

**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 March 31, 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
(Address of Principal Executive
Offices)

02139

(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 April 28, 2023, there were 381,209,341 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 vaccines, and our plans and expectations regarding future generations of our COVID-19 vaccines, 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 dosage for vaccines and authorization or approval for boosters), demand for COVID-19 vaccines, and third-party and governmental arrangements and potential arrangements;
- our expectations regarding an endemic, commercial market for COVID-19 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 vaccines in 2023;
- our goal to launch our first combination vaccines by 2025 and our ability to regularly update our combination vaccines with improved next-generation vaccine candidates;
- 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 vaccines 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 vaccines and the impact on our cost of sales for full year 2023;
- 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 expectation that our updated formulation of mRNA-1010 will have improved immunogenicity against influenza B strains;
- our plans with respect to our individualized neoantigen therapy, including our plan to initiate a Phase 3 study in adjuvant melanoma in 2023 and rapidly expand 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;
- 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, including our partnerships with various governments to establish mRNA vaccine manufacturing facilities;

- estimates of our future expenses, revenues and capital requirements;
- 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;
- the potential benefits associated with our acquisition of OriCiro Genomics K.K.;
- our financial performance;
- 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, [@moderna_tx](https://twitter.com/moderna_tx); and LinkedIn, www.linkedin.com/company/modernatx; contain a significant amount of information about us, including financial and other information for investors. We encourage investors to visit these websites and social media channels as information is frequently updated and new information is shared. Information contained on our website, corporate blog and social media channels shall not be deemed incorporated into, or be a part of, this Form 10-Q.

Table of Contents

	Page
PART I.	
Item 1.	<u>Financial Statements (Unaudited)</u> <u>5</u>
	<u>Condensed Consolidated Balance Sheets as of March 31, 2023 and December 31, 2022</u> <u>5</u>
	<u>Condensed Consolidated Statements of Operations for the three months ended March 31, 2023 and 2022</u> <u>6</u>
	<u>Condensed Consolidated Statements of Comprehensive Income for the three months ended March 31, 2023 and 2022</u> <u>7</u>
	<u>Condensed Consolidated Statements of Stockholders' Equity for the three months ended March 31, 2023 and 2022</u> <u>8</u>
	<u>Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2023 and 2022</u> <u>9</u>
	<u>Notes to Condensed Consolidated Financial Statements</u> <u>10</u>
Item 2.	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u> <u>29</u>
Item 3.	<u>Quantitative and Qualitative Disclosures about Market Risk</u> <u>39</u>
Item 4.	<u>Controls and Procedures</u> <u>40</u>
PART II.	
Item 1.	<u>Legal Proceedings</u> <u>40</u>
Item 1A.	<u>Risk Factors</u> <u>40</u>
Item 2.	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u> <u>41</u>
Item 6.	<u>Exhibits</u> <u>41</u>
SIGNATURES	<u>42</u>

Item 1. Financial Statements

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

	March 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	\$ 3,441	\$ 3,205
Investments	5,482	6,697
Accounts receivable	1,113	1,385
Inventory	732	949
Prepaid expenses and other current assets	1,354	1,195
Total current assets	12,122	13,431
Investments, non-current	7,442	8,318
Property, plant and equipment, net	2,018	2,018
Right-of-use assets, operating leases	117	121
Deferred tax assets	1,262	982
Other non-current assets	1,164	988
Total assets	<u>\$ 24,125</u>	<u>\$ 25,858</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 389	\$ 487
Accrued liabilities	1,613	2,101
Deferred revenue	1,219	2,038
Income taxes payable	66	48
Other current liabilities	212	249
Total current liabilities	3,499	4,923
Deferred revenue, non-current	673	673
Operating lease liabilities, non-current	96	92
Financing lease liabilities, non-current	831	912
Other non-current liabilities	163	135
Total liabilities	5,262	6,735
Commitments and contingencies (Note 13)		
Stockholders' equity:		
Preferred stock, par value \$0.0001; 162 shares authorized as of March 31, 2023 and December 31, 2022; no shares issued or outstanding at March 31, 2023 and December 31, 2022	—	—
Common stock, par value \$0.0001; 1,600 shares authorized as of March 31, 2023 and December 31, 2022; 384 and 385 shares issued and outstanding as of March 31, 2023 and December 31, 2022, respectively	—	—
Additional paid-in capital	731	1,173
Accumulated other comprehensive loss	(267)	(370)
Retained earnings	18,399	18,320
Total stockholders' equity	18,863	19,123
Total liabilities and stockholders' equity	<u>\$ 24,125</u>	<u>\$ 25,858</u>

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

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

	Three Months Ended March 31,	
	2023	2022
Revenue:		
Product sales	\$ 1,828	\$ 5,925
Other revenue	34	141
Total revenue	1,862	6,066
Operating expenses:		
Cost of sales	792	1,017
Research and development	1,131	554
Selling, general and administrative	305	268
Total operating expenses	2,228	1,839
(Loss) income from operations	(366)	4,227
Interest income	109	15
Other expense, net	(48)	(13)
(Loss) income before income taxes	(305)	4,229
(Benefit from) provision for income taxes	(384)	572
Net income	\$ 79	\$ 3,657
Earnings per share:		
Basic	\$ 0.20	\$ 9.09
Diluted	\$ 0.19	\$ 8.58
Weighted average common shares used in calculation of earnings per share:		
Basic	386	402
Diluted	405	426

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

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

	Three Months Ended March 31,	
	2023	2022
Net income	\$ 79	\$ 3,657
Other comprehensive income (loss), net of tax:		
Available-for-sale securities:		
Unrealized gains (losses) on available-for-sale debt securities	79	(178)
Less: net realized losses on available-for-sale securities reclassified in net income	16	7
Net increase (decrease) from available-for-sale debt securities	95	(171)
Cash flow hedges:		
Unrealized gains on derivative instruments	—	25
Less: net realized losses (gains) on derivative instruments reclassified in net income	8	(14)
Net increase from derivatives designated as hedging instruments	8	11
Total other comprehensive income (loss)	103	(160)
Comprehensive income	\$ 182	\$ 3,497

