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, 2023

OR

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

Moderna, Inc.

(Exact Name of Registrant as Specified in Its Charter)

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

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

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

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

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

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

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

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

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

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

As of October 27, 2023, there were 381,283,996 shares of the registrant's common stock, par value $0.0001 per share, outstanding.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q (Form 10-Q) contains express or implied forward-looking statements. All statements other than those of historical facts contained in this Form 10-Q are based on our management's beliefs and assumptions and on information currently available to our management. Forward-looking statements in this Form 10-Q include, but are not limited to, statements about:

- our activities with respect to our COVID-19 vaccine, and our plans and expectations regarding future generations of our COVID-19 vaccine, including boosters, that we may develop in response to variants of the SARS-CoV-2 virus, ongoing clinical development, manufacturing and supply, pricing, commercialization, regulatory matters (including authorization or approval for boosters), demand for COVID-19 vaccines, our provisions for product returns, and third-party and governmental arrangements and potential arrangements;
- our expectations regarding the endemic and seasonal commercial market for COVID-19 vaccines and our preparations for and ability to effectively compete in such a market, as well as the impact that the evolving market will have on our financial returns;
- expected sales and delivery of our COVID-19 vaccine in future periods, and expected seasonality for sales;
- our global regulatory submissions for our RSV vaccine candidate, mRNA-1345, and plans for commercialization of this product;
- our ability to successfully contract with third-party suppliers, distributors and manufacturers;
- our ability and the ability of third parties with whom we contract to successfully manufacture, supply and distribute our COVID-19 vaccine and boosters, and any future commercial products at scale as well as drug substances, delivery vehicles, development candidates, and investigational medicines for preclinical and clinical use;
- internal and external costs associated with manufacturing for our products, including our COVID-19 vaccine, and the impact on our cost of sales for the current year and future periods, and the impact of resizing initiatives on our cost of sales;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our commercial products, development candidates, investigational medicines and technology, including our ability to enter into license agreements, and our expectations regarding pending legal proceedings related to our intellectual property;
- our plans with respect to our individualized neoantigen therapy (INT), including our plan to expand the development program to additional tumor types, including non-small cell lung cancer;
- 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, including Merck and Vertex Pharmaceuticals;
- participant enrollment in our clinical trials, including enrollment demographics and timing;
- potential advantages of mRNA as compared to traditional medicine;
- our ability to obtain and maintain regulatory approval of our investigational medicines;
- the implementation of our business model and strategic plans for our business, investigational medicines and technology;
- potential product launches, including the timing of launches;
- our ability to successfully commercialize our products, if approved;
- the pricing and reimbursement of our medicines, if approved;
- the build out of our manufacturing and commercial operations;
- estimates of our future expenses, revenues and capital requirements;
- our operation and funding requirements, including our forecast of the period of time through which our financial resources will be adequate to support our operations;

- the potential benefits of strategic collaboration agreements and our ability to enter into strategic collaborations or other agreements with collaborators with development, regulatory and commercialization expertise;
- our financial performance;
- our tax provision and related tax liabilities;
- legal and regulatory developments in the United States and foreign countries;
- our ability to produce our products or investigational medicines 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 year ended December 31, 2022. If one or more of these risks or uncertainties occur, or if our underlying assumptions prove to be incorrect, actual results could differ materially from those expressed or implied by the forward-looking statements.

The forward-looking statements in this Form 10-Q represent our views as of the date of this Form 10-Q. We undertake no obligation to update any forward-looking statements, except as required by applicable securities law. You should therefore not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this Form 10-Q. However, any further disclosures made on related subjects in our subsequent reports filed with the Securities and Exchange Commission should be consulted.

TRADEMARKS

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

NOTE REGARDING COMPANY REFERENCES

Unless the context otherwise requires, the terms “Moderna,” the “Company,” “we,” “us” and “our” in this Form 10-Q refer to Moderna, Inc. and its consolidated subsidiaries.

ADDITIONAL INFORMATION

Our website, www.modernatx.com, including the Investor Relations section, www.investors.modernatx.com; and corporate blog www.modernatx.com/moderna-blog; as well as our social media channels: Facebook, www.facebook.com/modernatx; Twitter, www.twitter.com/moderna_tx (@moderna_tx); LinkedIn, www.linkedin.com/company/modernatx; Instagram (@moderna_tx); and Threads (@moderna_tx) contain a significant amount of information about us, including financial and other information for investors. We encourage investors to visit these websites and social media channels as information is frequently updated and new information is shared. Information contained on our website, corporate blog and social media channels shall not be deemed incorporated into, or be a part of, this Form 10-Q.

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Item 1. Financial Statements

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

	September 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 2,932	$ 3,205
Investments	4,641	6,697
Accounts receivable, net	1,866	1,385
Inventory	487	949
Prepaid expenses and other current assets	873	1,195
Total current assets	10,799	13,431
Investments, non-current	5,273	8,318
Property, plant and equipment, net	1,952	2,018
Right-of-use assets, operating leases	765	121
Deferred tax assets	—	982
Other non-current assets	661	988
Total assets	$ 19,450	$ 25,858
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 494	$ 487
Accrued liabilities	2,224	2,101
Deferred revenue	1,372	2,038
Income taxes payable	56	48
Other current liabilities	239	249
Total current liabilities	4,385	4,923
Deferred revenue, non-current	166	673
Operating lease liabilities, non-current	697	92
Financing lease liabilities, non-current	575	912
Other non-current liabilities	172	135
Total liabilities	5,995	6,735
Commitments and contingencies (Note 13)		
Stockholders' equity:		
Preferred stock, par value $0.0001; 162 shares authorized as of September 30, 2023 and December 31, 2022; no shares issued or outstanding at September 30, 2023 and December 31, 2022	—	—
Common stock, par value $0.0001; 1,600 shares authorized as of September 30, 2023 and December 31, 2022; 381 and 385 shares issued and outstanding as of September 30, 2023 and December 31, 2022, respectively	—	—
Additional paid-in capital	277	1,173
Accumulated other comprehensive loss	(211)	(370)
Retained earnings	13,389	18,320
Total stockholders' equity	13,455	19,123
Total liabilities and stockholders' equity	$ 19,450	$ 25,858

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Revenue:				
Net product sales	$ 1,757	$ 3,120	$ 3,878	$ 13,576
Other revenue	74	244	159	603
Total revenue	1,831	3,364	4,037	14,179
Operating expenses:				
Cost of sales	2,241	1,100	3,764	3,498
Research and development	1,160	820	3,439	2,084
Selling, general and administrative	442	278	1,079	757
Total operating expenses	3,843	2,198	8,282	6,339
(Loss) income from operations	(2,012)	1,166	(4,245)	7,840
Interest income	105	58	318	113
Other expense, net	(51)	(7)	(85)	(33)
(Loss) income before income taxes	(1,958)	1,217	(4,012)	7,920
Provision for income taxes	1,672	174	919	1,023
Net (loss) income	$ (3,630)	$ 1,043	$ (4,931)	$ 6,897
(Loss) earnings per share:				
Basic	$ (9.53)	$ 2.67	$ (12.89)	$ 17.41
Diluted	$ (9.53)	$ 2.53	$ (12.89)	$ 16.46
Weighted average common shares used in calculation of (loss) earnings per share:				
Basic	381	390	382	396
Diluted	381	412	382	419

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Net (loss) income	$ (3,630)	$ 1,043	$ (4,931)	$ 6,897
Other comprehensive income (loss), net of tax:				
Available-for-sale securities:				
Unrealized gains (losses) on available-for-sale debt securities	46	(126)	115	(384)
Less: net realized losses on available-for-sale securities reclassified in net (loss) income	6	3	36	18
Net increase (decrease) from available-for-sale debt securities	52	(123)	151	(366)
Cash flow hedges:				
Unrealized gains on derivative instruments	—	62	—	133
Less: net realized (gains) losses on derivative instruments reclassified in net (loss) income	—	(50)	8	(94)
Net increase from derivatives designated as hedging instruments	—	12	8	39
Total other comprehensive income (loss)	52	(111)	159	(327)
Comprehensive (loss) income	$ (3,578)	$ 932	$ (4,772)	$ 6,570

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

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

	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

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Retained Earnings	Total Stockholders' Equity
	Shares	Amount				
Balance at June 30, 2022	392	$ —	$ 2,413	$ (240)	$ 15,812	$ 17,985
Vesting of restricted common stock	1	—	—	—	—	—
Exercise of options to purchase common stock	1	—	11	—	—	11
Stock-based compensation	—	—	70	—	—	70
Other comprehensive loss, net of tax	—	—	—	(111)	—	(111)
Repurchase of common stock	(7)	—	(1,006)	—	—	(1,006)
Net income	—	—	—	—	1,043	1,043
Balance at September 30, 2022	387	$ —	$ 1,488	$ (351)	$ 16,855	$ 17,992

	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
Purchase 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

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Retained Earnings	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2021	403	$ —	$ 4,211	$ (24)	$ 9,958	$ 14,145
Vesting of restricted common stock	1	—	—	—	—	—
Exercise of options to purchase common stock	3	—	31	—	—	31
Purchase of common stock under employee stock purchase plan	—	—	9	—	—	9
Stock-based compensation	—	—	164	—	—	164
Other comprehensive loss, net of tax	—	—	—	(327)	—	(327)
Repurchase of common stock	(20)	—	(2,927)	—	—	(2,927)
Net income	—	—	—	—	6,897	6,897
Balance at September 30, 2022	387	$ —	$ 1,488	$ (351)	$ 16,855	$ 17,992

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

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

	Nine Months Ended September 30,	
	2023	**2022**
Operating activities		
Net (loss) income	$ (4,931)	$ 6,897
Adjustments to reconcile net (loss) income to net cash (used in) provided by operating activities:		
Stock-based compensation	226	164
Depreciation and amortization	419	268
Amortization/accretion of investments	(41)	35
Loss on equity investments, net	16	—
Deferred income taxes	934	(473)
Other non-cash items	25	36
Changes in assets and liabilities, net of acquisition of business:		
Accounts receivable, net	(481)	480
Prepaid expenses and other assets	772	(669)
Inventory	462	(636)
Right-of-use assets, operating leases	(657)	29
Accounts payable	(8)	89
Accrued liabilities	63	354
Deferred revenue	(1,173)	(2,691)
Income taxes payable	8	(810)
Operating lease liabilities	605	(27)
Other liabilities	21	273
Net cash (used in) provided by operating activities	(3,740)	3,319
Investing activities		
Purchases of marketable securities	(2,097)	(8,925)
Proceeds from maturities of marketable securities	4,711	2,222
Proceeds from sales of marketable securities	2,725	2,918
Purchases of property, plant and equipment	(487)	(308)
Acquisition of business, net of cash acquired	(85)	—
Investment in convertible notes and equity securities	(23)	(35)
Net cash provided by (used in) investing activities	4,744	(4,128)
Financing activities		
Proceeds from issuance of common stock through equity plans	31	40
Repurchase of common stock, including excise tax	(1,153)	(2,927)
Changes in financing lease liabilities	(146)	(123)
Net cash used in financing activities	(1,268)	(3,010)
Net decrease in cash, cash equivalents and restricted cash	(264)	(3,819)
Cash, cash equivalents and restricted cash, beginning of year	3,217	6,860
Cash, cash equivalents and restricted cash, end of period	$ 2,953	$ 3,041
Non-cash investing and financing activities		
Purchases of property and equipment included in accounts payable and accrued liabilities	$ 148	$ 80
Right-of-use assets obtained through finance lease modifications and reassessments	$ 213	$ —
Right-of-use assets obtained in exchange for financing lease liabilities	$ —	$ 781

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, autoimmune diseases and cardiovascular 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.

