)	—	—	(1,153)
Net loss	—	—	—	—	(4,931)	(4,931)
Balance at September 30, 2023	381	\$ —	\$ 277	\$ (211)	\$ 13,389	\$ 13,455

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

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

	Nine Months Ended September 30,	
	2024	2023
Operating activities		
Net loss	\$ (2,441)	\$ (4,931)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	325	226
Depreciation and amortization	129	419
Amortization/accretion of investments	(76)	(41)
Loss on equity investments, net	43	16
Deferred income taxes	—	934
Other non-cash items	6	25
Changes in assets and liabilities, net of acquisition of business:		
Accounts receivable, net	(672)	(481)
Prepaid expenses and other assets	(147)	772
Inventory	(208)	462
Right-of-use assets, operating leases	(63)	(657)
Accounts payable	(103)	(8)
Accrued liabilities	(415)	63
Deferred revenue	(177)	(1,173)
Income taxes payable	(58)	8
Operating lease liabilities	33	605
Other liabilities	(5)	21
Net cash used in operating activities	<u>(3,829)</u>	<u>(3,740)</u>
Investing activities		
Purchases of marketable securities	(4,641)	(2,097)
Proceeds from maturities of marketable securities	4,648	4,711
Proceeds from sales of marketable securities	3,010	2,725
Purchases of property, plant and equipment	(529)	(487)
Acquisition of business, net of cash acquired	—	(85)
Investment in convertible notes and equity securities	—	(23)
Net cash provided by investing activities	<u>2,488</u>	<u>4,744</u>
Financing activities		
Proceeds from issuance of common stock through equity plans	55	31
Repurchase of common stock, including excise tax	—	(1,153)
Changes in financing lease liabilities	4	(146)
Net cash provided by (used in) financing activities	<u>59</u>	<u>(1,268)</u>
Effect of changes in exchange rates on cash and cash equivalents	1	—
Net decrease in cash, cash equivalents and restricted cash	<u>(1,281)</u>	<u>(264)</u>
Cash, cash equivalents and restricted cash, beginning of year	2,928	3,217
Cash, cash equivalents and restricted cash, end of period	<u>\$ 1,647</u>	<u>\$ 2,953</u>
Non-cash investing and financing activities		
Purchases of property and equipment included in accounts payable and accrued liabilities	\$ 78	\$ 148
Right-of-use assets obtained through finance lease modifications and reassessments	\$ —	\$ 213
Right-of-use assets obtained in exchange for financing lease liabilities	\$ 75	\$ —

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 36 development candidates across our 45 development programs, of which 42 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 nine months ended September 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 nine months ended September 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.

[Table of Contents](#)**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 foreign currency translation, as well as, 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 income for the three and nine months ended September 30, 2024 were as follows (in millions):

	Unrealized Gains on Available-for-Sale Debt Securities	Pension and Postretirement Benefits	Gains on Foreign Currency Translation	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)
Other comprehensive income	74	—	8	82
Accumulated other comprehensive income, balance at September 30, 2024	<u>\$ 12</u>	<u>\$ (9)</u>	<u>\$ 8</u>	<u>\$ 11</u>

Restricted Cash

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

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

	September 30,	
	2024	2023
Cash and cash equivalents	\$ 1,644	\$ 2,932
Restricted cash ⁽¹⁾	—	17
Restricted cash, non-current ⁽²⁾	3	4
Total cash, cash equivalents and restricted cash shown in the condensed consolidated statements of cash flows	<u>\$ 1,647</u>	<u>\$ 2,953</u>

⁽¹⁾Included in prepaid expenses and other current assets in the condensed consolidated balance sheets.

⁽²⁾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

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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 September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
United States	\$ 1,215	\$ 913	\$ 1,477	\$ 916
Europe	281	103	281	739
Rest of world	324	741	413	2,223
Total	<u>\$ 1,820</u>	<u>\$ 1,757</u>	<u>\$ 2,171</u>	<u>\$ 3,878</u>

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
COVID-19	\$ 1,810	\$ 1,757	\$ 2,161	\$ 3,878
RSV	10	—	10	—
Total	<u>\$ 1,820</u>	<u>\$ 1,757</u>	<u>\$ 2,171</u>	<u>\$ 3,878</u>

As of September 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 and we commenced sales of our RSV vaccine in the third quarter of 2024.

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 September 30, 2024 and December 31, 2023, we had deferred revenue of \$443 million and \$613 million, respectively, related to customer deposits for our COVID-19 vaccine. We expect \$361 million of our deferred revenue related to customer deposits as of September 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 COVID-19 vaccine to the U.S. commercial market, in addition to continuing sales to foreign governments and international organizations. We also commenced sales of our RSV vaccine in the third quarter of 2024. In the U.S., our COVID-19 and RSV vaccines are 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.

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Gross product sales	\$ 2,964	\$ 2,420	\$ 3,377	\$ 4,541
Product sales provision:				
Wholesaler chargebacks, discounts and fees	(1,053)	(479)	(1,053)	(479)
Returns, rebates and other fees	(91)	(184)	(153)	(184)
Total product sales provision ⁽¹⁾	\$ (1,144)	\$ (663)	\$ (1,206)	\$ (663)
Net product sales	\$ 1,820	\$ 1,757	\$ 2,171	\$ 3,878

⁽¹⁾Includes an adjustment of approximately \$140 million in the third quarter of 2024, reflecting a reduction in prior period provision estimates, primarily related to returns for the previous COVID-19 vaccine season that closed during the quarter.

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

	Returns and other fees
Balance at December 31, 2023	\$ (556)
Provision related to sales made in 2024	(308)
Provision related to sales made in prior periods ⁽¹⁾	155
Payments and returns related to sales made in current period	42
Payments and returns related to sales made in prior year	264
Balance at September 30, 2024	\$ (403)

⁽¹⁾Primarily reflecting a reduction in prior period return estimates for the previous COVID-19 vaccine season that closed during the quarter.

4. Other Revenue

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Grant revenue	\$ 7	\$ 44	\$ 27	\$ 96
Collaboration revenue	28	30	35	63
Licensing and royalty revenue	7	—	37	—
Total other revenue	\$ 42	\$ 74	\$ 99	\$ 159

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 September 30, 2024, the remaining available funding, net of revenue earned was \$70 million.

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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 September 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. In the third quarter of 2024, we began recognizing royalty revenue by amortizing the deferred revenue as the underlying sales occurred.