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

MODERNA, INC.
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
FOR THE THREE MONTHS ENDED MARCH 31, 2023 AND 2022
(Unaudited, in millions)

	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 units	1	—	—	—	—	—
Exercise of options to purchase common stock	2	—	9	—	—	9
Stock-based compensation	—	—	75	—	—	75
Other comprehensive income, net of tax	—	—	—	103	—	103
Repurchase of common stock	(4)	—	(526)	—	—	(526)
Net income	—	—	—	—	79	79
Balance at March 31, 2023	<u>384</u>	<u>\$ —</u>	<u>\$ 731</u>	<u>\$ (267)</u>	<u>\$ 18,399</u>	<u>\$ 18,863</u>

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Retained Earnings	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2021	403	\$ —	\$ 4,211	\$ (24)	\$ 9,958	\$ 14,145
Exercise of options to purchase common stock	1	—	12	—	—	12
Stock-based compensation	—	—	44	—	—	44
Other comprehensive loss, net of tax	—	—	—	(160)	—	(160)
Repurchase of common stock	(4)	—	(623)	—	—	(623)
Net income	—	—	—	—	3,657	3,657
Balance at March 31, 2022	<u>400</u>	<u>\$ —</u>	<u>\$ 3,644</u>	<u>\$ (184)</u>	<u>\$ 13,615</u>	<u>\$ 17,075</u>

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)

	Three Months Ended March 31,	
	2023	2022
Operating activities		
Net income	\$ 79	\$ 3,657
Adjustments to reconcile net income to net cash (used in) provided by operating activities:		
Stock-based compensation	75	44
Depreciation and amortization	78	79
Amortization/accretion of investments	(17)	18
Loss on equity investments, net	18	—
Deferred income taxes	(310)	(146)
Other non-cash items	(4)	—
Changes in assets and liabilities, net of acquisition of business:		
Accounts receivable	272	1
Prepaid expenses and other assets	(212)	(414)
Inventory	216	(501)
Right-of-use assets, operating leases	4	10
Accounts payable	(117)	(35)
Accrued liabilities	(495)	114
Deferred revenue	(819)	(805)
Income taxes payable	18	716
Operating lease liabilities	4	(10)
Other liabilities	(15)	35
Net cash (used in) provided by operating activities	(1,225)	2,763
Investing activities		
Purchases of marketable securities	(1,085)	(5,572)
Proceeds from maturities of marketable securities	1,360	441
Proceeds from sales of marketable securities	1,957	1,377
Purchases of property, plant and equipment	(113)	(132)
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	2,011	(3,921)
Financing activities		
Proceeds from issuance of common stock through equity plans	9	12
Repurchase of common stock	(526)	(623)
Changes in financing lease liabilities	(25)	(31)
Net cash used in financing activities	(542)	(642)
Net increase (decrease) in cash, cash equivalents and restricted cash	244	(1,800)
Cash, cash equivalents and restricted cash, beginning of year	3,217	6,860
Cash, cash equivalents and restricted cash, end of period	<u>\$ 3,461</u>	<u>\$ 5,060</u>
Non-cash investing and financing activities		
Purchases of property and equipment included in accounts payable and accrued liabilities	\$ 98	\$ 64
Right-of-use assets reduced through finance lease modifications and reassessments	\$ (60)	\$ —
Right-of-use assets obtained in exchange for financing lease liabilities	\$ —	\$ 94

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

MODERNA, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

1. Description of the Business

Moderna, Inc. (collectively, with its consolidated subsidiaries, any of Moderna, we, us, our or the Company) is a biotechnology company pioneering 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 vaccines are marketed, where approved, under the name Spikevax. To date, we have developed three versions of our COVID-19 vaccine that have received regulatory authorizations or approvals in various jurisdictions: (1) our original vaccine targeting the SARS-CoV-2 ancestral strain (mRNA-1273), (2) our bivalent BA.1 Omicron-targeting vaccine (mRNA-1273.214) and (3) our bivalent BA.4/BA.5 Omicron-targeting vaccine (mRNA-1273.222). We currently sell mRNA-1273.214 and mRNA-1273.222 commercially.

We have a diverse and extensive development pipeline of 45 development candidates across our 47 development programs, of which 36 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 months ended March 31, 2023 are consistent with those described in our 2022 Form 10-K. The results of operations for the three months ended March 31, 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, income taxes, valuation allowance of deferred tax assets, inventory valuation, firm purchase commitment liabilities, leases, fair value of financial instruments, derivative financial instruments, useful lives of property and equipment, research and development expenses, stock-based compensation, intangible assets and goodwill. The actual results that we experience may differ materially from our estimates.

Comprehensive Income

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

The components of accumulated other comprehensive loss for the three months ended March 31, 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	<u>\$ (267)</u>	<u>\$ —</u>	<u>\$ (267)</u>

Restricted Cash

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

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

	March 31,	
	2023	2022
Cash and cash equivalents	\$ 3,441	\$ 5,048
Restricted cash, non-current ⁽¹⁾	20	12
Total cash, cash equivalents and restricted cash shown in the condensed consolidated statements of cash flows	<u>\$ 3,461</u>	<u>\$ 5,060</u>

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

Recently Issued Accounting Standards Not Yet Adopted

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies and adopted by us as of the specified effective date. Unless otherwise discussed, we believe that the impact of recently issued standards that are not yet effective will not have a material impact on our condensed consolidated financial statements and disclosures.

3. Product Sales

Product sales are primarily associated with our COVID-19 vaccine supply agreements with the U.S. Government, other international governments and organizations.

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

	Three Months Ended March 31,	
	2023	2022
United States	\$ 1	\$ 945
Europe	576	2,076
Rest of world	1,251	2,904
Total	<u>\$ 1,828</u>	<u>\$ 5,925</u>

As of March 31, 2023, our original COVID-19 vaccine (mRNA-1273) and Omicron-targeting bivalent boosters (mRNA-1273.214 and mRNA-1273.222) were our only commercial products authorized for use.