We have a diverse and extensive development pipeline of 41 development candidates across our 43 development programs, of which 38 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, 2022 (2022 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 2022 Form 10-K.

The condensed consolidated financial statements include Moderna, Inc. and its subsidiaries. All intercompany transactions and balances have been eliminated in consolidation. The significant accounting policies used in preparation of these condensed consolidated financial statements for the three and nine months ended September 30, 2023 are consistent with those described in our 2022 Form 10-K. The only exception pertains to the policy related to net product sales in the U.S. In the third quarter of 2023, we initiated sales of our COVID-19 vaccine in the U.S. commercial market. Please refer to Note 3 for further details regarding the policy. The results of operations for the three and nine months ended September 30, 2023 are not necessarily indicative of the operating results to be expected for the full fiscal year or future operating periods. Other revenue in the condensed consolidated statements of operations comprises grant revenue and collaboration revenue that were previously presented as separate line items in our consolidated statements of operations in our 2022 Form 10-K. The associated prior period amounts in the condensed consolidated financial statements, as well as in the notes thereto, have been reclassified to conform to the current presentation.

Use of Estimates

We have made estimates and judgments affecting the amounts reported in our condensed consolidated financial statements and the accompanying notes. We base our estimates on historical experience and various relevant assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting periods that are not readily apparent from other sources. Significant estimates relied upon in preparing these financial statements include, but are not limited to, critical accounting policies or estimates related to revenue recognition, product sales provisions, income taxes, valuation allowance of deferred tax assets, inventory valuation, firm purchase commitment liabilities, pre-launch inventory, leases, fair value of financial instruments, derivative financial instruments, useful lives of property and equipment, research and development expenses, stock-based compensation, intangible assets, goodwill, credit loss and impairment reviews. The actual results that we experience may differ materially from our estimates.

Comprehensive Income (Loss)

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

The components of accumulated other comprehensive loss for the three and nine months ended September 30, 2023 were as follows (in millions):

	Unrealized Gains on Available-for-Sale Debt Securities	Net Unrealized Gains on Derivatives Designated As Hedging Instruments	Total
Accumulated other comprehensive loss, balance at December 31, 2022	$ (362)	$ (8)	$ (370)
Other comprehensive income	95	8	103
Accumulated other comprehensive loss, balance at March 31, 2023	(267)	—	(267)
Other comprehensive income	4	—	4
Accumulated other comprehensive loss, balance at June 30, 2023	(263)	—	(263)
Other comprehensive income	52	—	52
Accumulated other comprehensive loss, balance at September 30, 2023	$ (211)	$ —	$ (211)

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,	
	2023	2022
Cash and cash equivalents	$ 2,932	$ 3,027
Restricted cash[(1)]	17	—
Restricted cash, non-current[(2)]	4	14
Total cash, cash equivalents and restricted cash shown in the condensed consolidated statements of cash flows	$ 2,953	$ 3,041

[(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. Unless otherwise discussed, we believe that the impact of recently issued standards that are not yet effective will not have a material impact on our condensed consolidated financial statements and disclosures.

3. 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,	
	2023	2022	2023	2022
United States	$ 913	$ 985	$ 916	$ 3,380
Europe	103	1,045	739	4,511
Rest of world	741	1,090	2,223	5,685
Total	$ 1,757	$ 3,120	$ 3,878	$ 13,576

As of September 30, 2023, our COVID-19 vaccine was our only commercial product authorized for use.

Prior to the third quarter of 2023, we sold our COVID-19 vaccine to the U.S. Government, other international governments and 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, 2023 and December 31, 2022, we had deferred revenue of $1.5 billion and $2.6 billion, respectively, related to customer deposits for our COVID-19 vaccine. We expect $1.4 billion of our deferred revenue related to customer deposits as of September 30, 2023 to be realized in less than one year. Timing of product delivery and manufacturing, and receipt of marketing approval for the applicable COVID-19 vaccine will determine the period in which product sales are recognized.

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

We recognize net product sales when control of the product transfers to the customer, typically upon delivery. Payment terms generally range from 30 to 60 days, in line with customary practices in each country. Net product sales are recognized net of estimated wholesaler chargebacks, invoice discounts for prompt payments and pre-orders, provisions for sales returns, and other related deductions. These provisions are recorded based on contractual terms and our estimate of returns for product sold during the period, using the expected value method or the most likely amount method. We update our estimates quarterly and record necessary adjustments in the period when we identify the adjustments. Product sales, net of provisions, are recorded only to the extent a significant reversal in the amount of cumulative revenue recognized is not probable when the uncertainty associated with the provisions is subsequently resolved. Shipping and handling activities are considered fulfillment activities and not a separate performance obligation. Taxes assessed by governmental authorities that are imposed on and collected from our product sales are excluded from net product sales.

Wholesaler chargebacks, discounts and fees

We contract with retailers, healthcare providers, and group purchasing organizations (GPO) to broaden our customer reach and offer contractual discounts. The chargeback represents the difference between the invoice price billed to the wholesaler and the negotiated price charged to the retailers, healthcare providers and GPO members. For distribution and related services, such as stocking and cold chain storage, we provide compensation to our wholesalers and distributors. We typically offer our customers invoice discounts on product sales for prompt payments and pre-orders. The estimation of these discounts and fees is based on contractual terms and our expectations regarding future customer payment behaviors. Wholesaler fees and invoice discounts are deducted from our gross product sales and accounts receivable at the time such product sales are recognized.

Product returns

We typically offer customers in the U.S. the right to return products, up to a certain limit as stipulated in our contracts. Estimated returns for our COVID-19 vaccine are determined considering available return rates for similar products, estimated levels of inventory in the distribution channel, projected market demand, and estimated product shelf life. The estimated amount for product returns is presented within accrued liabilities on our condensed consolidated balance sheets and is deducted from our gross product sales in the period the related product sales are recognized.

Other fees

Fees payable to third party payers and healthcare providers, along with fees to our direct customers that are settled via cash payments, including certain patient assistance programs, are recorded as accrued liabilities on our condensed consolidated balance sheets.

Determining the amount of variable consideration to recognize necessitates substantial judgment, especially when assessing factors outside our direct control such as lack of pertinent historical data and limited third-party information. Among all variables, estimating returns presents the most significant judgment due to the broad range of potential outcomes. As we receive more historical data on our product returns, we will incorporate this information into our estimates to improve accuracy. The actual results could differ from our estimates, and such differences could have a material impact to our financial statements.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Gross product sales	$ 2,420	$ 3,120	$ 4,541	$ 13,576
Product sales provision:				
Wholesaler chargebacks, discounts and fees	(479)	—	(479)	—
Returns and other fees	(184)	—	(184)	—
Total product sales provision	$ (663)	$ —	$ (663)	$ —
Net product sales	$ 1,757	$ 3,120	$ 3,878	$ 13,576

The following table summarizes the activities related to product sales provision recorded as accrued liabilities for the nine months ended September 30, 2023 (in millions):

	Returns and other fees
Balance at December 31, 2022	$ —
Provision related to sales made in current period	(184)
Balance at September 30, 2023	$ (184)

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,	
	2023	2022	2023	2022
Grant revenue	$ 44	$ 144	$ 96	$ 453
Collaboration revenue	30	100	63	150
Total other revenue	$ 74	$ 244	$ 159	$ 603

Grant Revenue

In April 2020, we entered into an agreement with the Biomedical Advanced Research and Development Authority (BARDA), a division of the Office of the Assistant Secretary for Preparedness and Response within the U.S. Department of Health and Human Services (HHS), for an award of up to $483 million to accelerate development of mRNA-1273. 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, 2023, the remaining available funding, net of revenue earned was $97 million.

In September 2020, we entered into an agreement with the Defense Advanced Research Projects Agency (DARPA) for an award of up to $56 million to fund development of a mobile manufacturing prototype leveraging our existing manufacturing technology that is capable of rapidly producing vaccines and therapeutics. As of September 30, 2023, we had earned the committed funding of $32 million. An additional $24 million of funding will be available if DARPA exercises additional contract options.

In January 2016, we entered a global health project framework agreement with the Bill & Melinda Gates Foundation (Gates Foundation) to advance mRNA development projects for various infectious diseases, including human immunodeficiency virus (HIV). As of September 30, 2023, the available funding, net of revenue earned was $4 million, with up to an additional $80 million available if additional follow-on projects are approved.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
BARDA	$ 44	$ 141	$ 88	$ 442
Other grant revenue	—	3	8	11
Total grant revenue	$ 44	$ 144	$ 96	$ 453

Collaboration Revenue

We have entered into collaboration agreements with strategic collaborators to accelerate the discovery and advancement of potential mRNA medicines across therapeutic areas. As of September 30, 2023 and December 31, 2022, we had collaboration agreements with Merck & Co., Inc (Merck), Vertex Pharmaceuticals Incorporated and Vertex Pharmaceuticals (Europe) Limited (together, Vertex), AstraZeneca plc (AstraZeneca) and others. Please refer to our 2022 Form 10-K under the heading “Third-Party Strategic Alliances” and Note 5 to our consolidated financial statements for further description of these collaboration agreements.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
Collaboration Revenue by Strategic Collaborator:	2023	2022	2023	2022
Vertex	$ 30	$ 4	$ 62	$ 33
Merck	—	20	—	35
AstraZeneca	—	76	—	80
Other	—	—	1	2
Total collaboration revenue	$ 30	$ 100	$ 63	$ 150

5. Collaboration Agreements

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. 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, 2023, we recognized expenses of $53 million and $122 million, respectively, related to the INT collaboration.

Generation Bio Co.

In March 2023, we entered into a strategic collaboration and license agreement with Generation Bio Co. (GBIO). The collaboration aims to expand the application of each company's platform by developing novel nucleic acid therapeutics, including those capable of reaching immune cells, to accelerate our respective pipelines of non-viral genetic medicines. Under the agreement, we have the option to license GBIO's proprietary cell-targeted lipid nanoparticle (ctLNP) and closed-ended DNA (ceDNA) technology for two immune cell programs and two liver programs, with an additional option for either a third immune cell or liver program. We made an upfront payment to GBIO of $40 million, a prepayment of research funding of $8 million, plus a $36 million equity investment. We will fund all research and development activities under the research plans. We expensed, as research and development expense, the upfront payment of $40 million and the equity premium of $13 million, representing the difference between the equity investment of $36 million paid to GBIO and the fair value of the equity instrument acquired in the first quarter of 2023. Additionally, we recorded an equity investment of $23 million, representing the fair value at the closing date, as other non-current assets in our condensed consolidated balance sheet as of March 31, 2023. The equity investment in GBIO is subsequently remeasured and recorded at the quoted market price of GBIO common stock at the end of each reporting period.

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.