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 nine months ended September 30, 2024, we recognized expenses, net of Merck's reimbursements, of \$109 million and \$280 million, respectively, related to the INT collaboration under the Merck Participation Term. For the three and nine months ended September 30, 2023, these expenses were \$53 million and \$122 million, respectively.

Additionally, for the three and nine months ended September 30, 2024, the net cost recovery for capital expenditures was \$25 million and \$82 million, respectively. For the three and nine months ended September 30, 2023, the net cost recovery for capital expenditures was \$16 million and \$34 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.

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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. For the three and nine months ended September 30, 2024, we recorded research and development expense reductions of \$30 million and \$35 million, respectively.

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 September 30, 2024 and December 31, 2023 (in millions):

	September 30, 2024						
	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value	Cash and Cash Equivalents	Current Marketable Securities	Non-Current Marketable Securities
Cash and cash equivalents	\$ 1,644	\$ —	\$ —	\$ 1,644	\$ 1,644	\$ —	\$ —
Available-for-sale:							
Certificates of deposit	27	—	—	27	—	27	—
U.S. treasury bills	538	1	—	539	—	539	—
U.S. treasury notes	3,234	7	(15)	3,226	—	2,244	982
Corporate debt securities	3,625	7	(18)	3,614	—	2,269	1,345
Government debt securities	153	—	(1)	152	—	144	8
Total	<u>\$ 9,221</u>	<u>\$ 15</u>	<u>\$ (34)</u>	<u>\$ 9,202</u>	<u>\$ 1,644</u>	<u>\$ 5,223</u>	<u>\$ 2,335</u>
	December 31, 2023						
	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value	Cash and Cash Equivalents	Current Marketable Securities	Non-Current Marketable Securities
Cash and cash equivalents	\$ 2,907	\$ —	\$ —	\$ 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	<u>\$ 13,426</u>	<u>\$ 6</u>	<u>\$ (151)</u>	<u>\$ 13,281</u>	<u>\$ 2,907</u>	<u>\$ 5,697</u>	<u>\$ 4,677</u>

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

	September 30, 2024	
	Amortized Cost	Estimated Fair Value
Due in one year or less	\$ 5,240	\$ 5,223
Due after one year through five years	2,337	2,335
Total	<u>\$ 7,577</u>	<u>\$ 7,558</u>

	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	<u>\$ 10,519</u>	<u>\$ 10,374</u>

In accordance with our investment policy, we place investments in investment grade securities with high credit quality issuers, and generally limit the amount of credit exposure to any one issuer. We evaluate securities for impairment at the end of each reporting period. Impairment is evaluated considering numerous factors, and their relative significance varies depending on the situation. Factors considered include whether a decline in fair value below the amortized cost basis is due to credit-related factors or non-credit-related factors, the financial condition and near-term prospects of the issuer, and our intent and ability to hold the investment to allow for an anticipated recovery in fair value. Any impairment that is not credit related is recognized in other comprehensive 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 nine months ended September 30, 2024 and 2023. We did not record any credit-related allowance for available-for-sale securities as of September 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 September 30, 2024 and December 31, 2023 (in millions):

	Less than 12 Months		12 Months or More		Total	
	Gross Unrealized Losses	Estimated Fair Value	Gross Unrealized Losses	Estimated Fair Value	Gross Unrealized Losses	Estimated Fair Value
As of September 30, 2024:						
U.S. treasury bills	\$ —	\$ 219	\$ —	\$ —	\$ —	\$ 219
U.S. treasury notes	—	300	(15)	1,581	(15)	1,881
Corporate debt securities	(1)	368	(18)	1,921	(19)	2,289
Government debt securities	—	—	—	76	—	76
Total	<u>\$ (1)</u>	<u>\$ 887</u>	<u>\$ (33)</u>	<u>\$ 3,578</u>	<u>\$ (34)</u>	<u>\$ 4,465</u>
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	<u>\$ (4)</u>	<u>\$ 1,369</u>	<u>\$ (147)</u>	<u>\$ 6,644</u>	<u>\$ (151)</u>	<u>\$ 8,013</u>

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As of September 30, 2024 and December 31, 2023, we held 233 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).

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

	Fair value at September 30, 2024	Fair Value Measurement Using	
		Level 1	Level 2
Assets:			
Money market funds	\$ 530	\$ 530	\$ —
Certificates of deposit	27	—	27
U.S. treasury bills	1,164	—	1,164
U.S. treasury notes	3,226	—	3,226
Corporate debt securities	3,975	—	3,975
Government debt securities	152	—	152
Equity investments ⁽¹⁾	23	23	—
Total	<u>\$ 9,097</u>	<u>\$ 553</u>	<u>\$ 8,544</u>
Liabilities:			
Derivative instruments	<u>\$ 2</u>	<u>\$ —</u>	<u>\$ 2</u>

	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	<u>\$ 12,904</u>	<u>\$ 1,596</u>	<u>\$ 11,308</u>
Liabilities:			
Derivative instruments	<u>\$ 9</u>	<u>\$ —</u>	<u>\$ 9</u>

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⁽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 expense, net, in our condensed consolidated statements of operations.

As of September 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 nine months ended September 30, 2024, we recognized net losses of \$8 million and \$43 million, respectively, on equity investments from changes in fair value of the securities. For the three and nine months ended September 30, 2023, we recognized net losses of \$33 million and \$16 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 September 30, 2024.

7. Inventory

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

	September 30, 2024	December 31, 2023
Raw materials	\$ 171	\$ 163
Work in progress	95	15
Finished goods	146	24
Total inventory	<u>\$ 412</u>	<u>\$ 202</u>
Inventory, non-current ⁽¹⁾	\$ 65	\$ 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 nine months ended September 30, 2024, inventory write-downs were \$214 million and \$302 million, respectively. For the three and nine months ended September 30, 2023, inventory write-downs were \$1.3 billion and \$1.9 billion, respectively. For both the three and nine months ended September 30, 2024, losses on firm purchase commitments were \$21 million. For the three and nine months ended September 30, 2023, losses on firm purchase commitments were zero and \$141 million, respectively. Inventory write-downs were mainly related to obsolete inventory due to inventory in excess of expected demand and shelf-life expiration. 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 September 30, 2024 and December 31, 2023, the accrued liability for losses on firm future purchase commitments in our condensed consolidated balance sheets was \$21 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 September 30, 2024 and December 31, 2023, we had inventory on hand of \$477 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.