As of March 31, 2023 and December 31, 2022, we had deferred revenue of \$1.8 billion and \$2.6 billion, respectively, related to customer deposits. We expect \$1.2 billion of our deferred revenue related to customer deposits as of March 31, 2023 to be realized in less than one year. Timing of product delivery, manufacturing, and receipt of marketing approval for the latest variant-targeted COVID-19 vaccines will determine the period in which product sales are recognized.

4. Other Revenue

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

	Three Months Ended March 31,	
	2023	2022
Grant revenue	\$ 24	\$ 126
Collaboration revenue	10	15
Total other revenue	<u>\$ 34</u>	<u>\$ 141</u>

Grant Revenue

In September 2020, we entered into an agreement with the Defense Advanced Research Projects Agency (DARPA) for an award of up to \$56 million to fund development of a mobile manufacturing prototype leveraging our existing manufacturing technology that is capable of rapidly producing vaccines and therapeutics. As of March 31, 2023, the committed funding, net of revenue earned was \$3 million. An additional \$24 million of funding will be available if DARPA exercises additional contract options.

In April 2020, we entered into an agreement with the Biomedical Advanced Research and Development Authority (BARDA), a division of the Office of the Assistant Secretary for Preparedness and Response within the U.S. Department of Health and Human Services (HHS), for an award of up to \$483 million to accelerate development of mRNA-1273. The agreement was amended subsequently in 2020, 2021 and 2022 to provide for additional commitments to support various late-stage clinical development efforts of mRNA-1273, including a 30,000 participant Phase 3 study, pediatric clinical trials, adolescent clinical trials and pharmacovigilance studies. The maximum award from BARDA, inclusive of the 2020, 2021 and 2022 amendments, was approximately \$1.7 billion. All contract options have been exercised. As of March 31, 2023, the remaining available funding, net of revenue earned was \$117 million.

In January 2016, we entered a global health project framework agreement with the Bill and Melinda Gates Foundation (Gates Foundation) to advance mRNA development projects for various infectious diseases, including human immunodeficiency virus (HIV). As of March 31, 2023, the available funding, net of revenue earned was \$6 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 March 31,	
	2023	2022
BARDA	\$ 20	\$ 122
Other grant revenue	4	4
Total grant revenue	<u>\$ 24</u>	<u>\$ 126</u>

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 March 31, 2023 and December 31, 2022, we had collaboration agreements with Merck & Co., Inc (Merck), Vertex Pharmaceuticals Incorporated and Vertex Pharmaceuticals (Europe) Limited (together, Vertex), 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):

Collaboration Revenue by Strategic Collaborator:	Three Months Ended March 31,	
	2023	2022
Merck	\$ —	\$ 10
Vertex	10	4
Other	—	1
Total collaboration revenue	<u>\$ 10</u>	<u>\$ 15</u>

5. Collaboration Agreements

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.

In addition to the collaboration agreement mentioned above, we have other collaborative and licensing arrangements that we do not consider to be individually significant to our business at this time. Pursuant to these agreements, we may be required to make upfront payments and payments upon achievement of various development, regulatory and commercial milestones, which in the aggregate could be significant. Future milestone payments, if any, will be reflected in our consolidated financial statements when the corresponding events 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 at March 31, 2023 and December 31, 2022 (in millions):

March 31, 2023							
	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value	Cash and Cash Equivalents	Current Marketable Securities	Non-Current Marketable Securities
Cash and cash equivalents	\$ 3,441	\$ —	\$ —	\$ 3,441	\$ 3,441	\$ —	\$ —
Available-for-sale:							
Certificates of deposit	47	—	—	47	—	47	—
U.S. treasury bills	30	—	—	30	—	30	—
U.S. treasury notes	6,958	5	(156)	6,807	—	3,864	2,943
Corporate debt securities	6,074	2	(184)	5,892	—	1,533	4,359
Government debt securities	156	—	(8)	148	—	8	140
Total	<u>\$ 16,706</u>	<u>\$ 7</u>	<u>\$ (348)</u>	<u>\$ 16,365</u>	<u>\$ 3,441</u>	<u>\$ 5,482</u>	<u>\$ 7,442</u>
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	<u>\$ 18,684</u>	<u>\$ —</u>	<u>\$ (464)</u>	<u>\$ 18,220</u>	<u>\$ 3,205</u>	<u>\$ 6,697</u>	<u>\$ 8,318</u>

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

March 31, 2023		
	Amortized Cost	Estimated Fair Value
Due in one year or less	\$ 5,575	\$ 5,482
Due after one year through five years	7,690	7,442
Total	<u>\$ 13,265</u>	<u>\$ 12,924</u>
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	<u>\$ 15,479</u>	<u>\$ 15,015</u>

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

Factors considered include whether a decline in fair value below the amortized cost basis is due to credit-related factors or non-credit-related factors, the financial condition and near-term prospects of the issuer, and our intent and ability to hold the investment to allow for an anticipated recovery in fair value. Any impairment that is not credit related is recognized in other comprehensive loss, net of applicable taxes. A credit-related impairment is recognized as an allowance on the balance sheet with a corresponding adjustment to earnings. We did not recognize any impairment charges related to available-for-sale securities for the three months ended March 31, 2023 and 2022. We did not record any credit-related allowance to available-for-sale securities as of March 31, 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 at March 31, 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 March 31, 2023:						
U.S. treasury bills	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —
U.S. treasury notes	(25)	1,783	(131)	4,063	(156)	5,846
Corporate debt securities	(33)	1,593	(151)	3,537	(184)	5,130
Government debt securities	(1)	38	(7)	102	(8)	140
Total	<u>\$ (59)</u>	<u>\$ 3,414</u>	<u>\$ (289)</u>	<u>\$ 7,702</u>	<u>\$ (348)</u>	<u>\$ 11,116</u>
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	<u>\$ (241)</u>	<u>\$ 7,635</u>	<u>\$ (223)</u>	<u>\$ 5,524</u>	<u>\$ (464)</u>	<u>\$ 13,159</u>

At March 31, 2023 and December 31, 2022, we held 516 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 March 31, 2023 and December 31, 2022 (in millions):