6. Acquisition

On January 31, 2023, we acquired all outstanding shares of OriCiro Genomics K.K., a Japan-based, privately held biotech company primarily focused on cell-free DNA synthesis and amplification technologies, for $86 million in cash. With this acquisition, we obtained tools for cell-free synthesis and amplification of plasmid DNA, a key building block in mRNA manufacturing. OriCiro's technology strategically complements our manufacturing process and further accelerates our research and development efforts. The acquisition was accounted for as a business combination requiring all assets acquired and liabilities assumed to be recognized at their fair value as of the acquisition date. Following the acquisition, OriCiro was renamed as Moderna Enzymatics.

The following table summarizes the estimated fair values of assets acquired and liabilities assumed as of the acquisition date (in millions):

	January 31, 2023
Finite-lived intangible asset	
Developed technology	$ 48
Deferred tax liabilities	(15)
Other assets and liabilities, net	1
Total identifiable net assets	34
Goodwill	52
Total consideration	$ 86

The developed technology of $48 million represents the estimated fair value of the cell-free DNA synthesis and amplification technologies, as of the acquisition date. The fair value was determined by applying the cost saving method under the income approach, which is a valuation technique that provides an estimate of the fair value of an asset based on market participant expectations of the cash flows an asset would generate over its remaining useful life. To estimate the expected cash flows attributable to the development technology, it requires the use of Level 3 fair value measurements and inputs, including estimated expense savings and a discount rate that is based on the estimated weighted-average cost of capital for companies with profiles similar to ours and represents the estimated rate that market participants would use to value this intangible asset. The developed technology is being amortized on a straight-line basis over an estimated useful life of 12 years.

The excess of the consideration over the fair values assigned to the assets acquired and the liabilities assumed of $52 million was recorded as goodwill, which is not deductible for tax purposes. The goodwill is primarily attributable to the expected synergies from the acquired technologies combining with our existing platform technologies and manufacturing capabilities. Our accounting for this acquisition is preliminary and will be finalized upon completion of our analysis to determine the acquisition date fair values of certain assets acquired, liabilities assumed and tax-related items as we obtain additional information during the measurement period of up to one year from the acquisition date.

7. Financial Instruments

Cash and Cash Equivalents and Investments

The following tables summarize our cash and available-for-sale securities by significant investment category as of September 30, 2023 and December 31, 2022 (in millions):

	September 30, 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	$ 2,932	$ —	$ —	$ 2,932	$ 2,932	$ —	$ —
Available-for-sale:							
U.S. treasury bills	529	—	—	529	—	529	—
U.S. treasury notes	4,643	—	(121)	4,522	—	2,354	2,168
Corporate debt securities	4,854	—	(141)	4,713	—	1,680	3,033
Government debt securities	156	—	(6)	150	—	78	72
Total	$ 13,114	$ —	$ (268)	$ 12,846	$ 2,932	$ 4,641	$ 5,273

	December 31, 2022						
	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value	Cash and Cash Equivalents	Current Marketable Securities	Non-Current Marketable Securities
Cash and cash equivalents	$ 3,205	$ —	$ —	$ 3,205	$ 3,205	$ —	$ —
Available-for-sale:							
Certificates of deposit	188	—	—	188	—	188	—
U.S. treasury bills	767	—	—	767	—	767	—
U.S. treasury notes	7,781	—	(229)	7,552	—	4,182	3,370
Corporate debt securities	6,595	—	(226)	6,369	—	1,560	4,809
Government debt securities	148	—	(9)	139	—	—	139
Total	$ 18,684	$ —	$ (464)	$ 18,220	$ 3,205	$ 6,697	$ 8,318

The amortized cost and estimated fair value of available-for-sale securities by contractual maturity as of September 30, 2023 and December 31, 2022 were as follows (in millions):

	September 30, 2023	
	Amortized Cost	Estimated Fair Value
Due in one year or less	$ 4,720	$ 4,641
Due after one year through five years	5,462	5,273
Total	$ 10,182	$ 9,914

	December 31, 2022	
	Amortized Cost	Estimated Fair Value
Due in one year or less	$ 6,792	$ 6,697
Due after one year through five years	8,687	8,318
Total	$ 15,479	$ 15,015

In accordance with our investment policy, we place investments in investment grade securities with high credit quality issuers, and generally limit the amount of credit exposure to any one issuer. We evaluate securities for impairment at the end of each reporting period. Impairment is evaluated considering numerous factors, and their relative significance varies depending on the situation. Factors considered include whether a decline in fair value below the amortized cost basis is due to credit-related factors or non-credit-

related factors, the financial condition and near-term prospects of the issuer, and our intent and ability to hold the investment to allow for an anticipated recovery in fair value. Any impairment that is not credit related is recognized in other comprehensive loss, net of applicable taxes. A credit-related impairment is recognized as an allowance on the balance sheet with a corresponding adjustment to earnings. We did not recognize any impairment charges related to available-for-sale securities for the three and nine months ended September 30, 2023 and 2022. We did not record any credit-related allowance to available-for-sale securities as of September 30, 2023 and December 31, 2022.

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, 2023 and December 31, 2022 (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, 2023:						
U.S. treasury bills	$ —	$ 284	$ —	$ —	$ —	$ 284
U.S. treasury notes	(9)	904	(112)	3,545	(121)	4,449
Corporate debt securities	(5)	562	(136)	3,716	(141)	4,278
Government debt securities	—	8	(6)	141	(6)	149
Total	$ (14)	$ 1,758	$ (254)	$ 7,402	$ (268)	$ 9,160
As of December 31, 2022:						
U.S. treasury bills	$ —	$ 128	$ —	$ —	$ —	$ 128
U.S. treasury notes	(101)	3,956	(128)	3,541	(229)	7,497
Corporate debt securities	(138)	3,505	(88)	1,890	(226)	5,395
Government debt securities	(2)	46	(7)	93	(9)	139
Total	$ (241)	$ 7,635	$ (223)	$ 5,524	$ (464)	$ 13,159

As of September 30, 2023 and December 31, 2022, we held 416 and 582 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, 2023 and December 31, 2022 (in millions):

	Fair value at September 30, 2023	Fair Value Measurement Using	
		Level 1	Level 2
Assets:			
Money market funds	$ 1,438	$ 1,438	$ —
Certificates of deposit	30	—	30
U.S. treasury bills	1,163	—	1,163
U.S. treasury notes	4,522	—	4,522
Corporate debt securities	5,012	—	5,012
Government debt securities	150	—	150
Equity investments[1]	44	44	—
Derivative instruments (Note 8)	7	—	7
Total	$ 12,366	$ 1,482	$ 10,884
Liabilities:			
Derivative instruments (Note 8)	$ 12	$ —	$ 12

	Fair value at December 31, 2022	Fair Value Measurement Using	
		Level 1	Level 2
Assets:			
Money market funds	$ 1,079	$ 1,079	$ —
Certificates of deposit	188	—	188
U.S. treasury bills	767	—	767
U.S. treasury notes	7,552	—	7,552
Corporate debt securities	6,369	—	6,369
Government debt securities	139	—	139
Derivative instruments (Note 8)	6	—	6
Total	$ 16,100	$ 1,079	$ 15,021
Liabilities:			
Derivative instruments (Note 8)	$ 32	$ —	$ 32

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

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. We did not have equity investments in publicly traded securities with readily determinable fair values during 2022.

As of September 30, 2023 and December 31, 2022, we did not have non-financial assets or liabilities measured at fair value on a recurring basis and did not have any Level 3 financial assets or financial liabilities.

In addition, as of September 30, 2023 and December 31, 2022, we had $42 million, at each balance sheet date, in equity investments without readily determinable fair values, which are recorded within other non-current assets in our condensed consolidated balance sheets and excluded from the fair value measurement tables above.

8. Derivative Financial Instruments

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

Cash Flow Hedges

We mitigate the foreign exchange risk arising from the fluctuations in foreign currency denominated product sales in Euro and Japanese Yen through a foreign currency cash flow hedging program, using forward contracts and foreign currency options that do not exceed 15 months in duration. We hedge these cash flow exposures to reduce the risk that our earnings and cash flows will be adversely affected by changes in exchange rates. To receive hedge accounting treatment, all hedging relationships are formally documented at the inception of the hedge, and the hedges must be highly effective in offsetting changes to future cash flows on hedged transactions. The derivative assets or liabilities associated with our hedging activities are recorded at fair value in other current assets or other current liabilities, respectively, in our condensed consolidated balance sheets. The gains or losses resulting from changes in the fair value of these hedges are initially recorded as a component of accumulated other comprehensive income (loss) (AOCI) in stockholders' equity and subsequently reclassified to product sales in the period during which the hedged transaction affects earnings. In the event the underlying forecasted transaction does not occur, or it becomes probable that it will not occur, within the defined hedge period, we reclassify the gains or losses on the related cash flow hedge from AOCI to other expense, net in our condensed consolidated statements of operations. We evaluate hedge effectiveness at the inception of the hedge prospectively, and on an ongoing basis both retrospectively and prospectively. If we do not elect hedge accounting, or the contract does not qualify for hedge accounting treatment, the changes in fair value from period to period are recorded as a component of other expense, net in our condensed consolidated statements of operations. As of September 30, 2023, we had no deferred gains or losses on our foreign currency forward contracts included in AOCI that are expected to be recognized into product sales within the next 12 months.

Balance Sheet Hedges

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

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

	September 30, 2023		
		Fair Value	
	Notional Amount	Asset[1]	Liability[2]
Derivatives not designated as hedging instruments:			
Foreign currency forward contracts	$ 1,147	$ 7	$ 12
Total derivatives	$ 1,147	$ 7	$ 12

	December 31, 2022		
		Fair Value	
	Notional Amount	Asset[1]	Liability[2]
Derivatives designated as cash flow hedging instruments:			
Foreign currency forward contracts	$ 120	$ —	$ 11
Derivatives not designated as hedging instruments:			
Foreign currency forward contracts	1,368	6	21
Total derivatives	$ 1,488	$ 6	$ 32

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

Gains on our foreign currency derivatives, net of tax recognized in our condensed consolidated statements of comprehensive income (loss) for the three and nine months ended September 30, 2023 and 2022 were as follows (in millions):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Derivatives in cash flow hedging relationships:				
Foreign currency forward contracts	$ —	$ 62	$ —	$ 133

The effect of our foreign currency derivatives in our condensed consolidated statements of operations for the three and nine months ended September 30, 2023 and 2022 was as follows (in millions):

		Three Months Ended September 30,		Nine Months Ended September 30,	
	Statement of Income Classification	2023	2022	2023	2022
Derivatives in cash flow hedging relationships:					
Foreign currency forward contracts					
Net gain (loss) reclassified from AOCI into income	Product sales	$ —	$ 50	$ (8)	$ 94
Derivatives not designated as hedging instruments:					
Foreign currency forward contracts					
Net realized and unrealized gain	Other expense, net	$ 1	$ 26	$ 50	$ 95

9. Inventory

Inventory as of September 30, 2023 and December 31, 2022 consisted of the following (in millions):

	September 30, 2023	December 31, 2022
Raw materials	$ 149	$ 575
Work in progress	61	205
Finished goods	277	169
Total inventory	$ 487	$ 949
Inventory, non-current[(1)]	$ 211	$ 910

[(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, 2023, inventory write-downs were $1.3 billion and $1.9 billion, respectively. For the three and nine months ended September 30, 2022, inventory write-downs were $333 million and $1.0 billion, respectively. For the three and nine months ended September 30, 2023, losses on firm purchase commitments were zero and $141 million, respectively. For the three and nine months ended September 30, 2022, losses on firm purchase commitments were $7 million and $349 million, respectively. Inventory write-downs were mainly related to obsolete inventory due to shelf-life expiration and inventory in excess of expected demand. Losses on firm purchase commitments were primarily related to excess raw material purchase commitments that will expire before the anticipated consumption of those raw materials. These charges in 2023 were primarily driven by a continued shift in product demand to the latest variant-targeted COVID-19 vaccine and a decline in customer demand as the COVID-19 vaccine market continues to transition to an endemic seasonal market in 2023. In the third quarter of 2023, we completed our long-range financial planning process, incorporating revised forecasts of vaccination rates. This resulted in the reassessment of future demand for our COVID-19 vaccine, leading to a strategic initiative to resize our manufacturing cost structure. This initiative, launched in the same quarter, involved reassessing our inventory levels and renegotiating with our suppliers to reduce our purchase commitments related to raw materials which were not expected to be consumed before expiration. This initiative resulted in a raw materials write-down of $903 million, included in the total inventory write-down amount for the quarter, and incurred other related expenses during the quarter.