[Table of Contents](#)**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 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. During the third quarter of 2024 and the subsequent period, our vaccine targeting the KP.2 strain received approval from the FDA and Health Canada, while our vaccine targeting the JN.1 strain was approved by regulatory authorities in the European Union, the United Kingdom, and other global markets. We have since commenced the supply of this updated vaccine to customers.

8. Property, Plant and Equipment, Net

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

	September 30, 2024	December 31, 2023
Land and land improvements	\$ 22	\$ 22
Building and building improvements	87	—
Manufacturing and laboratory equipment	384	345
Leasehold improvements	674	522
Furniture, fixtures and other	33	26
Computer equipment and software	153	74
Construction in progress	975	860
Right-of-use assets, financing (Note 10)	604	529
Total	2,932	2,378
Less: Accumulated depreciation	(551)	(433)
Property, plant and equipment, net	\$ 2,381	\$ 1,945

Depreciation and amortization expense for three and nine months ended September 30, 2024 was \$51 million and \$126 million, respectively. Depreciation and amortization expense for the three and nine months ended September 30, 2023 was \$246 million and \$414 million, respectively.

9. Other Balance Sheet Components***Accounts Receivable, net***

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

	September 30, 2024	December 31, 2023
Accounts receivable	\$ 2,732	\$ 1,584
Less: Wholesalers chargebacks, discounts and fees	(1,168)	(692)
Accounts receivable, net	\$ 1,564	\$ 892

[Table of Contents](#)**Prepaid Expenses and Other Current Assets**

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

	September 30, 2024	December 31, 2023
Prepaid services	\$ 286	\$ 182
Down payments and prepayments related to manufacturing and materials	193	168
Income tax receivable	105	19
Collaboration receivable	99	61
Interest receivable	50	59
Prepaid income tax	26	—
Value added tax receivable	18	50
Other current assets	46	88
Prepaid expenses and other current assets	<u>\$ 823</u>	<u>\$ 627</u>

Other Non-Current Assets

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

	September 30, 2024	December 31, 2023
Down payments and prepayments, non-current	\$ 355	\$ 342
Inventory, non-current ⁽¹⁾	65	170
Goodwill	52	52
Finite-lived intangible asset	41	44
Equity investments	23	66
Other	20	11
Other non-current assets	<u>\$ 556</u>	<u>\$ 685</u>

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

[Table of Contents](#)**Accrued Liabilities**

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

	September 30, 2024	December 31, 2023
Provisions related to product sales (Note 3)	\$ 403	\$ 556
Compensation-related	244	245
Other external goods and services	177	137
Manufacturing	137	167
Royalties	92	122
Development operations	80	140
Property, plant and equipment	78	94
Raw materials	57	27
Clinical trials	51	175
Commercial	36	56
Loss on future firm purchase commitments ⁽¹⁾	21	79
Accrued liabilities	<u>\$ 1,376</u>	<u>\$ 1,798</u>

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

	September 30, 2024	December 31, 2023
Lease liabilities - financing (Note 10)	\$ 30	\$ —
Lease liabilities - operating (Note 10)	\$ 21	\$ 25
Other	18	41
Other current liabilities	<u>\$ 69</u>	<u>\$ 66</u>

Other Non-Current Liabilities

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

	September 30, 2024	December 31, 2023
Tax liabilities	\$ 241	\$ 235
Other	35	21
Other non-current liabilities	<u>\$ 276</u>	<u>\$ 256</u>

[Table of Contents](#)**Deferred Revenue**

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

	December 31, 2023	Additions	Deductions	September 30, 2024
Product sales	\$ 613	\$ 224	\$ (394)	\$ 443
Grant revenue	4	8	(1)	11
Collaboration revenue	34	7	(34)	7
Licensing and royalty revenue	—	20	(7)	13
Total deferred revenue	<u>\$ 651</u>	<u>\$ 259</u>	<u>\$ (436)</u>	<u>\$ 474</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, as well as office, lab, and manufacturing 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 MTC 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.

In September 2024, we entered into a purchase and sale agreement for the properties we currently lease in Norwood, Massachusetts, where the MTC is located. The total purchase price for the properties is approximately \$370 million. In October 2024, we made a nonrefundable deposit of \$50 million as part of the transaction. The closing of the transaction is subject to certain conditions, with an anticipated closing date in December 2024.

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

	September 30, 2024	December 31, 2023
Assets:		
Right-of-use assets, operating, net ^{(1) (2)}	\$ 784	\$ 713
Right-of-use assets, financing, net ^{(3) (4)}	498	436
Total	<u>\$ 1,282</u>	<u>\$ 1,149</u>
Liabilities:		
Current:		
Operating lease liabilities ⁽⁵⁾	\$ 21	\$ 25
Financing lease liabilities ⁽⁵⁾	30	—
Total current lease liabilities	<u>51</u>	<u>25</u>
Non-current:		
Operating lease liabilities, non-current	679	643
Financing lease liabilities, non-current	625	575
Total non-current lease liabilities	<u>1,304</u>	<u>1,218</u>
Total	<u>\$ 1,355</u>	<u>\$ 1,243</u>

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

⁽²⁾Net of accumulated amortization.

⁽³⁾These assets are real estate assets related to the MTC leases and contract manufacturing service agreements.

⁽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 September 30, 2024, were as follows (in millions):

Fiscal Year	Operating Leases	Financing Leases ⁽¹⁾
2024 (remainder of the year)	\$ 17	\$ 19
2025	71	47
2026	73	47
2027	78	42
2028	81	23
Thereafter	841	1,074
Total minimum lease payments	<u>1,161</u>	<u>1,252</u>
Less amounts representing interest or imputed interest	<u>(461)</u>	<u>(597)</u>
Present value of lease liabilities	<u>\$ 700</u>	<u>\$ 655</u>

⁽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.

[Table of Contents](#)***Indemnification Obligations***

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

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

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

Through the three and nine months ended September 30, 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 September 30, 2024, we had \$1.2 billion of non-cancelable purchase commitments related to raw materials and manufacturing agreements, which are expected to be paid through 2029. As of September 30, 2024, we had \$342 million of non-cancelable purchase commitments related to research and development and other goods and services which are expected to be paid through 2031. 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 September 30, 2024, we had cancelable open purchase orders of \$3.3 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 September 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 nine months ended September 30, 2024, we recognized \$92 million and \$110 million, respectively, of royalty expenses associated with our product sales. For the three and nine months ended September 30, 2023, we recognized \$78 million and \$176 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 September 30, 2024.