	Fair value at March 31, 2023	Fair Value Measurement Using	
		Level 1	Level 2
Assets:			
Money market funds	\$ 3,067	\$ 3,067	\$ —
Certificates of deposit	47	—	47
U.S. treasury bills	30	—	30
U.S. treasury notes	6,807	—	6,807
Corporate debt securities	6,024	—	6,024
Government debt securities	148	—	148
Equity investments ⁽¹⁾	41	41	—
Derivative instruments (Note 8)	7	—	7
Total	\$ 16,171	\$ 3,108	\$ 13,063
Liabilities:			
Derivative instruments (Note 8)	\$ 11	\$ —	\$ 11

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

As of March 31, 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 March 31, 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 March 31, 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):

	March 31, 2023		
	Notional Amount	Fair Value	
		Asset ⁽¹⁾	Liability ⁽²⁾
Derivatives not designated as hedging instruments:			
Foreign currency forward contracts	1,367	7	11
Total derivatives	\$ 1,367	\$ 7	\$ 11

	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 for the three months ended March 31, 2023 and 2022 were as follows (in millions):

	Three Months Ended March 31,	
	2023	2022
Derivatives in cash flow hedging relationships:		
Foreign currency forward contracts	\$ —	\$ 25

The effect of our foreign currency derivatives in our condensed consolidated statements of operations for the three months ended March 31, 2023 and 2022 was as follows (in millions):

	Statement of Income Classification	Three Months Ended March 31,	
		2023	2022
Derivatives in cash flow hedging relationships:			
Foreign currency forward contracts			
Net (loss) gain reclassified from AOCI into income	Product sales	\$ (8)	\$ 14
Derivatives not designated as hedging instruments:			
Foreign currency forward contracts			
Net realized and unrealized gain	Other expense, net	\$ 16	\$ 28

9. Inventory

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

	March 31, 2023	December 31, 2022
Raw materials	\$ 475	\$ 575
Work in progress	193	205
Finished goods	64	169
Total inventory	<u>\$ 732</u>	<u>\$ 949</u>
Inventory, non-current ⁽¹⁾	\$ 874	\$ 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 months ended March 31, 2023 and 2022, inventory write-downs were \$148 million and \$189 million, respectively. For the three months ended March 31, 2023 and 2022, losses on firm purchase commitments were \$66 million and \$159 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 vaccines and a decline in customer demand, primarily from lower-income countries, as the COVID-19 vaccine market continues to shift to an endemic seasonal market in 2023. As of March 31, 2023 and December 31, 2022, the accrued liability for losses on firm future purchase commitments in our condensed consolidated balance sheets was \$220 million and \$268 million, respectively.

As of March 31, 2023, we had inventory on hand of \$1.6 billion. 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 products is nine months.

10. Property, Plant and Equipment, Net

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

	March 31, 2023	December 31, 2022
Land	\$ 11	\$ 11
Manufacturing and laboratory equipment	312	284
Leasehold improvements	471	460
Furniture, fixtures and other	23	21
Computer equipment and software	46	38
Construction in progress	370	281
Right-of-use asset, financing (Note 12)	1,521	1,581
Total	2,754	2,676
Less: Accumulated depreciation	(736)	(658)
Property and equipment, net	<u>\$ 2,018</u>	<u>\$ 2,018</u>

Depreciation and amortization expense for the three months ended March 31, 2023 and 2022 was \$78 million and \$79 million, respectively.

11. Other Balance Sheet Components

Prepaid Expenses and Other Current Assets

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

	March 31, 2023	December 31, 2022
Prepaid services	\$ 292	\$ 216
Down payments for materials and supplies	219	219
Value added tax receivable	201	140
Prepaid income taxes	187	187
Down payments to manufacturing vendors	184	229
Income tax receivable	96	10
Interest receivable	69	61
Tenant improvement allowance receivable	42	42
Convertible note receivable	—	36
Other current assets	64	55
Prepaid expenses and other current assets	<u>\$ 1,354</u>	<u>\$ 1,195</u>

Other Non-Current Assets

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

	March 31, 2023	December 31, 2022
Inventory, non-current ⁽¹⁾	\$ 874	\$ 910
Equity investments	83	42
Finite-lived intangible asset (Note 6)	48	—
Goodwill (Note 6)	52	—
Restricted cash	20	12
Other	87	24
Other non-current assets	<u>\$ 1,164</u>	<u>\$ 988</u>

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

Accrued Liabilities

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

	March 31, 2023	December 31, 2022
Manufacturing	\$ 397	\$ 400
Other external goods and services	313	264
Clinical trials	263	319
Loss on future firm purchase commitments ⁽¹⁾	220	268
Development operations	98	88
Royalties	86	203
Compensation-related	73	190
Raw materials	58	316
Property and equipment	58	5
Other	47	48
Accrued liabilities	<u>\$ 1,613</u>	<u>\$ 2,101</u>

⁽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 March 31, 2023 and December 31, 2022 consisted of the following (in millions):

	March 31, 2023	December 31, 2022
Lease liabilities - financing (Note 12)	\$ 153	\$ 161
Lease liabilities - operating (Note 12)	28	35
Other	31	53
Other current liabilities	<u>\$ 212</u>	<u>\$ 249</u>

Deferred Revenue

The following table summarizes the activities in deferred revenue for the three months ended March 31, 2023 (in millions):

	December 31, 2022	Additions	Deductions	March 31, 2023
Product sales	\$ 2,626	\$ 45	\$ (855)	\$ 1,816
Grant revenue	4	—	(1)	3
Collaboration revenue	81	2	(10)	73
Total deferred revenue	<u>\$ 2,711</u>	<u>\$ 47</u>	<u>\$ (866)</u>	<u>\$ 1,892</u>

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.

We are also investing in a new Moderna Science Center (MSC) in Cambridge, Massachusetts to create a purpose-built space to support our next chapter of discovery (see [Note 13](#)). As of March 31, 2023, we did not gain control of the underlying leased asset at the MSC, and therefore, we did not recognize 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 lease agreements to allow for an option for early termination of the leases, either in part or full. Notification of the intent to exercise the option must be provided by August 2023. We have not elected to exercise this option.