As of September 30, 2023 and December 31, 2022, the accrued liability for losses on firm future purchase commitments in our condensed consolidated balance sheets was $98 million and $268 million, respectively. As of September 30, 2023 and December 31, 2022, we had inventory on hand of $698 million and $1.9 billion, respectively. Our raw materials and work-in-progress inventory had variable shelf lives and were expected to be consumed over the next three years. The shelf life of our COVID-19 vaccine product is nine months.

Pre-launch Inventory

In June 2023, we completed submission of a regulatory application to the U.S. Food and Drug Administration (FDA) for our updated COVID-19 vaccine candidate targeting the Omicron XBB.1.5 sublineage of SARS-CoV-2 (mRNA-1273.815). The submission was based on guidance from the FDA, which advised that COVID-19 vaccines should be updated to a monovalent XBB.1.5 composition. This guidance from the FDA was in alignment with other regulators and global public health agencies recommending a monovalent XBB.1.5 composition. We started manufacturing and capitalizing pre-launch inventory costs related to mRNA-1273.815 in the second quarter of 2023, prior to regulatory approval. As of June 30, 2023, we had capitalized pre-launch inventory of $183 million in our condensed consolidated balance sheets. Beginning in September 2023, we received authorization for the use of mRNA-1273.815 in several countries and commenced supply of this vaccine to customers.

10. Property, Plant and Equipment, Net

Property, plant and equipment, net, as of September 30, 2023 and December 31, 2022 consisted of the following (in millions):

	September 30, 2023	December 31, 2022
Land	$ 32	$ 11
Manufacturing and laboratory equipment	334	284
Leasehold improvements	490	460
Furniture, fixtures and other	26	21
Computer equipment and software	55	38
Construction in progress	720	281
Right-of-use assets, financing (Note 12)	1,367	1,581
Total	3,024	2,676
Less: Accumulated depreciation	(1,072)	(658)
Property, plant and equipment, net	$ 1,952	$ 2,018

Depreciation and amortization expense for three and nine months ended September 30, 2023 was $246 million and $414 million, respectively. Depreciation and amortization expense for the three and nine months ended September 30, 2022 was $113 million and $268 million, respectively.

11. Other Balance Sheet Components

Accounts Receivable, net

Accounts receivable, net, as of September 30, 2023 and December 31, 2022 consisted of the following (in millions):

	September 30, 2023	December 31, 2022
Accounts receivable	$ 2,360	$ 1,385
Less: Wholesalers chargebacks, discounts and fees	(479)	—
Less: Allowance for expected credit loss	(15)	—
Accounts receivable, net	$ 1,866	$ 1,385

Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets, as of September 30, 2023 and December 31, 2022 consisted of the following (in millions):

	September 30, 2023	December 31, 2022
Prepaid income taxes	$ 210	$ 187
Prepaid services	187	216
Income tax receivable	116	10
Down payments for materials and supplies	61	219
Interest receivable	52	61
Collaboration receivable	44	11
Tenant improvement allowance receivable	42	42
Down payments to manufacturing vendors	39	229
Value added tax receivable	26	140
Convertible note receivable	—	36
Other current assets	96	44
Prepaid expenses and other current assets	$ 873	$ 1,195

Other Non-Current Assets

Other non-current assets, as of September 30, 2023 and December 31, 2022 consisted of the following (in millions):

	September 30, 2023	December 31, 2022
Downpayments and prepayments, non-current	$ 238	$ —
Inventory, non-current[1]	211	910
Equity investments	86	42
Goodwill (Note 6)	52	—
Finite-lived intangible asset (Note 6)	45	—
Restricted cash	4	12
Other	25	24
Other non-current assets	$ 661	$ 988

[1]Consisted of raw materials with an anticipated consumption beyond one year.

Accrued Liabilities

Accrued liabilities, as of September 30, 2023 and December 31, 2022 consisted of the following (in millions):

	September 30, 2023	December 31, 2022
Manufacturing	$ 779	$ 400
Clinical trials	263	319
Compensation-related	251	190
Provisions related to product sales (Note 3)	184	—
Other external goods and services	145	264
Commercial	137	48
Development operations	110	88
Property, plant and equipment	108	5
Loss on future firm purchase commitments[1]	98	268
Royalties	78	203
Raw materials	71	316
Accrued liabilities	$ 2,224	$ 2,101

[1]Related to losses that are expected to arise from firm, non-cancellable, commitments for future raw material purchases (Note 9).

Other Current Liabilities

Other current liabilities, as of September 30, 2023 and December 31, 2022 consisted of the following (in millions):

	September 30, 2023	December 31, 2022
Lease liabilities - financing (Note 12)	$ 150	$ 161
Lease liabilities - operating (Note 12)	33	35
Other	56	53
Other current liabilities	$ 239	$ 249

Deferred Revenue

The following table summarizes the activities in deferred revenue for the nine months ended September 30, 2023 (in millions):

	December 31, 2022	Additions	Deductions	September 30, 2023
Product sales	$ 2,626	$ 207	$ (1,340)	$ 1,493
Grant revenue	4	2	(2)	4
Collaboration revenue	81	19	(59)	41
Total deferred revenue	$ 2,711	$ 228	$ (1,401)	$ 1,538

12. Leases

We have entered into various long-term non-cancelable lease arrangements for our facilities and equipment expiring at various times through 2042. Certain of these arrangements have free rent periods or escalating rent payment provisions. We recognize lease cost under such arrangements on a straight-line basis over the life of the lease. We have two main campuses in Massachusetts, our Cambridge campus and our Moderna Technology Center (MTC), an industrial technology center located in Norwood. We also lease other office and lab spaces globally for our business operations.

Cambridge Campus

We occupy a multi-building campus in Technology Square in Cambridge, Massachusetts with a mix of offices and research laboratory space totaling approximately 292,000 square feet. Our Cambridge campus leases have expiry ranges from 2024 to 2029. All our Cambridge leases are classified as operating leases.

In September 2021, we entered into a lease agreement for a building space, approximately 462,000 square feet, in Cambridge, Massachusetts. This space is designated to be the Moderna Science Center (MSC). Following an estimated 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. In connection with our MSC investment, in September 2021, we entered into amendments to our Technology Square lease agreements to allow for an option for early termination of the leases, either in part or full. Notification of the intent to exercise the option must be provided by December 2023. We have not elected to exercise this option.

Moderna Technology Center

Our MTC is comprised 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.

Embedded Leases

We have entered into multiple contract manufacturing service agreements with third parties which contain embedded leases within the scope of ASC 842. These leases will expire by the end of 2023. In the third quarter of 2023, as part of our strategic initiative to optimize our manufacturing footprint, we amended a contract manufacturing service agreement, resulting in decreases of $262 million in each of the right-of-use assets and lease liabilities. Additionally, it resulted in accelerated depreciation of the right-of-use assets of $161 million. As of September 30, 2023 and December 31, 2022, we had lease liabilities of $149 million and $440 million, respectively, related to the embedded leases. As of September 30, 2023 and December 31, 2022, we had right-of-use assets of $161 million and $639 million, respectively, related to the embedded leases. All our embedded leases are classified as finance leases.

Operating and financing lease right-of-use assets and lease liabilities as of September 30, 2023 and December 31, 2022 were as follows (in millions):

	September 30, 2023	December 31, 2022
Assets:		
Right-of-use assets, operating, net[1] [2]	$ 765	$ 121
Right-of-use assets, financing, net[3] [4]	601	1,150
Total	$ 1,366	$ 1,271
Liabilities:		
Current:		
Operating lease liabilities[5]	$ 33	$ 35
Financing lease liabilities[5]	150	161
Total current lease liabilities	183	196
Non-current:		
Operating lease liabilities, non-current	697	92
Financing lease liabilities, non-current	575	912
Total non-current lease liabilities	1,272	1,004
Total	$ 1,455	$ 1,200

[1] These assets are real estate related assets, which include land, office, and laboratory spaces.
[2] Net of accumulated amortization.
[3] These assets are real estate assets related to the MTC leases as well as assets related to contract manufacturing service agreements.
[4] Included in property and equipment in the condensed consolidated balance sheets, net of accumulated depreciation.
[5] Included in other current liabilities in the condensed consolidated balance sheets.

Future minimum lease payments under our non-cancelable lease agreements as of September 30, 2023, were as follows (in millions):

Fiscal Year	Operating Leases	Financing Leases[1]
2023 (remainder of the year)	$ 6	$ 154
2024	102	21
2025	80	22
2026	82	23
2027	84	23
Thereafter	869	1,097
Total minimum lease payments	1,223	1,340
Less amounts representing interest or imputed interest	(493)	(615)
Present value of lease liabilities	$ 730	$ 725

[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.

13. Commitments and Contingencies

Legal Proceedings

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

Indemnification Obligations

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

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

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

Through the three and nine months ended September 30, 2023 and the year ended December 31, 2022, 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, 2023, we had $2.1 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, 2023, $98 million of the purchase commitments related to raw materials was recorded as an accrued liability for loss on future firm purchase commitments. As of September 30, 2023, we had $273 million of non-cancelable purchase commitments related to clinical services and other goods and services which are expected to be paid through 2038. These amounts represent our minimum contractual obligations, including termination fees.

In addition to purchase commitments, we have agreements with third parties for various goods and services, including services related to clinical operations and support and contract manufacturing, for which we are not contractually able to terminate for convenience and avoid any and all future obligations to the vendors. Certain agreements provide for termination rights subject to termination fees or wind down costs. Under such agreements, we are contractually obligated to make certain payments to vendors, mainly, to reimburse them for their unrecoverable outlays incurred prior to cancellation. As of September 30, 2023, we had cancelable open purchase orders of $3.1 billion in total under such agreements for our significant clinical operations and support and contract manufacturing. These amounts represent only our estimate of those items for which we had a contractual commitment to pay as of September 30, 2023, 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 2022 Form 10-K under the heading "In-licensed intellectual property" and Note 12 to our consolidated financial statements contained therein.

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. For the three and nine months ended September 30, 2022, we recognized $106 million and $470 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, 2023.