[Table of Contents](#)**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 nine months ended September 30, 2024 and 2023 as follows (in millions):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Options	\$ 44	\$ 32	\$ 124	\$ 102
Restricted Stock Units (RSUs) and Performance Stock Units (PSUs)	68	43	196	117
Employee Stock Purchase Plan (ESPP)	—	2	5	7
Total	<u>\$ 112</u>	<u>\$ 77</u>	<u>\$ 325</u>	<u>\$ 226</u>
Cost of sales	\$ 6	\$ 7	\$ 19	\$ 28
Research and development	69	40	196	115
Selling, general and administrative	37	30	110	83
Total	<u>\$ 112</u>	<u>\$ 77</u>	<u>\$ 325</u>	<u>\$ 226</u>

As of September 30, 2024, there was \$875 million of total unrecognized compensation cost related to unvested stock-based compensation with respect to options, RSUs and PSUs granted. That cost is expected to be recognized over a weighted-average period of 2.6 years as of September 30, 2024.

Share Repurchase Programs

As of September 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 nine months ended September 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 September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Income (loss) before income taxes	\$ 21	\$ (1,958)	\$ (2,423)	\$ (4,012)
Provision for income taxes	\$ 8	\$ 1,672	\$ 18	\$ 919
Effective tax rate	39.2 %	(85.5)%	(0.7)%	(22.9)%

The effective tax rate for the three and nine months ended September 30, 2024 was higher than the statutory rate, primarily due to our global valuation allowance, which limits our ability to recognize tax benefits from the loss. The higher effective tax rate was also due to certain of our foreign subsidiaries that have taxable income, while we incurred a net loss before income taxes in other jurisdictions. The decrease in our effective tax rate, compared to the same periods in 2023, was primarily attributable to the establishment of a \$1.7 billion valuation allowance on deferred tax assets in the third quarter of 2023. This valuation allowance has been applied consistently since its initial recognition 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.

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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. Earnings (Loss) per Share

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
<i>Numerator:</i>				
Net income (loss)	\$ 13	\$ (3,630)	\$ (2,441)	\$ (4,931)
<i>Denominator:</i>				
Basic weighted-average common shares outstanding	385	381	383	382
Effect of dilutive securities	14	—	—	—
Diluted weighted-average common shares outstanding	399	381	383	382
Basic EPS	\$ 0.03	\$ (9.53)	\$ (6.37)	\$ (12.89)
Diluted EPS	\$ 0.03	\$ (9.53)	\$ (6.37)	\$ (12.89)
Common stock equivalents excluded from the EPS computation above because their inclusion would have been anti-dilutive	11	28	33	28

[Table of Contents](#)**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 several 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 36 development candidates across our 45 development programs, of which 42 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*COVID-19*

Consistent with guidance from regulators, we updated our COVID-19 vaccine to target the KP.2 and JN.1 strains of the SARS-CoV-2 virus for the 2024-2025 season. During the third quarter of 2024, our vaccine targeting the KP.2 strain received approval from the FDA and Health Canada, while our vaccine targeting the JN.1 strain was approved by regulatory authorities in the European Union (EU), the United Kingdom, Japan, Taiwan and other jurisdictions. We have since commenced the supply of these vaccines to customers.

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. 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. In August 2024, the European Commission (EC) granted marketing authorization for mRESVIA to protect adults aged 60 years and older from lower respiratory tract disease caused by RSV infection. The authorization is valid in all 27 EU member states, as well as Iceland, Liechtenstein and Norway. We have also filed for mRNA-1345 approval with regulators in multiple markets worldwide and commenced sales in the U.S. in the third quarter of 2024.

Moderna's Canadian Manufacturing Facility

In September 2024, our manufacturing facility in Laval, Quebec, received a Drug Establishment License (DEL) from Health Canada, certifying the site's compliance with the required safety and quality standards to produce drug substance. This certification marked a significant step in enabling our Canadian facility to become fully operational, supporting domestic manufacturing of mRNA vaccines, including COVID-19 vaccines, with production expected to begin in 2025.

Net Product Sales and Net Loss Per Share

For the third quarter of 2024, we recognized net product sales of \$1.8 billion from sales of our COVID-19 and RSV vaccines,

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compared to \$1.8 billion for the third quarter of 2023. Earnings per share was \$0.03 for the third quarter of 2024, compared to loss per share of \$(9.53) for the third quarter of 2023.

Recent Program Developments

Respiratory Virus Vaccines

- *RSV*. In September 2024, we announced positive Phase 3 results for our RSV vaccine (mRNA-1345) for high-risk adults aged 18 to 59. In the trial, mRNA-1345 met all primary immunogenicity endpoints and the 50 µg dose, which is the same for the currently approved mRESVIA vaccine for adults 60 years and above, was well tolerated with no safety concerns identified.
- *Next-generation COVID-19*. In September 2024, we shared positive Phase 3 vaccine efficacy and immunogenicity data for our next-generation COVID-19 vaccine (mRNA-1283).
- *Flu*. In September 2024, we announced that we are no longer pursuing an accelerated approval pathway for the regulatory submission of our standalone flu vaccine, mRNA-1010, to focus our resources on the submission of a potentially more impactful Flu+COVID combination vaccine, mRNA-1083. In September 2024, we initiated a Phase 3 efficacy study (P304) for mRNA-1010, funded by previously announced project financing through Blackstone Life Sciences.
- We intend to file in 2024 for approval of our next-generation COVID-19 vaccine (mRNA-1283) and our RSV vaccine (mRNA-1345) for high-risk adults ages 18 to 59. We intend to use priority review vouchers for those programs. For our Flu+COVID combination vaccine (mRNA-1083), we intend to file in 2024, subject to ongoing discussions with the FDA, and we have decided not to use a priority review voucher.

Latent and Other Virus Vaccines

- *Cytomegalovirus (CMV)*. We expect to have accrued the 81 cases necessary to trigger the first interim analysis of the Phase 3 vaccine efficacy study of our CMV vaccine candidate (mRNA-1647) by the end of 2024.
- *Norovirus*. In September 2024, we announced that the first participant in the U.S. had been dosed in the pivotal Phase 3 trial of our investigational mRNA trivalent norovirus vaccine, mRNA-1403. We had previously announced that an interim analysis had shown that a single dose of mRNA-1403 elicited a robust immune response across all dose levels evaluated with a clinically acceptable reactogenicity and safety profile. Additionally, robust histo-blood group antigen (HBGA) blocking antibody titers were observed against vaccine-matched norovirus genogroup I and II selected strains across all dose levels evaluated. Similar mRNA-1403-induced HBGA-blocking antibody titers were observed in younger adult and older adult age groups.