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 expire from 2023 through 2026. As of March 31, 2023 and December 31, 2022, we had lease liabilities of \$410 million and \$440 million, respectively, related to the embedded leases. As of March 31, 2023 and December 31, 2022, we had right-of-use assets of \$587 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 March 31, 2023 and December 31, 2022 were as follows (in millions):

	March 31, 2023	December 31, 2022
Assets:		
Right-of-use assets, operating, net ^{(1) (2)}	\$ 117	\$ 121
Right-of-use assets, financing, net ^{(3) (4)}	1,033	1,150
Total	<u>\$ 1,150</u>	<u>\$ 1,271</u>
Liabilities:		
Current:		
Operating lease liabilities ⁽⁵⁾	\$ 28	\$ 35
Financing lease liabilities ⁽⁵⁾	153	161
Total current lease liabilities	<u>181</u>	<u>196</u>
Non-current:		
Operating lease liabilities, non-current	96	92
Financing lease liabilities, non-current	831	912
Total non-current lease liabilities	<u>\$ 927</u>	<u>\$ 1,004</u>
Total	<u>\$ 1,108</u>	<u>\$ 1,200</u>

⁽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 March 31, 2023, were as follows (in millions):

Fiscal Year	Operating Leases	Financing Leases ⁽¹⁾
2023 (remainder of the year)	\$ 31	\$ 154
2024	23	128
2025	20	128
2026	18	107
2027	19	23
Thereafter	48	1,097
Total minimum lease payments	159	1,637
Less amounts representing interest or imputed interest	(35)	(653)
Present value of lease liabilities	\$ 124	\$ 984

⁽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 months ended March 31, 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 March 31, 2023, we had \$1.9 billion of non-cancelable purchase commitments related to raw materials and manufacturing agreements, which are expected to be paid through 2026. As of March 31, 2023, \$220 million of the purchase commitments related to raw materials was recorded as an accrued liability for loss on future firm purchase commitments. As of March 31, 2023, we had \$192 million of non-cancelable purchase commitments related to clinical services and other goods and services which are expected to be paid through 2028. These amounts represent our minimum contractual obligations, including termination fees.

In addition to purchase commitments, we have agreements with third parties for various goods and services, including services related to clinical operations and support and contract manufacturing, for which we are not contractually able to terminate for convenience and avoid any and all future obligations to the vendors. Certain agreements provide for termination rights subject to termination fees or wind down costs. Under such agreements, we are contractually obligated to make certain payments to vendors, mainly, to reimburse them for their unrecoverable outlays incurred prior to cancellation. At March 31, 2023, we had cancelable open purchase orders of \$2.9 billion in total under such agreements for our significant clinical operations and support and contract manufacturing. These amounts represent only our estimate of those items for which we had a contractual commitment to pay at March 31, 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

In 2017, we entered into sublicense agreements with Cellscript, LLC and its affiliate, mRNA RiboTherapeutics, Inc., to sublicense certain patent rights. Pursuant to each agreement, we are required to pay certain license fees, annual maintenance fees, minimum royalties on future net sales and milestone payments contingent on achievement of certain development, regulatory and commercial milestones for specified products, on a product-by-product basis. Commercial milestone payments and royalties based on annual net sales of licensed products for therapeutic and prophylactic products are accounted for as additional expense of the related product sales in the period in which the corresponding sales occur.

In December 2022, we entered into a non-exclusive patent license agreement with the National Institute of Allergy and Infectious Diseases (NIAID), an Institute or Center of the National Institutes of Health (NIH) to license certain patent rights concerning stabilizing prefusion coronavirus spike proteins and the resulting stabilized proteins for use in COVID-19 vaccine products. Pursuant to the agreement, we have agreed to pay low single-digit royalties on future net sales, a minimum annual royalty payment, and certain contingent development, regulatory and commercial milestone payments on a licensed product-by-licensed product basis.

For the three months ended March 31, 2023 and 2022, we recognized \$86 million and \$207 million, respectively, of royalty expenses associated with our product sales, which was 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 March 31, 2023.

Moderna Science Center

In September 2021, we announced an investment in the development of the MSC in Cambridge, Massachusetts. The MSC is expected to integrate scientific and non-scientific spaces, including our principal executive offices, and is built to support our growth as we continue to advance our pipeline of mRNA medicines. In relation to the investment, we entered into a lease agreement for approximately 462,000 square feet and are currently undergoing an approximately two-year building project. Following completion of the building project, the lease term is 15 years, subject to our right to extend the lease for up to two additional seven-year terms. Pursuant to this lease agreement, we are committed to approximately \$1.0 billion non-cancellable rent payments for the initial lease term. We expect to begin a phased move-in process in the fourth quarter of 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 months ended March 31, 2023 and 2022 as follows (in millions):

	Three Months Ended March 31,	
	2023	2022
Options	\$ 36	\$ 25
Restricted Common Stock (RSUs) and Performance Stock Units (PSUs)	37	17
Employee Stock Purchase Plan (ESPP)	2	2
Total	<u>\$ 75</u>	<u>\$ 44</u>
Cost of sales	\$ 5	\$ 8
Research and development	42	20
Selling, general and administrative	28	16
Total	<u>\$ 75</u>	<u>\$ 44</u>

As of March 31, 2023, there was \$789 million of total unrecognized compensation cost related to unvested stock-based compensation with respect to options, RSUs and PSUs granted. That cost is expected to be recognized over a weighted-average period of 3.2 years at March 31, 2023.

Share Repurchase Programs

As of March 31, 2023, \$2.3 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 three months ended March 31, 2023 (in millions, except per share data):

	Three Months Ended March 31,	
	2023	
Number of shares repurchased		4
Average price per share ⁽¹⁾	\$	145.31
Aggregate purchase price	\$	526
Remaining authorization at end of period	\$	2,291

⁽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 March 31,	
	2023	2022
(Loss) income before income taxes	\$ (305)	\$ 4,229
(Benefit from) provision for income taxes	\$ (384)	\$ 572
Effective tax rate	125.9 %	13.5 %

The effective tax rate for the three months ended March 31, 2023 was higher than the U.S. statutory tax rate, primarily due to international provisions of the Tax Cuts and Jobs Act and research and development credits. The effective tax rate includes a discrete benefit from stock-based compensation, a state deferred tax rate change, and a valuation allowance release on a portion of its state tax attributes. The decrease in income tax expense was primarily due to a decrease in income.