14. 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, 2023 and 2022 as follows (in millions):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Options	$ 32	$ 15	$ 102	$ 67
Restricted Common Stock (RSUs) and Performance Stock Units (PSUs)	43	54	117	93
Employee Stock Purchase Plan (ESPP)	2	1	7	4
Total	$ 77	$ 70	$ 226	$ 164
Cost of sales	$ 7	$ 10	$ 28	$ 31
Research and development	40	28	115	67
Selling, general and administrative	30	32	83	66
Total	$ 77	$ 70	$ 226	$ 164

As of September 30, 2023, there was $701 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 2.9 years as of September 30, 2023.

Share Repurchase Programs

As of September 30, 2023, $1.7 billion of our Board of Directors' authorization for repurchases of our common stock remains outstanding (the 2022 Repurchase Programs), 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.

The following table summarizes activity related to our share repurchase programs for the nine months ended September 30, 2023 (in millions, except per share data):

	Nine Months Ended September 30,
	2023
Number of shares repurchased	8
Average price per share[(1)]	$ 143.31
Aggregate purchase price	$ 1,153
Remaining authorization at end of period	$ 1,667

[(1)] Average price paid per share includes related expenses and excise tax.

15. 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,	
	2023	2022	2023	2022
(Loss) income before income taxes	$ (1,958)	$ 1,217	$ (4,012)	$ 7,920
Provision for income taxes	$ 1,672	$ 174	$ 919	$ 1,023
Effective tax rate	(85.5)%	14.3 %	(22.9)%	12.9 %

The effective tax rate for the three and nine months ended September 30, 2023 was higher than the statutory rate, primarily due to an increase in valuation allowance against deferred tax assets. The effective tax rates for the three and nine months ended September 30, 2023 also include a discrete benefit from stock-based compensation. The increase in income tax expense for the three months ended September 30, 2023 was predominantly driven by an increase in valuation allowance on deferred tax assets of $1.7 billion. The decrease in income tax expense for the nine months ended September 30, 2023 was predominantly driven by a significant decrease in pre-tax income, partially offset by an increase in valuation allowance of $1.7 billion.

As of December 31, 2022, we maintained a state valuation allowance on deferred tax assets of $155 million, primarily due to tax attributes that we expected would expire prior to their utilization, and we maintained no valuation allowance on federal or foreign deferred tax assets. 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. In the third quarter of 2023, following the completion of our long-range financial planning process, we reassessed the evidence and concluded that a valuation allowance was necessary due to the preponderance of negative evidence, including:

- A year-to-date pre-tax loss and a projected pre-tax loss for the full year 2023, serving as a significant source of objectively verifiable negative evidence in accordance with ASC 740 (*Income Taxes*).

- A projected three-year cumulative loss resulting from our long-range financial planning process. This projection is due to a significant decrease in expected sales of our COVID-19 vaccine as we transition to a seasonal market. Additionally, we anticipate substantial research and development expenses for our on-going Phase 3 clinical trials and to advance our product candidates into later-stage development. These factors contribute additional negative evidence with respect to the realizability of our deferred tax assets. The projections are based upon revenue from our currently approved drug product, which we believe can be reasonably estimated. In contrast, future taxable income projections from our investigational medicines are deemed inherently subjective and not objectively verifiable; they are insufficient to override negative evidence, and therefore, they are not assigned any weight in our valuation allowance analysis assessment.

Our evaluation also included whether there were other sources of taxable income that would allow us to realize our deferred tax assets, such as taxable income in carryback years, available tax planning strategies and the future reversals of taxable temporary differences. After assessing these strategies and all evidence, we determined it was more likely than not that we will not realize all of our deferred tax assets and therefore increased the valuation allowance by $1.7 billion in the third quarter of 2023. 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.

16. (Loss) Earnings per Share

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

Basic and diluted EPS for the three and nine months ended September 30, 2023 and 2022 were calculated as follows (in millions, except per share data):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Numerator:				
Net (loss) income	$ (3,630)	$ 1,043	$ (4,931)	$ 6,897
Denominator:				
Basic weighted-average common shares outstanding	381	390	382	396
Effect of dilutive securities	—	22	—	23
Diluted weighted-average common shares outstanding	381	412	382	419
Basic EPS	$ (9.53)	$ 2.67	$ (12.89)	$ 17.41
Diluted EPS	$ (9.53)	$ 2.53	$ (12.89)	$ 16.46
Anti-dilutive potential common shares excluded from the EPS computation above	28	4	28	3

17. Subsequent Events

In September 2023, we entered into a strategic research and development collaboration agreement with Immatics, a clinical-stage biopharmaceutical company in the discovery and development of T cell-redirecting cancer immunotherapies. Upon satisfaction of all closing conditions, the transaction was finalized in October 2023, and we made an upfront payment of $120 million to Immatics. We are currently in the process of evaluating the accounting implications for this transaction.

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

You should read the following discussion and analysis of our financial condition and results of operations together with our unaudited financial information and related notes included in this Form 10-Q and our consolidated financial statements and related notes and other financial information in our Annual Report on Form 10-K for the year ended December 31, 2022, which was filed with the Securities and Exchange Commission (the SEC) on February 24, 2023 (the 2022 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, autoimmune diseases and cardiovascular diseases, independently and with our strategic collaborators.

Since our founding in 2010, we have transformed from a research-stage company advancing programs in the field of mRNA to a commercial enterprise with a diverse clinical portfolio of vaccines and therapeutics across six modalities, a broad intellectual property portfolio and integrated manufacturing capabilities that allow for rapid clinical and commercial production at scale. We have a diverse and extensive development pipeline of 41 development candidates across our 43 development programs, of which 38 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.

Business Highlights

On September 11, 2023, we received approval of the supplemental Biologics License Application from the U.S. Food and Drug Administration (FDA) for our updated COVID-19 vaccine, which targets the Omicron XBB.1.5 sublineage of SARS-CoV-2 (mRNA-1273.815), for individuals 12 years and older. The FDA also issued an Emergency Use Authorization for mRNA-1273.815 for children aged 6 months to 11 years old. We subsequently received authorization from regulatory authorities around the globe for mRNA-1273.815 and initiated the shipment of doses both in the U.S. and internationally.

In January 2023, we announced positive data from the interim analysis of our pivotal ConquerRSV study of our vaccine candidate against respiratory syncytial virus (RSV) (mRNA-1345). ConquerRSV is a randomized, double-blind, placebo-controlled study of approximately 37,000 adults 60 years or older in 22 countries. In the study, mRNA-1345 met primary efficacy endpoints, demonstrating vaccine efficacy of 83.7% against RSV lower respiratory tract disease in older adults. We have filed for a Biologics License Application to the FDA for our RSV vaccine for adults aged 60 years or older, and used a Priority Review Voucher to accelerate review. We have also submitted marketing authorization applications for the vaccine for adults aged 60 years or older to medical authorities in several countries beyond the U.S. We have initiated the manufacturing of mRNA-1345 and are preparing for a marketing launch, subject to approval.

In September 2023, we announced a strategic research and development collaboration agreement with Immatics, a clinical-stage biopharmaceutical company active in the discovery and development of T cell-redirecting cancer immunotherapies. Upon effectiveness of the agreement in October 2023, we made an upfront payment of $120 million to Immatics. This collaboration between Moderna and Immatics focuses on three pillars:

- Applying Moderna's mRNA technology for *in vivo* expression of Immatics' next-generation, half-life extended T-cell receptor (TCR) bispecifics (TCER) targeting cancer-specific HLA-presented peptides.
- Enabling the discovery and development of novel mRNA-based cancer vaccines by leveraging Moderna's mRNA science and customized information from Immatics' tumor and normal tissue data included in the target discovery platform XPRESIDENT and its bioinformatics and AI platform XCUBE.
- Evaluating Immatics' IMA203 TCR-T therapy targeting PRAME in combination with Moderna's PRAME mRNA-based cancer vaccine. The collaboration contemplates conducting preclinical studies and a Phase 1 clinical trial evaluating the safety and efficacy of the combination with the objective of further enhancing IMA203 T cell responses.

This partnership presents an opportunity to leverage our mRNA technology alongside Immatics' TCR platform, potentially diversifying and augmenting the way we approach cancer treatment.

During the third quarter of 2023, we embarked on a strategic initiative to optimize the cost structure of our COVID-19 business, with a focus on resizing our manufacturing cost structure. The launch of this initiative was prompted by the completion of our long-range planning within the quarter, which incorporated revised forecasts of vaccination rates. These projections accounted for the market's transition from COVID-19 pandemic conditions towards an endemic seasonal market. Consequently, this strategic shift resulted in charges of $1.4 billion for the quarter. Despite the immediate impact to our financial statements, we believe this strategic initiative will enhance the efficiency of our manufacturing operations and equip us with the agility to better adjust our scale according to future market demands.

For the third quarter of 2023, we recognized net product sales of $1.8 billion from sales of our COVID-19 vaccine, compared to $3.1 billion for the third quarter of 2022. Diluted loss per share was $(9.53) for the third quarter of 2023, compared to diluted earnings per share of $2.53 for the third quarter of 2022.

Recent Program Developments

Individualized neoantigen therapy (mRNA-4157)

- We are developing mRNA-4157, an investigational mRNA individualized neoantigen therapy (INT), in collaboration with Merck & Co., Inc (Merck). In July 2023, we and Merck announced the initiation of the pivotal Phase 3 randomized V940-001 clinical trial evaluating mRNA-4157 in combination with KEYTRUDA (pembrolizumab), Merck's anti-PD-1 therapy, as an adjuvant treatment in patients with resected high-risk melanoma (Stage IIB-IV). The trial is underway globally, and the patients are enrolling in several countries. The trial is expected to enroll approximately 1,089 patients at more than 165 sites in over 25 countries around the world. The primary endpoint of the study is recurrence-free survival (RFS) and secondary endpoints include distant metastasis-free survival (DMFS), overall survival and safety.

- We and Merck are also preparing for the commencement of a Phase 3 trial of mRNA-4157 during the fourth quarter 2023 in non-small cell lung cancer (NSCLC) in patients with resected stage II-IIIB NSCLC who have received adjuvant chemotherapy, with no recurrence. The primary endpoint is disease free survival compared to pembrolizumab. Secondary endpoints are overall survival, DMFS and safety. The trial is expected to enroll approximately 868 patients.

Combination vaccine against influenza and COVID-19 (mRNA-1083)

- In October 2023, we reported positive interim results from the Phase 1/2 trial of mRNA-1083, an investigational combination vaccine against influenza and COVID-19. The ongoing Phase 1/2 clinical trial is a randomized, observer blind study evaluating the safety and immunogenicity of mRNA-1083 compared to a standard dose influenza vaccine, Fluarix, in adults 50 to 64 years of age and against an enhanced influenza vaccine, Fluzone HD, in adults 65 to 79 years of age. For both age groups, mRNA-1083 was compared against Spikevax booster. The mRNA-1083 candidate selected to advance to Phase 3 achieved hemagglutination inhibition antibody titers similar to or greater than both licensed quadrivalent influenza vaccines and achieved SARS-CoV-2 neutralizing antibody titers similar to the Spikevax bivalent booster in the Phase 1/2 study. mRNA-1083 resulted in geometric mean titer (GMT) ratios >1.0 relative to Fluarix in adults 50 to 64 years of age, for all four influenza vaccine strains. GMT ratios for mRNA-1083 relative to Fluzone HD in adults 65 to 79 were also >1.0, for all four influenza vaccine strains. The GMT ratios of mRNA-1083 relative to Spikevax bivalent were > 0.9 in adults 50 to 64 years of age and > 1.0 in adults 65 to 79 years of age, relative to Spikevax. Reported rates of solicited local and systemic adverse reactions after mRNA-1083 administration were similar to the standalone COVID-19 vaccine group in the trial. The majority of solicited adverse reactions were grade 1 or 2 in severity. Grade 3 solicited local or solicited systemic reactions were reported in less than 4% of participants ages 50 and above. No new safety concerns were identified for mRNA-1083 compared to the standalone vaccines.