Oncology Therapeutics

- *Individualized neoantigen therapy (INT)*. In October 2024, we and Merck initiated a Phase 3 study evaluating adjuvant INT (mRNA-4157) in combination with KEYTRUDA after neoadjuvant KEYTRUDA and chemotherapy in patients with certain types of resected non-small cell lung cancer. This is the third Phase 3 trial for the investigational INT focused on earlier stages of cancer.

Discontinued Programs

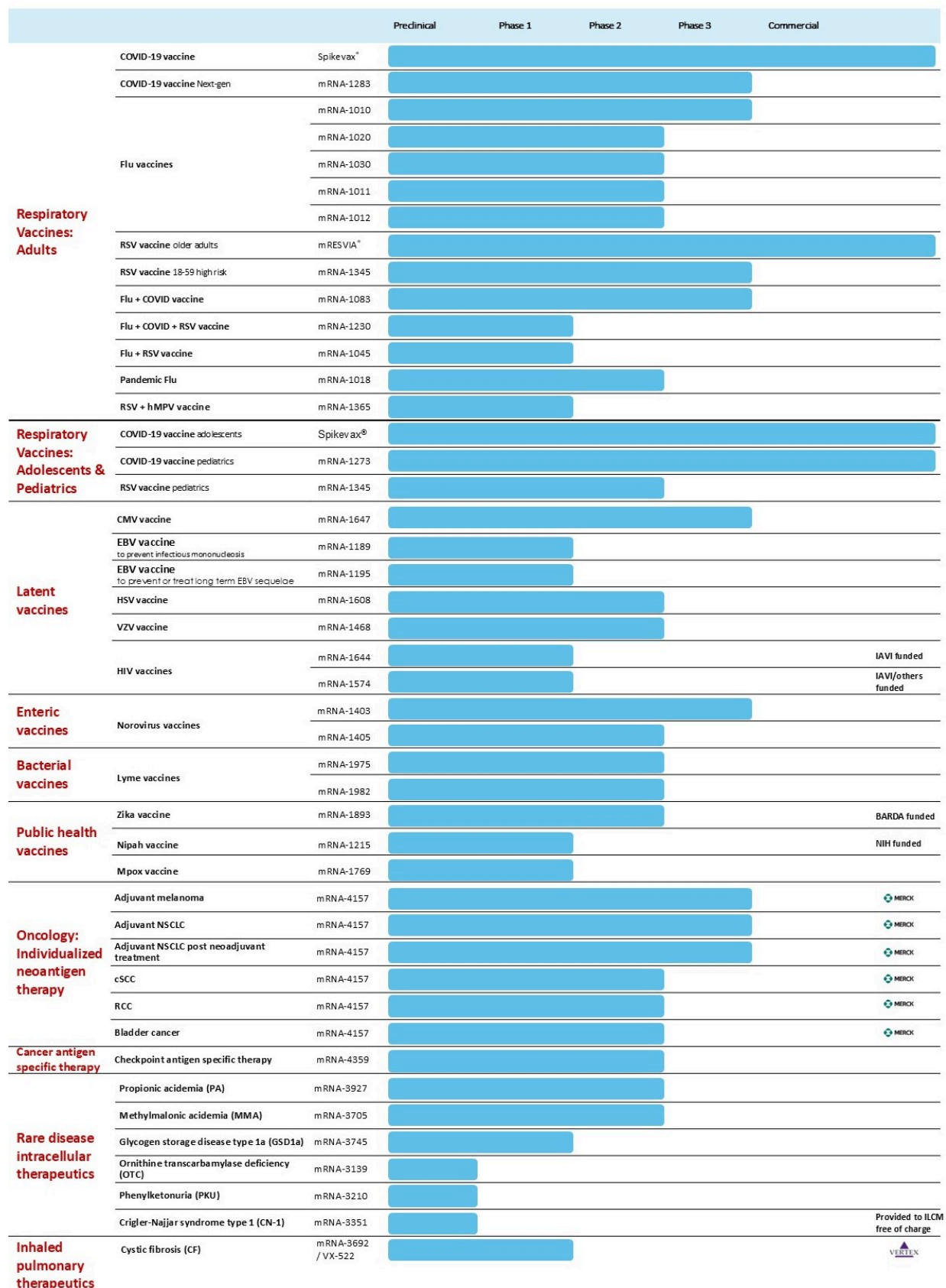
In the third quarter of 2024, we announced that five programs in our pipeline have been discontinued due to our strategic prioritization efforts:

- Endemic HCoV (mRNA-1287): The preclinical program will not advance into Phase 1.
- RSV infants (seronegative, <2 years) (mRNA-1345): We do not expect the program to advance beyond the ongoing Phase 1 based on emerging clinical data.
- KRAS antigen-specific therapy (mRNA-5671): We have no further development plans.
- Triplet (OX40L/IL-23/IL-36γ) (mRNA-2752): We have deprioritized further development based on emerging clinical data.
- Relaxin (mRNA-0184): The program is wrapping up Phase 1.

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Our Pipeline

The following chart shows our current pipeline of 45 development programs across our several modalities.



Abbreviations: BARDA, Biomedical Advanced Research and Development Authority; CMV, cytomegalovirus; cSCC, cutaneous squamous cell carcinoma; EBV, Epstein-Barr virus; HIV, human immunodeficiency virus; hMPV, human metapneumovirus; HSV, herpes simplex virus; IAVI, International AIDS Vaccine Initiative;

ILCM, Institute for Life Changing Medicines; IM, infectious mononucleosis; NIH, National Institutes of Health; NSCLC, non-small cell lung cancer; RCC, renal cell carcinoma; RSV, respiratory syncytial virus; VZV, varicella-zoster virus.