We file U.S. federal income tax returns and income tax returns in various state, local and foreign jurisdictions. We are not currently subject to any tax assessment from an income tax examination in the United States or any other major taxing jurisdiction.

On a periodic basis, we reassess any valuation allowances that we maintain on our deferred tax assets, and weigh positive and negative evidence to assess the recoverability of the deferred tax assets. As of the year ended December 31, 2022, we maintained a state valuation allowance of \$155 million. For the three months ended March 31, 2023, we reassessed the state valuation allowance noting the increase in positive evidence, including investments in research and development and future profitability with increased market expansions in the United States. After assessing both the positive evidence and negative evidence, we determined it was more likely than not that we will realize a portion of the state tax attributes and released \$44 million. We will continue to maintain a valuation allowance on certain state tax attributes that we expect to expire prior to utilization.

The President signed into law the Inflation Reduction Act (the “IRA”) on August 16, 2022. The Act includes a new 15% corporate minimum tax and a 1% excise tax on the value of corporate stock repurchase, net of new share issuances, after December 31, 2022. We currently are not expecting these provisions to have a material adverse impact to our financial statements. We expect additional guidance and regulations to be issued in future periods and will continue to assess its potential impact on our business and results of operations as further information becomes available.

16. Earnings per Share

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

Basic and diluted EPS for the three months ended March 31, 2023 and 2022 were calculated as follows (in millions, except per share data):

	Three Months Ended March 31,	
	2023	2022
<i>Numerator:</i>		
Net income	\$ 79	\$ 3,657
<i>Denominator:</i>		
Basic weighted-average common shares outstanding	386	402
Effect of dilutive securities	19	24
Diluted weighted-average common shares outstanding	405	426
Basic EPS	\$ 0.20	\$ 9.09
Diluted EPS	\$ 0.19	\$ 8.58
Anti-dilutive potential common shares excluded from the EPS computation above	5	2

17. Subsequent Events

On April 27, 2023, we acquired a real estate property in Marlborough, Massachusetts for \$91 million, where we plan to build a GMP manufacturing facility. This property includes approximately 24 acres of land and a 140,000 square foot shell that we plan to expand to 200,000 square feet.

Subsequent to March 31, 2023, we have entered into additional binding purchase commitments with third-party contractual manufacturing organizations for fill and finish services under newly executed and amended agreements. We are currently committed to minimum non-cancelable purchase obligations of \$702 million related to these agreements, which are expected to be paid through 2027.

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 pioneering 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 seven 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 45 development candidates across our 47 development programs, of which 36 are in clinical studies currently.

Our COVID-19 vaccines are marketed, where approved, under the name Spikevax. To date, we have developed three versions of our COVID-19 vaccine: (1) our original vaccine targeting the SARS-CoV-2 ancestral strain (mRNA-1273), (2) our bivalent BA.1 Omicron-targeting vaccine (mRNA-1273.214) and (3) our bivalent BA.4/BA.5 Omicron-targeting vaccine (mRNA-1273.222). We currently sell mRNA-1232.214 and mRNA-1273.222 commercially.

Business Highlights

In January 2023, we acquired OriCiro Genomics K.K., a Japan-based, privately held biotech company primarily focused on cell-free DNA synthesis and amplification technologies, for \$86 million. 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 will allow us to further accelerate our research and development efforts.

In February 2023, we entered into a strategic collaboration and license agreement with Life Edit Therapeutics Inc. (Life Edit) to collaborate on the discovery and development of *in vivo* mRNA gene editing therapies. The partnership will combine Life Edit's suite of proprietary gene editing technologies, including base editing, with our mRNA platform to advance *in vivo* gene editing therapies against a select set of therapeutic targets.

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.

In March 2023, we and the Government of the Republic of Kenya finalized an agreement to establish an mRNA manufacturing facility in Kenya. In partnership with the Kenyan Government, we plan to build a state-of-the-art mRNA facility in Kenya to produce up to 500 million doses of vaccines each year. We expect the new facility to enable drug substance and drug product manufacturing for Kenya and the African continent. In addition, this facility is expected to have surge capacity to rapidly scale and respond to public health emergencies on the continent and around the world. With this agreement, we have commitments to establish mRNA manufacturing facilities in Kenya, Canada, Australia and the United Kingdom, in addition to our manufacturing facilities in the United States.

For the first quarter of 2023, we recognized product sales of \$1.8 billion from sales of our COVID-19 vaccines, compared to \$5.9 billion in the first quarter of 2022. Diluted earnings per share was \$0.19 for the first quarter of 2023, compared to diluted earnings per share of \$8.58 in the first quarter of 2022.

Recent Program Developments

COVID-19 vaccines (mRNA-1273/Spikevax®, mRNA-1273.214, mRNA-1273.222 and mRNA-1283)

- We expect to continue to meet the evolving needs of the endemic COVID-19 market including through multivalent boosters and by advancing next-generation vaccines. We perform continuous epidemiological monitoring and risk assessment of SARS-CoV-2 variants to select which variant-targeted vaccines to evaluate in preclinical and clinical studies. Our monitoring activities allow for expedited delivery of new vaccines in the event that regulatory agencies request specific vaccine composition updates to address public health needs. Our mRNA platform can produce variant-matched vaccines on an accelerated time horizon, consistent with recent U.S. Food and Drug Administration (FDA) comments on the timing of potential strain selection for the fall booster season.
- Our next-generation, refrigerator-stable COVID-19 vaccine, mRNA-1283, has demonstrated encouraging results in multiple clinical studies and recently began dosing participants in a Phase 3 trial.