- The first participants were dosed in the Phase 3 trial of mRNA-1083 in October 2023. The Phase 3 study will evaluate the immunogenicity, safety and reactogenicity of mRNA-1083 as compared with active control, co-administered licensed influenza and SARS-CoV-2 vaccines in 8,000 healthy adults 50 years of age or older.

Seasonal influenza (flu) vaccines (mRNA-1010, mRNA-1011 and mRNA-1012)

- In September 2023, we announced that our updated vaccine candidate against seasonal influenza, mRNA-1010, met all co-primary endpoints in an interim analysis of the P303 study across all four A and B strains (A/H1N1, A/H3N2, influenza B/Yamagata, B/Victoria). mRNA-1010 has demonstrated an acceptable safety and tolerability profile across all clinical trials to date, including three Phase 3 trials (P301, P302, P303), and independent data and safety monitoring boards (DSMBs) have raised no safety concerns. The Company has decided not to continue the earlier P302 study for mRNA-1010 into a second season, in light of the fact that all primary endpoints have been met in the P303 study.

- We continue to advance a portfolio of influenza vaccine candidates that include additional hemagglutinin (HA) antigens for broader coverage of circulating influenza A strains (mRNA-1011 and mRNA-1012) and candidates that incorporate both HA and neuraminidase (NA) antigens to target multiple proteins involved in the influenza virus lifecycle to reduce the potential of viral antigenic escape (mRNA-1020 and mRNA-1030).

CMV vaccine (mRNA-1647)

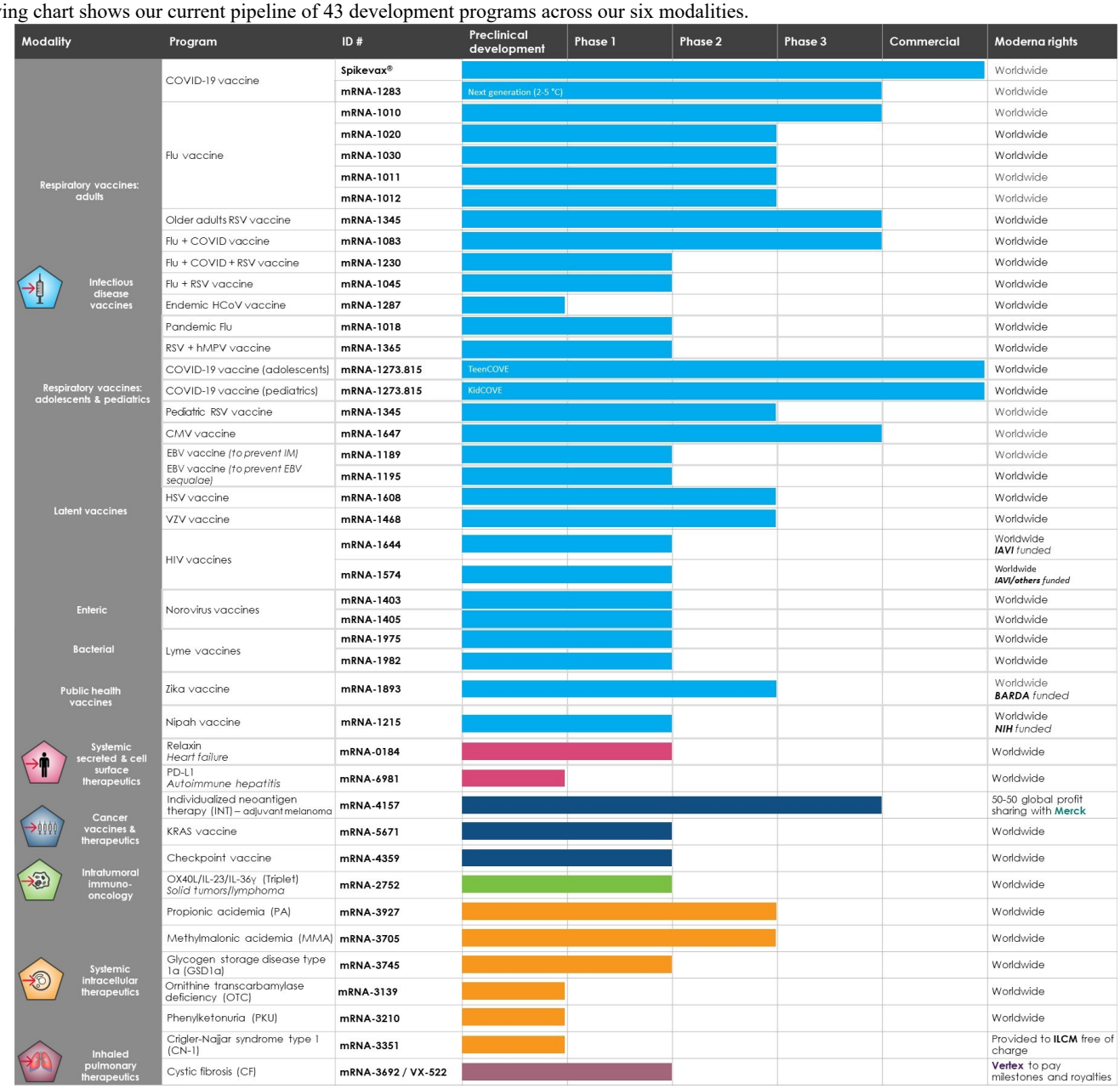
- The pivotal Phase 3 trial (CMVictory) of our CMV vaccine candidate, mRNA-1647, is fully enrolled with adult women from approximately 150 clinical sites. CMVictory is evaluating the vaccine's ability to protect against primary CMV infection in women ages 16 to 40 years. The trial is a randomized, observer-blind, placebo-controlled study designed to evaluate the efficacy, safety, and immunogenicity of mRNA-1647 to evaluate the prevention of primary infection. The primary efficacy analysis will be triggered based on the accrual of seroconversion cases.

Discontinued Programs

- In September 2023, we announced the discontinuation of four programs from our pipeline as we prioritize investments in other programs: VEGF-A (AZD8601); IL-12 (MEDI1191); pediatric hMPV + PIV3 (mRNA-1653); and our COVID + flu combination vaccine based on our original COVID vaccine (mRNA-1073).

Our Pipeline

The following chart shows our current pipeline of 43 development programs across our six modalities.



Abbreviations: BARDA, Biomedical Advanced Research and Development Authority; CMV, Cytomegalovirus; EBV, Epstein-Barr virus; HIV, human immunodeficiency virus; hMPV, human metapneumovirus; HSV, herpes simplex virus; ILCM, Institute for Life Changing Medicines; IL-23, interleukin 23; IL-36γ, interleukin-36 gamma; NIAID, National Institute of Allergy and Infectious Diseases; NIH, National Institutes of Health; OX40L, wildtype OX40 ligand; RSV, respiratory syncytial virus; VZV, varicella-zoster virus.

Results of operations

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

	Three Months Ended September 30,		Change 2023 vs. 2022	
	2023	2022	$	%
Revenue:				
Net product sales	$ 1,757	$ 3,120	$ (1,363)	(44)%
Other revenue	74	244	(170)	(70)%
Total revenue	1,831	3,364	(1,533)	(46)%
Operating expenses:				
Cost of sales	2,241	1,100	1,141	104%
Research and development	1,160	820	340	41%
Selling, general and administrative	442	278	164	59%
Total operating expenses	3,843	2,198	1,645	75%
(Loss) income from operations	(2,012)	1,166	(3,178)	(273)%
Interest income	105	58	47	81%
Other expense, net	(51)	(7)	(44)	629%
(Loss) income before income taxes	(1,958)	1,217	(3,175)	(261)%
Provision for income taxes	1,672	174	1,498	861%
Net (loss) income	$ (3,630)	$ 1,043	$ (4,673)	(448)%

	Nine Months Ended September 30,		Change 2023 vs. 2022	
	2023	2022	$	%
Revenue:				
Net product sales	$ 3,878	$ 13,576	$ (9,698)	(71)%
Other revenue	159	603	(444)	(74)%
Total revenue	4,037	14,179	(10,142)	(72)%
Operating expenses:				
Cost of sales	3,764	3,498	266	8%
Research and development	3,439	2,084	1,355	65%
Selling, general and administrative	1,079	757	322	43%
Total operating expenses	8,282	6,339	1,943	31%
(Loss) income from operations	(4,245)	7,840	(12,085)	(154)%
Interest income	318	113	205	181%
Other expense, net	(85)	(33)	(52)	158%
(Loss) income before income taxes	(4,012)	7,920	(11,932)	(151)%
Provision for income taxes	919	1,023	(104)	(10)%
Net (loss) income	$ (4,931)	$ 6,897	$ (11,828)	(171)%

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,	
	2023	2022	2023	2022
United States	$ 913	$ 985	$ 916	$ 3,380
Europe	103	1,045	739	4,511
Rest of world	741	1,090	2,223	5,685
Total	$ 1,757	$ 3,120	$ 3,878	$ 13,576

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 international governments and organizations. In the U.S., our COVID-19 vaccine is now sold primarily to wholesalers and distributors, and to a lesser extent, directly to retailers and healthcare providers. Net product sales are recognized net of estimated wholesaler chargebacks, invoice discounts for prompt payments and pre-orders, provisions for sales returns, and other related deductions. Please refer to Note 3 to our condensed consolidated financial statements.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Gross product sales	$ 2,420	$ 3,120	$ 4,541	$ 13,576
Product sales provision:				
Wholesaler chargebacks, discounts and fees	(479)	—	(479)	—
Returns and other fees	(184)	—	(184)	—
Total product sales provision	$ (663)	$ —	$ (663)	$ —
Net product sales	$ 1,757	$ 3,120	$ 3,878	$ 13,576

As of September 30, 2023, our COVID-19 vaccine was our only commercial product authorized for use.

As of September 30, 2023, we had deferred revenue of $1.5 billion associated with customer deposits received or billable under supply agreements for delivery of our COVID-19 vaccine in 2023.

We believe that the COVID-19 vaccine market continues to shift to an endemic seasonal market. Our net product sales for the nine months ended September 30, 2023 declined significantly as compared to the same period in 2022, and we expect net product sales for the full year 2023 will similarly reflect a significant decline as compared to full year 2022. In addition, we anticipate greater seasonality for sales, with greater demand in the fall/winter seasons in each hemisphere as countries seek to provide booster vaccinations to their populations.

Other revenue

Other than net product sales, our revenue has been primarily derived from government-sponsored and private organizations including the Biomedical Advanced Research and Development Authority (BARDA), the Defense Advanced Research Projects Agency (DARPA) and the Bill & Melinda Gates Foundation and from strategic alliances with Merck & Co., Inc (Merck), Vertex Pharmaceuticals Incorporated and Vertex Pharmaceuticals (Europe) Limited (together, Vertex) and AstraZeneca plc (AstraZeneca) to discover, develop, and commercialize potential mRNA medicines.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Grant revenue	$ 44	$ 144	$ 96	$ 453
Collaboration revenue	30	100	63	150
Total other revenue	$ 74	$ 244	$ 159	$ 603

Total revenue decreased by $1.5 billion and $10.1 billion, or 46% and 72%, for the three and nine months ended September 30, 2023, respectively, compared to the same periods in 2022, mainly due to decreases in net product sales of our COVID-19 vaccine.