[Table of Contents](#)**Results of operations**

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

	Three Months Ended September 30,		Change 2024 vs. 2023	
	2024	2023	\$	%
Revenue:				
Net product sales	\$ 1,820	\$ 1,757	\$ 63	4%
Other revenue	42	74	(32)	(43)%
Total revenue	1,862	1,831	31	2%
Operating expenses:				
Cost of sales	514	2,241	(1,727)	(77)%
Research and development	1,137	1,160	(23)	(2)%
Selling, general and administrative	281	442	(161)	(36)%
Total operating expenses	1,932	3,843	(1,911)	(50)%
Loss from operations	(70)	(2,012)	1,942	(97)%
Interest income	103	105	(2)	(2)%
Other expense, net	(12)	(51)	39	(76)%
Income (loss) before income taxes	21	(1,958)	1,979	101%
Provision for income taxes	8	1,672	(1,664)	(100)%
Net income (loss)	\$ 13	\$ (3,630)	\$ 3,643	100%

	Nine Months Ended September 30,		Change 2024 vs. 2023	
	2024	2023	\$	%
Revenue:				
Net product sales	\$ 2,171	\$ 3,878	\$ (1,707)	(44)%
Other revenue	99	159	(60)	(38)%
Total revenue	2,270	4,037	(1,767)	(44)%
Operating expenses:				
Cost of sales	725	3,764	(3,039)	(81)%
Research and development	3,421	3,439	(18)	(1)%
Selling, general and administrative	823	1,079	(256)	(24)%
Total operating expenses	4,969	8,282	(3,313)	(40)%
Loss from operations	(2,699)	(4,245)	1,546	(36)%
Interest income	334	318	16	5%
Other expense, net	(58)	(85)	27	(32)%
Loss before income taxes	(2,423)	(4,012)	1,589	(40)%
Provision for income taxes	18	919	(901)	(98)%
Net loss	\$ (2,441)	\$ (4,931)	\$ 2,490	(50)%

Revenue***Net product sales***

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
United States	\$ 1,215	\$ 913	\$ 1,477	\$ 916
Europe	281	103	281	739
Rest of world	324	741	413	2,223
Total	\$ 1,820	\$ 1,757	\$ 2,171	\$ 3,878

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
COVID-19	\$ 1,810	\$ 1,757	\$ 2,161	\$ 3,878
RSV	10	—	10	—
Total	\$ 1,820	\$ 1,757	\$ 2,171	\$ 3,878

As of September 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.

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. We also commenced sales of our RSV vaccine in the third quarter of 2024. In the U.S., our COVID-19 and RSV vaccines are 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 government rebates, and other related deductions.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Gross product sales	\$ 2,964	\$ 2,420	\$ 3,377	\$ 4,541
Product sales provision:				
Wholesaler chargebacks, discounts and fees	(1,053)	(479)	(1,053)	(479)
Returns, rebates and other fees	(91)	(184)	(153)	(184)
Total product sales provision ⁽¹⁾	\$ (1,144)	\$ (663)	\$ (1,206)	\$ (663)
Net product sales	\$ 1,820	\$ 1,757	\$ 2,171	\$ 3,878

⁽¹⁾Includes an adjustment of approximately \$140 million in the third quarter of 2024, reflecting a reduction in prior period provision estimates, primarily related to returns for the previous COVID-19 vaccine season that closed during the quarter.

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 September 30, 2024, we had deferred revenue of \$443 million associated with customer deposits received or billable under supply agreements, with the majority of our COVID-19 vaccine deliveries scheduled in 2024.

Other revenue

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

Total revenue for the three months ended September 30, 2024 remained relatively flat compared to the same period in 2023. For the nine months ended September 30, 2024, total revenue decreased by \$1.8 billion, or 44%, compared to the same period in 2023, mainly due to lower net product sales of our COVID-19 vaccine.

Net product sales for the three months ended September 30, 2024 increased by \$63 million, or 4%, compared to the same period in 2023, primarily driven by higher sales in the U.S. market following the earlier launch of our updated COVID-19 vaccine for the season, and an approximately \$140 million adjustment related to the reduction in prior period sales provision estimates. With FDA approval granted three weeks earlier than in the previous year, we were able to meet demand more effectively. This increase was partially offset by lower international sales, which in 2023 had benefited from the fulfillment of orders deferred from 2022. For the nine months ended September 30, 2024, net product sales decreased by \$1.7 billion, or 44%, compared to the same period in 2023. This decline reflects the transition of the COVID-19 vaccine market from pandemic-driven demand to a more seasonal commercial pattern, with sales in 2024 exhibiting greater seasonality and reduced overall demand.

We expect higher demand for our COVID-19 and RSV vaccines in the fall and winter seasons each year across both hemispheres, as countries prepare for seasonal vaccination campaigns. For the full year of 2024, we anticipate further reductions in net product sales

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for our COVID-19 vaccine compared to 2023 as the market continues to evolve into a seasonal commercial model. Although we commenced sales of our RSV vaccine in the third quarter of 2024, these sales are not expected to have a significant impact on our overall product sales for the year.

Other revenue decreased by \$32 million, or 43%, and \$60 million, or 38%, for the three and nine months ended September 30, 2024, respectively, compared to the same periods in 2023. The decrease for the three and nine months ended was mainly due to a reduction in grant revenue under our agreement with Biomedical Advanced Research and Development Authority (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 September 30, 2024 was \$514 million, which included third-party royalties of \$92 million, inventory write-downs of \$214 million, unutilized manufacturing capacity and wind-down costs of \$27 million. Cost of sales for the nine months ended September 30, 2024 was \$725 million, which included third-party royalties of \$110 million, inventory write-downs of \$302 million, primarily related to our finished and semi-finished COVID-19 vaccine inventory and certain raw materials, unutilized manufacturing capacity and wind-down costs of \$109 million, and a \$57 million benefit from the sale of previously written-down zero-cost inventory. Please refer to [Note 7](#) to our condensed consolidated financial statements for inventory related charges. These charges in 2024, other than royalties, were largely driven by customer demand forecast adjustments and commitments related to manufacturing capacity.

Cost of sales for the three months ended September 30, 2024 decreased by \$1.7 billion, or 77%, compared to the same period in 2023. Cost of sales as a percentage of net product sales for the three months ended September 30, 2024 was 28%, compared to 128% for the same period in 2023. Cost of sales for the nine months ended September 30, 2024 decreased by \$3.0 billion, or 81%, compared to the same period in 2023. Cost of sales as a percentage of net product sales for the nine months ended September 30, 2024 was 33%, compared to 97% for the same period in 2023. The decrease in cost of sales for both the three- and nine-month periods in 2024 was primarily driven by reduced inventory write-downs, unutilized manufacturing capacity, and purchase commitment related cancellation fees. In addition, the reduction reflects the impact of a strategic cost initiative launched in the third quarter of 2023 to optimize our COVID-19 business by resizing manufacturing operations in response to the shift toward an endemic seasonal market. This initiative, which incurred \$1.4 billion in charges during the third quarter of 2023, helped drive improved manufacturing efficiency and cost reductions in 2024. The decrease in cost of sales as a percentage of net product sales for both the three- and nine-month periods in 2024 was mainly driven by reduced costs, while the decrease for the nine-month period was partially offset by the lower sales volume, reflecting a decline in product demand and increased 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, with the fourth quarter anticipated to be higher than the third quarter.