Seasonal influenza (flu) vaccines (mRNA-1010)

- Our first seasonal influenza vaccine candidate, mRNA-1010, is currently being evaluated in two Phase 3 trials (the P302 and P303 trials). The first Phase 3 trial (P301) of mRNA-1010 was conducted in the Southern Hemisphere to evaluate safety and non-inferior immunogenicity compared to a licensed flu vaccine. The previously announced interim results from the P301 trial indicated that mRNA-1010 demonstrated superiority in geometric mean titers (GMT) for A/H3N2 and non-inferiority in GMT for A/H1N1. mRNA-1010 did not meet non-inferiority for the influenza B/Victoria- and B/Yamagata-lineage strains. mRNA-1010 demonstrated an acceptable safety and tolerability profile in the trial, and the independent Data and Safety Monitoring Board (DSMB) for P301 did not identify any safety concerns.
- The second Phase 3 trial (P302) for mRNA-1010 is being conducted in the Northern Hemisphere to evaluate safety and non-inferior efficacy compared to a licensed flu vaccine. The independent DSMB has completed the first interim analysis of efficacy and informed the us that mRNA-1010 did not meet the statistical threshold necessary to declare early success and recommended that the trial continue with efficacy follow-up towards the next analysis. The DSMB did not identify any safety concerns. Blinded follow-up for safety and efficacy is ongoing in this trial. A preliminary analysis of immunogenicity from a subset of participants in the P302 trial has also been completed. In this analysis, mRNA-1010 demonstrated geometric mean titer ratios consistent with superiority against both influenza A strains (A/H1N1, A/H3N2) and consistent with non-inferiority against both influenza B strains (B/Victoria, B/Yamagata) relative to the licensed comparator. The P302 study did not pre-specify success criteria for immunogenicity endpoints.
- We have developed an update to mRNA-1010 that is expected to have improved immunogenicity against influenza B strains and commenced enrollment in a confirmatory Phase 3 trial (P303) in April 2023.

Respiratory syncytial virus (RSV) vaccine (mRNA-1345)

- Our vaccine candidate against RSV, mRNA-1345, is in an ongoing Phase 2/3, randomized, observer-blind, placebo-controlled case-driven trial (ConquerRSV) in adults aged 60 years and older. In this study, 35,541 participants from 22 countries were randomized 1:1 to receive one dose of mRNA-1345 or placebo. Following review by an independent DSMB, the primary efficacy endpoints have been met, including vaccine efficacy (VE) of 83.7% (95.88% CI: 66.1%, 92.2%; p<0.0001) against RSV-associated lower respiratory tract disease (RSV-LRTD) as defined by two or more symptoms. Vaccine efficacy was maintained in participants over 70 years of age and participants with comorbidities. mRNA-1345 was well tolerated; solicited adverse reactions were mostly grade 1 or grade 2 in severity. No cases of Guillain-Barre Syndrome (GBS) have been reported.
- In January 2023, based on the positive topline data from the pivotal Phase 3 efficacy trial, the FDA granted mRNA-1345 Breakthrough Therapy Designation for the prevention of RSV-LRTD in adults 60 years or older.
- Pediatric RSV mRNA-1345 is ongoing in a Phase 1 study of children five to less than 24 months old.

Respiratory combination vaccines (mRNA-1073, mRNA-1083, mRNA-1230, mRNA-1045 and mRNA-1365)

- We are evaluating several respiratory combination vaccines in the clinic. Phase 1 studies have completed the enrollment and started for our mRNA-1073 combination vaccine (COVID+Flu), mRNA-1230 combination vaccine (COVID+Flu+RSV), and mRNA-1045 combination vaccine (Flu+RSV). mRNA-1073 encodes for the COVID-19 spike protein and the flu HA

glycoproteins. mRNA-1230 encodes for the COVID-19 spike protein, the flu HA glycoproteins and the RSV prefusion F glycoprotein. mRNA-1045 encodes for RSV prefusion F glycoprotein and the flu HA glycoprotein.

- We are conducting a Phase 1 trial of mRNA-1365, our pediatric RSV and human metapneumovirus (hMPV) combination vaccine, which has dosed its first participants. mRNA-1365 encodes for the RSV prefusion F glycoprotein and the hMPV F protein.
- We are conducting a Phase 1 trial of mRNA-1083, our next-generation COVID+Flu vaccine, which has dosed its first participants.
- We intend to launch our first combination vaccines by 2025, subject to successful completion of clinical trials and receipt of regulatory approvals. Our strategy is to regularly update these combination vaccines with improved next-generation vaccine candidates as appropriate.

CMV vaccine (mRNA-1647)

- Our vaccine candidate against CMV, mRNA-1647, is in a pivotal Phase 3 trial (CMVVictory) 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 trial is more than 50% enrolled, with an expectation to enroll up to 7,300 women from approximately 150 clinical sites. The primary efficacy analysis will be triggered based on the accrual of seroconversion cases.
- Since the majority of cases of disabling congenital CMV infection could be prevented by a universal vaccination policy, we are testing mRNA-1647 in adolescents. A Phase 1/2 open-label and placebo-controlled study of mRNA-1647 to evaluate safety and immunogenicity in male and female participants ages 9 to 15 years has begun enrollment.

Human immunodeficiency virus (HIV) vaccine (mRNA-1644 and mRNA-1574)

- In collaboration with the International AIDS Vaccine Initiative (IAVI) and the Bill & Melinda Gates Foundation, mRNA-1644 is testing a novel HIV vaccine strategy in humans as delivered by mRNA to elicit broadly neutralizing HIV-1 antibodies (bnAbs) through sequential vaccination of novel prime and boost antigens that induce specific B-cell responses. In collaboration with IAVI and the HIV Vaccine Trials Network, mRNA-1574 is testing multiple native-like HIV trimer mRNAs in humans to improve our understanding of how to make stable and immunogenic native-HIV trimers.
- We are advancing three Phase 1 clinical trials of HIV vaccines with partners (mRNA-1644/IAVI G002, mRNA-1644/IAVI G003, mRNA-1574/NIAID) to expand on proof-of-concept data and evaluate the potential of mRNA technology to successfully deliver immunogens. The goal of these trials is to determine whether this approach is safe and immunogenic, meaning that the immunogens elicit the right type of broadly neutralizing HIV-1 antibodies (bnAbs). The trials are the beginning of an iterative research process with the expectation for multiple Phase 1 trials to converge on a potentially protective vaccine that merits advancement to Phase 2. These trials are conducted in parallel to accelerate the advancement of immunogens into vaccine candidates.