Net product sales decreased by $1.4 billion and $9.7 billion, or 44% and 71%, for the three and nine months ended September 30, 2023, respectively, compared to the same periods in 2022, primarily due to lower sales volume in 2023, partially offset by higher average selling price.

Other revenue decreased by $170 million and $444 million, or 70% and 74%, for the three and nine months ended September 30, 2023, respectively, compared to the same periods in 2022, mainly due to decreases in grant revenue under our agreement with BARDA for the development of our COVID-19 vaccine.

Operating expenses

Cost of sales

In the third quarter 2023, we launched a strategic initiative aimed at optimizing the cost structure of our COVID-19 business, with an emphasis on resizing our manufacturing cost structure. This initiative was triggered by the completion of our long-range planning within the quarter, which incorporated revised forecasts of vaccination rates reflecting the market's transition from COVID-19 pandemic conditions to an endemic seasonal market. The initiative involved scaling down our capacity and commitments with our third-party contract manufacturing organizations (CMO), reevaluating our raw material inventory levels, and reducing our purchase commitments related to raw materials not anticipated to be consumed before expiration. As a result of this initiative, we incurred inventory write-downs of $903 million related to raw materials, and CMO wind down costs and cancellation fees of $513 million. We believe that this strategic initiative will enhance the efficiency of our manufacturing operations and provide us with the flexibility to better scale according to future market needs.

Cost of sales for the three months ended September 30, 2023 was $2.2 billion, including third-party royalties of $78 million, inventory write-down of $353 million related to our finished and semi-finished COVID-19 vaccine inventory, unutilized manufacturing capacity of $90 million, and $1.4 billion in charges related to the strategic initiative. Cost of sales for the nine months ended September 30, 2023 was $3.8 billion, including third-party royalties of $176 million, inventory write-downs of $1.9 billion, unutilized manufacturing capacity and wind down costs of $781 million, and losses on firm purchase commitments and cancellation fees of $205 million (please refer to Note 9 to our condensed consolidated financial statements for inventory related charges). These charges, other than royalties, were largely attributable to a shift in product demand to our latest monovalent XBB.1.5 COVID-19 vaccine and a decline in customer demand, which ultimately led to our strategic initiative.

Cost of sales for the three months ended September 30, 2023 increased by $1.1 billion, or 104%, compared to the same period in 2022. Cost of sales as a percentage of net product sales for the three months ended September 30, 2023 was 128%, compared to 35% for the same period in 2022. Cost of sales for the nine months ended September 30, 2023 increased by $266 million, or 8%, compared to the same period in 2022. Cost of sales as a percentage of net product sales for the nine months ended September 30, 2023 was 97%, compared to 26% for the same period in 2022. The increases in cost of sales in 2023 were primarily driven by our strategic initiative implemented during the third quarter of 2023, partially offset by lower sales volume. The increases in cost of sales as a percentage of net product sales in 2023 were mainly due to the strategic initiative, and other aforementioned charges (excluding royalties) over lower net product sales, driven by a decline in product demand and increased product seasonality. Absent the charges resulting from the strategic initiative, the cost of sales as a percentage of net product sales would have been 47% and 61% for the three and nine months ended September 30, 2023, respectively.

We expect our cost of sales as a percentage of net product sales to remain elevated for 2023 as we transition from a pandemic market to an endemic market, characterized by greater seasonality, for our COVID-19 vaccine. We expect that this transition will result in our cost of sales for the full year 2023 to represent a higher percentage of our net product sales than the percentage experienced in 2022. Similarly, our per unit manufacturing cost in 2023 is expected to be significantly higher than the prior year. However, in light of our recent strategic initiative, we expect a reduction in our cost of sales as a percentage of net product sales for the fourth quarter of 2023, compared to the preceding quarters of the same year.

Research and development expenses

Research and development expenses increased by $340 million, or 41%, for the three months ended September 30, 2023, compared to the same period in 2022. The increase was primarily attributable to increases in personnel-related costs and stock-based compensation of $97 million, consulting and outside services of $71 million, clinical trial expenses of $63 million, manufacturing costs for clinical trial materials of $56 million, and digital- and facility-related costs of $33 million. Research and development expenses increased by $1.4 billion, or 65%, for the nine months ended September 30, 2023, compared to the same period in 2022. The increase was primarily attributable to increases in clinical trial expenses of $478 million, personnel-related costs and stock-based compensation of $279 million, manufacturing costs for clinical trial materials of $273 million, and consulting and outside services of $157 million. These increases for the three and nine month periods in 2023 were largely driven by increased clinical development, particularly for our RSV, flu and CMV programs and our next-generation COVID-19 vaccine candidate (mRNA-1283), increased headcount and our collaboration agreements with Life Edit and Generation Bio executed in the first quarter of 2023.

We expect that research and development expenses will remain higher through year-end 2023, as compared to 2022, as we continue to progress the development of variant-specific and next-generation COVID-19 vaccine candidates and continue to develop our pipeline and advance our product candidates into later-stage development, in particular those in ongoing Phase 3 studies, including our RSV, seasonal flu and CMV vaccine programs, as well as our individualized neoantigen therapy (personalized cancer vaccine) program.

Selling, general and administrative expenses

Selling, general and administrative expenses increased by $164 million, or 59%, for the three months ended September 30, 2023, compared to the same period in 2022. The increase was mainly due to increases in personnel-related costs of $74 million, commercial and marketing expense of $44 million, and consulting and outside services of $28 million. Selling, general and administrative expenses increased by $322 million, or 43%, for the nine months ended September 30, 2023, compared to the same period in 2022. The increase was mainly due to increases in personnel-related costs and stock-based compensation of $157 million, outside services of $143 million, and commercial and marketing expense of $73 million, partially offset by a decrease in distributor fees of $60 million driven by a reduction in net product sales, and an endowment to the Moderna Charitable Foundation of $50 million contributed in 2022. These increases for the three and nine month periods in 2023 were primarily driven by increased headcount and spend in digital, medical affairs and commercial functions to support our digital initiatives, marketed products and company expansion.

We expect that selling, general and administrative expenses will remain higher through year-end 2023, as compared to 2022, due to our build out of our global commercial, regulatory, sales and marketing infrastructure, as we continue to invest in our business operations and programs.

Interest income

Interest income increased by $47 million, or 81%, for the three months ended September 30, 2023, compared to the same period in 2022. Interest income increased by $205 million, or 181%, for the nine months ended September 30, 2023, compared to the same period in 2022. The increases in interest income from our investments in marketable securities for the three and nine month periods in 2023 were mainly driven by an 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 2023 vs. 2022	
	2023	2022	$	%
Loss on investments	$ (37)	$ (4)	$ (33)	825%
Interest expense	(10)	(8)	(2)	25%
Other (expense) income, net	(4)	5	(9)	180%
Total other expense, net	$ (51)	$ (7)	$ (44)	629%

	Nine Months Ended September 30,		Change 2023 vs. 2022	
	2023	2022	$	%
Loss on investments	$ (50)	$ (18)	$ (32)	178%
Interest expense	(32)	(19)	(13)	68%
Other (expense) income, net	(3)	4	(7)	175%
Total other expense, net	$ (85)	$ (33)	$ (52)	158%

Total other expense, net increased by $44 million, or 629%, for the three months ended September 30, 2023, compared to the same period in 2022. The increase in other expense, net for the three months ended September 30, 2023 was primarily due to losses on equity investments and losses on foreign currency transactions and remeasurements. Total other expense, net increased by $52 million, or 158%, for the nine months ended September 30, 2023, compared to the same period in 2022. The increase in other expense, net for the nine months ended September 30, 2023 was primarily due to losses on available-for-sale debt securities and equity investments and an increase in interest expense. Our interest expense is primarily related to our finance leases. Please refer to Note 12 to our condensed consolidated financial statements.

Income taxes

We had a tax provision of $1.7 billion and $919 million for the three and nine months ended September 30, 2023. Provision for income taxes increased by $1.5 billion for the three months ended September 30, 2023, compared to the same period in 2022, primarily due to an increase in valuation allowance on deferred tax assets of $1.7 billion. Provision for income taxes decreased by $104 million, or 10%, for the nine months ended September 30, 2023, compared to the same period in 2022, primarily due to a significant decrease in pre-tax income, partially offset by an increase in valuation allowance on deferred tax assets of $1.7 billion. As a result of the significant reduction in pre-tax income and the valuation allowance, the 2023 effective tax rate will not be comparable to the prior year. Please refer to Note 15 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, 2023 and December 31, 2022 (in millions):

	September 30, 2023	December 31, 2022
Financial assets:		
Cash and cash equivalents	$ 2,932	$ 3,205
Investments	4,641	6,697
Investments, non-current	5,273	8,318
Total	$ 12,846	$ 18,220
Working capital:		
Current assets	$ 10,799	$ 13,431
Current liabilities	4,385	4,923
Total	$ 6,414	$ 8,508

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, 2023 decreased by $5.4 billion, or 29%, compared to December 31, 2022. During the nine months ended September 30, 2023, we had a net cash outflow from operating activities of $3.7 billion, repurchases of our common stock of $1.2 billion, purchases of property and equipment of $487 million, and a business acquisition, net of cash acquired of $85 million, partially offset by unrealized gains on available-for-sale debt securities of $196 million.

Working capital, which is current assets less current liabilities, as of September 30, 2023 decreased by $2.1 billion, or 25%, compared to December 31, 2022, primarily due to a decrease in cash, cash equivalents and short-term investments of $2.3 billion, primarily to fund our operating activities and repurchases of common stock, and a decrease in inventory of $462 million, mainly due to write down of inventory. This was partially offset by a decrease in short-term deferred revenue of $666 million, mainly driven by revenue recognized from deferred revenue in excess of customer deposits received.

As of September 30, 2023, we did not have any off-balance sheet arrangements.

Cash flow

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

	Nine Months Ended September 30,	
	2023	2022
Net cash provided by (used in):		
Operating activities	$ (3,740)	$ 3,319
Investing activities	4,744	(4,128)
Financing activities	(1,268)	(3,010)
Net decrease in cash, cash equivalents and restricted cash	$ (264)	$ (3,819)

Operating activities

We derive cash flows from operations primarily from cash collected from customer deposits and accounts receivable, net related to our COVID-19 vaccine product sales, as well as certain government-sponsored and private organizations and strategic alliances. Our cash flows from operating activities are significantly affected by our use of cash for operating expenses and working capital to support the business.

Beginning in the third quarter of 2020, we entered into supply agreements with the U.S. Government and other 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 international governments and organizations. In the U.S., our COVID-19 vaccine is sold primarily to wholesalers and distributors, and to a lesser extent, directly to retailers and healthcare providers. Wholesalers and distributors typically do not make upfront payments to us. As of September 30, 2023, we had $1.5 billion in deferred revenue related to customer deposits received or billable.