Research and development expenses

Research and development expenses decreased by \$23 million, or 2%, for the three months ended September 30, 2024, compared to the same period in 2023. This reduction was primarily due to decreases in clinical trial expenses of \$182 million and clinical manufacturing expenses of \$92 million. These decreases were partially offset by the purchase of a priority review voucher, along with a \$38 million increase in personnel-related costs and stock-based compensation. For the nine months ended September 30, 2024, research and development expenses decreased by \$18 million, or 1%, compared to the same period in 2023. This reflects a \$332 million reduction in clinical trial expenses, a \$150 million reduction in clinical manufacturing expenses, and an \$85 million reduction in upfront license payments. These reductions were offset by a \$193 million increase in personnel-related costs and stock-based compensation, as well as the purchase of two priority review vouchers. 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 the three months ended September 30, 2024, was mainly due to reduced spending on our COVID-19 and RSV programs. For the nine-month period, the decrease was largely attributable to reduced spending on our COVID-19, RSV and seasonal flu programs, in line 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, norovirus and combination vaccine programs, as well as our INT program.

[Table of Contents](#)***Selling, general and administrative expenses***

Selling, general and administrative expenses decreased by \$161 million, or 36%, for the three months ended September 30, 2024, compared to the same period in 2023. This decrease was primarily due to a reduction of \$105 million in consulting and outside services across all functions, as well as a \$36 million reduction in commercial and marketing related expenses. For the nine months ended September 30, 2024, selling, general and administrative expenses decreased by \$256 million, or 24%, compared to the same period in 2023. The decline for the nine-month period was mainly due to a \$250 million reduction in consulting and outside services across all functions, along with a \$51 million reduction in commercial and marketing related expenses. These decreases were partially offset by a \$48 million increase in personnel-related costs and stock-based compensation, primarily driven by an expanded headcount in digital, medical affairs and commercial functions to support our digital and artificial intelligence initiatives, as well as our marketed products. The decrease in both periods reflects cost discipline and efficiencies gained by reducing reliance on external consultants and bringing more functions in-house.

We anticipate that selling, general and administrative expenses in 2024 will be 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, while continuing to invest in digital capabilities and leverage artificial intelligence technologies. These efforts align with our strategic focus on advancing our program development and enhancing our overall business processes.

Interest income

For the three months ended September 30, 2024, interest income decreased by \$2 million, or 2%, compared to the same period in 2023. For the nine months ended September 30, 2024, interest income increased by \$16 million, or 5%, compared to the same period in 2023. Overall, interest income from our investments in marketable securities remained relatively flat across both periods. The decrease in the three-month period was primarily due to lower average investment balances, while the increase for the nine-month period was driven by the overall higher interest rate environment.

Other expense, net

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

	Three Months Ended September 30,		Change 2024 vs. 2023	
	2024	2023	\$	%
Loss on investments	\$ (9)	\$ (37)	\$ 28	(76)%
Interest expense	(6)	(10)	4	(40)%
Other income (loss), net	3	(4)	7	175%
Total other expense, net	<u>\$ (12)</u>	<u>\$ (51)</u>	<u>\$ 39</u>	<u>(76)%</u>
	Nine Months Ended September 30,		Change 2024 vs. 2023	
	2024	2023	\$	%
Loss on investments	\$ (47)	\$ (50)	\$ 3	(6)%
Interest expense	(18)	(32)	14	(44)%
Other income (loss), net	7	(3)	10	333%
Total other expense, net	<u>\$ (58)</u>	<u>\$ (85)</u>	<u>\$ 27</u>	<u>(32)%</u>

For the three and nine months ended September 30, 2024, total other expense, net decreased by \$39 million and \$27 million, or 76% and 32%, respectively, compared to the same periods in 2023. The decrease in total other expense, net for the three-month period was primarily driven by a reduction in losses on equity investments. For the nine-month period, the decrease was mainly due to lower losses on available-for-sale debt securities and reduced interest expense, partially offset by an increase in losses on equity investments. Our interest expense is primarily related to our finance leases. Please refer to [Note 10](#) to our condensed consolidated financial statements.

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Income taxes

Provision for income taxes decreased by \$1.7 billion and \$901 million, or 100% and 98%, for the three and nine months ended September 30, 2024, compared to the same periods in 2023. The decrease in both periods was primarily due to the establishment of a \$1.7 billion valuation allowance on deferred tax assets in the third quarter of 2023. This valuation allowance has been applied consistently since its initial recognition in the third quarter of 2023. As a result, we are unable to recognize tax benefits from the loss due to our global valuation allowance. Consequently, the effective tax rates for the three and nine months ended September 30, 2024 are not comparable to the same periods in the prior year. Please refer to [Note 13](#) to our condensed consolidated financial statements.

Liquidity and capital resources

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

	September 30, 2024	December 31, 2023
Financial assets:		
Cash and cash equivalents	\$ 1,644	\$ 2,907
Investments	5,223	5,697
Investments, non-current	2,335	4,677
Total	<u>\$ 9,202</u>	<u>\$ 13,281</u>
Working capital:		
Current assets	\$ 9,666	\$ 10,325
Current liabilities	2,201	3,015
Total	<u>\$ 7,465</u>	<u>\$ 7,310</u>

Our cash, cash equivalents and investments are invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation. Investments, consisting primarily of government and corporate debt securities, are stated at fair value. Cash, cash equivalents and investments as of September 30, 2024 decreased by \$4.1 billion, or 31%, 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 \$3.8 billion and purchases of property and equipment of \$529 million during the nine months ended September 30, 2024.

Working capital, which is current assets less current liabilities, as of September 30, 2024 increased by \$155 million, compared to December 31, 2023, primarily due to an increase in accounts receivable of \$672 million, mainly due to timing of collections, a decrease in accrued liabilities and accounts payable of \$569 million, driven by lower spend during the period, and an increase in inventory of \$210 million, driven by manufacturing of COVID-19 product, partially offset by a decrease in cash and cash equivalents of \$1.3 billion.

As of September 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):

	Nine Months Ended September 30,	
	2024	2023
Net cash (used in) provided by:		
Operating activities	\$ (3,829)	\$ (3,740)
Investing activities	2,488	4,744
Financing activities	59	(1,268)

Operating activities

We derive cash flows from operations primarily from cash collected from customer deposits and accounts receivable related to our product sales, as well as certain government-sponsored and private organizations, strategic alliances and funding arrangements. Our

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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. We also commenced sales of our RSV vaccine in the third quarter of 2024. Wholesalers and distributors typically do not make upfront payments to us. As of September 30, 2024, we had \$443 million in deferred revenue related to customer deposits received or billable.

Net cash used in operating activities for the nine months ended September 30, 2024 was \$3.8 billion and consisted of net loss of \$2.4 billion, non-cash adjustments of \$427 million and a net change in assets and liabilities of \$1.8 billion. Non-cash items primarily included stock-based compensation of \$325 million, and depreciation and amortization of \$129 million. The net change in assets and liabilities was mainly due to an increase in accounts receivable of \$672 million driven by timing of invoicing, a decrease in accrued liabilities and accounts payable of \$518 million, driven by overall lower spend in the period, an increase in inventory of \$208 million, driven by manufacturing of COVID-19 products, and a decrease in deferred revenue of \$177 million due to revenue recognized in excess of customer deposits received.

Net cash used in operating activities increased by \$89 million, or 2%, during the nine months ended September 30, 2024, compared to the same period in 2023, primarily attributable to a change in deferred income taxes of \$934 million driven by an increase in valuation allowance, a change in prepaid expense and other assets of \$919 million mainly related to prepayment of clinical studies and contract manufacturing organization activities, a change in inventory of \$670 million driven by less inventory write-downs, partially offset by a decrease in net loss of \$2.5 billion.

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 nine months ended September 30, 2024 was \$2.5 billion, which primarily included proceeds from maturities and sales of marketable securities of \$7.7 billion, partially offset by purchases of marketable securities of \$4.6 billion, and purchases of property and equipment of \$529 million.

Net investing cash flows decreased by \$2.3 billion, or 48%, during the nine months ended September 30, 2024, compared to the same period in 2023, primarily due to an increase in purchases of marketable securities of \$2.5 billion.

Financing activities

Net cash provided by financing activities for the nine months ended September 30, 2024 was \$59 million, primarily due to proceeds from issuance of common stock through equity plans of \$55 million.

Net cash provided by financing activities increased by \$1.3 billion, or 105%, during the nine months ended September 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 September 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 \$2.4 billion for the nine months ended September 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 September 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, CMV and norovirus vaccine candidates, individualized neoantigen therapy, next generation COVID-19 vaccine, combination vaccines, late-stage clinical development, investments in digital

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capabilities and artificial intelligence technologies, 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.

We believe that our cash, cash equivalents, and investments as of September 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 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 September 30, 2024 compared to those disclosed in our 2023 Form 10-K.

Contractual Obligations

As of September 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 nine months ended September 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 September 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 September 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

Except for a change in our logistics provider to support vaccine distribution and order management, 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

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ended September 30, 2024 that 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.

Proceedings Related to Patents Owned by Alnylam

As previously disclosed in our 2023 Form 10-K, in May 2023, Alnylam Pharmaceuticals, Inc. filed a complaint against us in the U.S. District Court for the District of Delaware asserting three U.S. patents concerning cationic lipids. In November 2023, the District Court entered an order of partial dismissal with respect to two of the patents at issue. Subsequently, in October 2024, the District Court entered a final judgment of non-infringement in our favor with respect to the third patent at issue. The decision is subject to appeal.

Proceedings Related to Patents Owned by GSK

COVID-19 Vaccines

In October 2024, GlaxoSmithKline Biologicals SA (GSK) filed a complaint against us in the U.S. District Court for the District of Delaware asserting that our manufacture and sale of our COVID-19 vaccines infringe certain U.S. patents directed to lipid-mRNA vaccine formulation technology. The complaint seeks a judgment of infringement of the asserted patents and unspecified damages, but does not seek injunctive relief.

RSV Vaccine

Also in October 2024, GSK filed a complaint against us in the U.S. District Court for the District of Delaware asserting that our manufacture and sale of our RSV vaccine infringes certain U.S. patents directed to lipid-mRNA vaccine formulation technology. The complaint seeks a judgment of infringement of the asserted patents, unspecified damages and injunctive relief in the United States.

Proceedings Related to Patents Owned by Northwestern University

In October 2024, Northwestern University filed a complaint against us in the U.S. District Court for the District of Delaware asserting that our COVID-19 and RSV vaccines infringe several U.S. patents concerning lipid nanoparticle technology. The complaint seeks a judgment of infringement of the asserted patents and unspecified damages. The complaint does not seek injunctive relief.

[Table of Contents](#)*Securities Class Action Litigation*

In August 2024, a putative shareholder class action complaint was filed against the Company and certain officers in the U.S. District Court for the District of Massachusetts. The action is purportedly brought on behalf of a class of shareholders who purchased Moderna common stock between January 18, 2023 and June 25, 2024. The complaint asserts claims under the Securities Exchange Act of 1934 regarding statements about our RSV vaccine (mRNA-1345) and seeks unspecified damages.

Derivative Litigation

Between September and November 2024, purported shareholder derivative complaints were filed in the U.S. District Court for the District of Massachusetts against certain of our officers and directors and against the Company as a nominal defendant. The complaints allege breaches of fiduciary duty and claims under the Securities Exchange Act of 1934 regarding statements about mRNA-1345 and seek declaratory and injunctive relief and unspecified damages payable to us.

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 September 30, 2024, there were no shares repurchased. As of September 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.

[Table of Contents](#)**Item 6. Exhibits**

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

<u>Exhibit No.</u>	<u>Exhibit Index</u>
10.1#*	2018 Employee Stock Purchase Plan, as amended.
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

Indicates a management contract or any compensatory plan, contract or arrangement.

+ The certification furnished in Exhibit 32.1 hereto is deemed to accompany this Form 10-Q and will not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended. Such certification will not be deemed to be incorporated by reference into any filings under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, except to the extent that the Registrant specifically incorporates it by reference.

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SIGNATURES

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

MODERNA, INC.

Date:
November 7, 2024

By: /s/ Stéphane Bancel

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

Date:
November 7, 2024

By: /s/ James M. Mock

James M. Mock
Chief Financial Officer
(*Principal Financial Officer*)