Net cash used in operating activities for the nine months ended September 30, 2023 was $3.7 billion and consisted of net loss of $4.9 billion, a net change in assets and liabilities, net of acquisition of business, of $388 million and non-cash adjustments of $1.6 billion. Non-cash items primarily included deferred income taxes of $934 million, depreciation and amortization of $419 million, and stock-based compensation of $226 million. The net change in assets and liabilities was mainly due to a decrease in deferred revenue of $1.2 billion due to revenue recognized upon shipments of our COVID-19 vaccine, an increase in right-of-use assets, operating leases of $657 million due to the lease commencement of our future corporate headquarters, and an increase in accounts receivable, net of $481 million primarily due to shipments of our COVID-19 vaccine in the U.S. for the fall vaccination season, partially offset by a decrease in prepaid expenses and other assets of $772 million primarily due to write downs of non-current inventory, an increase in operating lease liabilities of $605 million due to the lease commencement of our future corporate headquarters, and a decrease in inventory of $462 million due to inventory write downs.

Net operating cash flows decreased by $7.1 billion, or 213%, during the nine months ended September 30, 2023, compared to the same period in 2022, primarily attributable to a decrease in net income of $11.8 billion, partially offset by a change in deferred revenue of $1.5 billion due to revenue recognized from deferred revenue in excess of customer deposits received, deferred income taxes of $1.4 billion due to an increase in valuation allowance, and prepaid expense and other assets of $1.4 billion due to inventory write-downs.

Investing activities

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

Net cash provided by investing activities for the nine months ended September 30, 2023 was $4.7 billion, which primarily included proceeds from maturities and sales of marketable securities of $7.4 billion, partially offset by purchases of marketable securities of $2.1 billion, purchases of property and equipment of $487 million, and a business acquisition, net of cash acquired of $85 million.

Net investing cash flows increased by $8.9 billion, or 215%, during the nine months ended September 30, 2023, compared to the same period in 2022, primarily due to a decrease in purchases of marketable securities of $6.8 billion and an increase in proceeds from maturities of marketable securities of $2.5 billion.

Financing activities

Net cash used in financing activities for the nine months ended September 30, 2023 was $1.3 billion, primarily due to repurchases of common stock of $1.2 billion.

Net cash used in financing activities decreased by $1.7 billion, or 58%, during the nine months ended September 30, 2023, compared to the same period in 2022, mainly due to a decrease in repurchases of common stock.

Operation and funding requirements

Our principal sources of funding as of September 30, 2023 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 2022 and 2021, following the authorization of our first commercial product in December 2020. From our inception to the end of 2020, we incurred significant losses from operations due to our significant research and development expenses. We also incurred a net loss of $4.9 billion for the nine months ended September 30, 2023. We have retained earnings of $13.4 billion as of September 30, 2023.

We have significant future capital requirements including expected operating expenses to conduct research and development activities, operate our organization, meet capital expenditure needs, and fund our share repurchase programs (refer to Note 14 to our condensed consolidated financial statements). We anticipate maintaining substantial expenses across all areas of our ongoing activities, particularly as we continue research and development of our development candidates and clinical activities for our investigational medicines. This also extends to our manufacturing costs, including our arrangements with our supply and manufacturing partners. Our ongoing work on our RSV, seasonal flu and CMV vaccine candidates, individualized neoantigen therapy, COVID-19 vaccines, including development of any new generations of boosters and vaccines against variants of SARS-CoV-2, combination vaccines, late-stage clinical development, and buildout of global commercial, regulatory, sales and marketing infrastructure 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 12 and Note 13 to our condensed consolidated financial statements). We have entered into certain collaboration and licensing agreements with third parties that include the funding of certain research and development activities and potential future milestone and royalty payments by us.

We believe that our cash, cash equivalents, and investments as of September 30, 2023, together with cash expected to be generated from product sales, will be sufficient to enable us to fund our projected operations, capital expenditures and stock repurchases through at least the next 12 months from the issuance of these financial statements included in this Form 10-Q. We are subject to all the risks related to the development and commercialization of novel medicines, and we may encounter unforeseen expenses, difficulties, complications, delays, and other unknown factors, which may adversely affect our business. For example, we have experienced a decline in customer demand for our COVID-19 vaccine, reflecting the market's ongoing transition to an endemic seasonal market in 2023. 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, 2023 compared to those disclosed in our 2022 Form 10-K, other than as set forth below with respect to our accounting policy related to net product sales in the U.S. In the third quarter of 2023, we initiated sales of our COVID-19 vaccine in the U.S. commercial market. While our inventory policy remains unchanged, we have observed an increase in the judgment and estimates involved in inventory valuation. A summary of the policy and the significant judgments and estimates associated with inventory valuation is provided below.

Net product sales

Prior to the third quarter of 2023, we sold our COVID-19 vaccine to the U.S. Government, other international governments and organizations. The agreements and related amendments with these entities generally do not include variable consideration, such as discounts, rebates or returns. In the third quarter of 2023, we commenced sales of our latest COVID-19 vaccine to the U.S. commercial market, in addition to continuing sales to international governments and 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 recognize net product sales when control of the product transfers to the customer, typically upon delivery. Net product sales in the U.S. are recognized net of estimated wholesaler chargebacks, invoice discounts for prompt payments and pre-orders, provisions for

sales returns, and other related deductions. These provisions are recorded based on contractual terms and our estimate of returns for product sold during the period, using the expected value method or the most likely amount method. Estimates are assessed each period and adjusted as required to revise information or actual experience.

The application of our critical accounting policies necessitates substantial management judgment and estimation, particularly when determining the amount of variable consideration to recognize. The subjectivity of this process is heightened when assessing factors outside our direct control such as lack of pertinent historical data and limited third-party information. Among all variables, estimating returns presents the most significant judgment due to the broad range of potential outcomes. As we receive more historical data on our product returns, we will incorporate this information into our estimates to improve accuracy. The actual results could differ from our estimates, and such differences could have a material impact to our financial statements.

Please refer to Note 3 to our condensed consolidated financial statements for additional details.

Inventory

Inventory is recorded at the lower of cost or net realizable value, with cost determined using first-in, first-out and average cost methods for different inventory components. We periodically review the composition of inventory in order to identify excess, obsolete, slow-moving or otherwise unsaleable items. If unsaleable items are observed and there are no alternate uses for the inventory, we will record a write-down to net realizable value in the period that the decline in value is first recognized through a charge to cost of sales. The process of determining whether inventory cost will be realizable requires significant judgment and estimates by management. If actual market conditions prove less favorable than projected by management, additional write-downs of inventory may be required. On a quarterly basis, we also assess whether we have any excess firm, non-cancelable, purchase commitment liabilities, resulting from our supply agreements with third-party vendors. The determination of net realizable value and firm purchase commitment liabilities requires significant judgment, including consideration of many factors, such as estimates of future product demand, product net selling prices, current and future market conditions, potential product obsolescence, expiration and utilization of raw materials under firm purchase commitments and contractual minimums, among others. We maintain raw materials beyond our one-year forecasted production plan, which were classified as non-current and included in other non-current assets in our consolidated balance sheets. The classification and valuation of these materials involve significant judgment and estimates. While we consider the assumptions used in estimating inventory write-downs to be reasonable, any significant future changes in these assumptions or shifts in future events and market conditions could lead to different estimates.

Contractual Obligations

As of September 30, 2023, other than disclosed within Note 12 and Note 13 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 2022 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 2022 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, 2023.

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, 2023. 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, 2023, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the three months ended September 30, 2023, which have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting, except for the controls established pertaining to our new commercial sales process in the U.S. In the third quarter of 2023, we initiated the sales of our COVID-19 vaccine in the U.S. commercial market. Please refer to Note 3 to our condensed consolidated financial statements for additional details.

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 2022 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 2022 Form 10-K, including the discussion under the headings entitled “Risks related to our intellectual property” and “Risks related to the manufacturing of our commercial products, development candidates, investigational medicines and our future pipeline.” The outcome of any such proceedings, regardless of the merits, is inherently uncertain; therefore, assessing the likelihood of loss and any estimated damages is difficult and subject to considerable judgment.

Proceedings Related to Patents Owned by Alnylam

As previously disclosed in the 2022 10-K, in March 2022, Alnylam Pharmaceuticals, Inc. (Alnylam) 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 vaccine infringes a U.S. patent concerning cationic lipids. In August 2023, the District Court entered a final judgment of non-infringement in our favor. Alnylam has appealed that decision to the U.S. Court of Appeals for the Federal Circuit.

Item 1A. Risk Factors

Information regarding risk and uncertainties related to our business appears in Part I, Item 1A. “Risk Factors” of our 2022 Form 10-K. There have been no material changes from the risk factors previously disclosed in the 2022 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, 2023, there were no shares repurchased. As of September 30, 2023, $1.7 billion of our Board of Directors' authorization for repurchases of our common stock remains outstanding, with no expiration date.

Refer to Note 14 to condensed consolidated financial statements for information regarding our share repurchase programs.

Item 5. Other Information

During the three months ended September 30, 2023, the following officers (as defined in Rule 16a-1(f) of the Securities Exchange Act of 1934, as amended) of the Company took the following actions regarding trading arrangements with respect to our securities:

On August 11, 2023, Stephane Bancel, our Chief Executive Officer, terminated a trading arrangement that was intended to satisfy the affirmative defense of Rule 10b5-1(c) (the Bancel 10b5-1 Plan). The Bancel 10b5-1 Plan was entered into on March 7, 2023, and was scheduled to commence on September 6, 2023, with a termination date of the earlier of August 29, 2025 or the date all shares under the plan were sold. The aggregate number of securities to be sold pursuant to the Bancel 10b5-1 Plan was 1,200,000.

On August 24, 2023, Arpa Garay, our Chief Commercial Officer, adopted a trading arrangement that is intended to satisfy the affirmative defense of Rule 10b5-1(c) (the Garay 10b5-1 Plan). Between November 27, 2023 and August 30, 2024, the Garay 10b5-1 Plan provides for the potential sale of approximately 4,540 shares of the Company's common stock and for the potential exercise of vested stock options and the associated sale of up to 24,897 shares. The plan expires on August 30, 2024, or upon the earlier completion of all authorized transactions under the plan.

Item 6. Exhibits

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

Exhibit No.	Exhibit Index
31.1*	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1+	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS*	XBRL Instance Document - The instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Taxonomy Extension Calculation Document
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	XBRL Taxonomy Extension Presentation Link Document
104*	Cover Page Interactive Data File (formatted as Inline XBRL with applicable taxonomy extension information contained in Exhibits 101.)

* Filed herewith

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

SIGNATURES

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

MODERNA, INC.

Date:
November 3, 2023

By: /s/ Stéphane Bancel

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

Date:
November 3, 2023

By: /s/ James M. Mock

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

Exhibit 31.1

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

CERTIFICATIONS

I, Stéphane Bancel, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Moderna, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 3, 2023

By: /s/ Stéphane Bancel

Stéphane Bancel
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

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

CERTIFICATIONS

I, James M. Mock, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Moderna, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 3, 2023

By: /s/ James M. Mock

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

Exhibit 32.1

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

In connection with the Quarterly Report on Form 10-Q of Moderna, Inc. (the "Company") for the period ended September 30, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), we, Stéphane Bancel, Chief Executive Officer of the Company, and James M. Mock, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of our knowledge:

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

Date: November 3, 2023

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

Date: November 3, 2023

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