Individualized neoantigen therapy (Personalized cancer vaccine) (mRNA-4157)

- We are developing mRNA-4157, an investigational mRNA individualized neoantigen therapy (INT), which we previously referred to as our personalized cancer vaccine, in collaboration with Merck. In December 2022, we announced that the randomized Phase 2 trial of mRNA-4157 had met its primary endpoint. The open-label Phase 2 study is investigating a 1 mg dose of mRNA-4157 in combination with Merck's pembrolizumab (KEYTRUDA®), compared to pembrolizumab alone, for the adjuvant treatment of high-risk resected melanoma. The study showed that mRNA-4157 in combination with KEYTRUDA reduced the risk of recurrence or death by 44% (HR=0.56 [95% CI, 0.31-1.08]; one-sided p value=0.0266) compared with KEYTRUDA alone. The results are the first demonstration of efficacy for an investigational mRNA cancer treatment in a randomized clinical trial in melanoma. Adverse events observed were consistent with those previously reported in a Phase 1 clinical trial, which showed mRNA-4157 to be well-tolerated at all dose levels. We and Merck plan to discuss results with regulatory authorities and to initiate a Phase 3 study in adjuvant melanoma in 2023 and rapidly expand to additional tumor types, including non-small cell lung cancer (NSCLC).
- In February 2023, mRNA-4157 received a Breakthrough Therapy Designation from the FDA. In April 2023, mRNA-4157 received a Priority Medicines (PRIME) scheme designation by the European Medicines Agency (EMA) for the adjuvant treatment of patients with high-risk stage III/IV melanoma following complete resection. The FDA granted Breakthrough

Therapy Designation and the EMA granted PRIME scheme designation based on positive data from the Phase 2b KEYNOTE-942/mRNA-4157-P201 trial.

Cystic Fibrosis (CF) (VX-522)

- CF is a rare genetic disease, which is progressive from birth and leads to multi-organ damage and early death due to lung dysfunction. It is caused by the mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene which results in the loss of CFTR chloride ion channel function. This decreased function of CFTR at the cell surface leads to thick, sticky mucus in multiple organ systems but most pathologically the lungs. Our program is designed to treat the underlying cause of CF by enabling cells in the lungs to produce functional CFTR protein for the treatment of the 10% of patients who do not produce any modulator-responsive CFTR protein. This would be the first demonstration of a nebulized mRNA therapy produced by Moderna. We are collaborating with Vertex on our CF candidate, VX-522.
- In January 2023, Vertex announced that it has initiated a Phase 1, single ascending dose clinical trial in CF patients who cannot benefit from CFTR modulators, and the FDA has granted VX-522 Fast Track designation. The trial is active and enrolling patients. Vertex expects to complete the single ascending dose study and to initiate the multiple ascending dose study.

Emerging Programs

- In April 2023, we announced new development candidates against Lyme disease, representing our first bacterial vaccine candidates, and norovirus, constituting our first vaccine candidates against an enteric virus. To address Lyme's biological complexity, we are advancing a seven-valent approach with two Lyme disease vaccine candidates that will be developed in parallel. mRNA-1982 is designed to elicit antibodies specific for *Borrelia burgdorferi*, which causes almost all Lyme disease in the U.S. mRNA-1975 is designed to elicit antibodies specific for the four major *Borrelia* species causing disease in the U.S. and Europe.
- A broadly effective norovirus vaccine will require a multivalent vaccine design, given the wide genetic and antigenic diversity of noroviruses. We are developing pentavalent (mRNA-1405) and trivalent (mRNA-1403) candidates for norovirus.

Our Pipeline

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

Modality	Program	ID #	Preclinical development	Phase 1	Phase 2	Phase 3	Commercial	Moderna rights
	COVID-19 vaccine	Spikevax®/mRNA-1273.214/.222						Worldwide
		mRNA-1283	Next generation (2-5 °C)					Worldwide
	Flu vaccine	mRNA-1010						Worldwide
		mRNA-1020						Worldwide
		mRNA-1030						Worldwide
		mRNA-1011						Worldwide
		mRNA-1012						Worldwide
	Older adults RSV vaccine	mRNA-1345						Worldwide
	COVID + Flu vaccine	mRNA-1073						Worldwide
	COVID + Flu vaccine	mRNA-1083						Worldwide
	COVID + Flu + RSV vaccine	mRNA-1230						Worldwide
Flu + RSV vaccine	mRNA-1045						Worldwide	
Endemic HCoV	mRNA-1287						Worldwide	
Pandemic Flu	mRNA-1018						Worldwide	
Respiratory vaccines: adolescents & pediatrics	COVID-19 vaccine (adolescents)	mRNA-1273.214/.222	TeenCOVE					Worldwide
	COVID-19 vaccine (pediatrics)	mRNA-1273.214/.222	KidCOVE					Worldwide
	Pediatric RSV vaccine	mRNA-1345						Worldwide
	Pediatric hMPV + PIV3 vaccine	mRNA-1653						Worldwide
Latent vaccines	Pediatric RSV + hMPV vaccine	mRNA-1365						Worldwide
	CMV vaccine	mRNA-1647						Worldwide
	EBV vaccine (to prevent IM)	mRNA-1189						Worldwide
	EBV vaccine (to prevent EBV sequelae)	mRNA-1195						Worldwide
	HSV vaccine	mRNA-1608						Worldwide
	VZV vaccine	mRNA-1468						Worldwide
	HIV vaccines	mRNA-1644						Worldwide IAVI funded
		mRNA-1574						Worldwide IAVI/others funded
Enteric	Norovirus vaccines	mRNA-1403						Worldwide
		mRNA-1405						Worldwide
Bacterial	Lyme vaccines	mRNA-1975						Worldwide
		mRNA-1982						Worldwide
Public health vaccines	Zika vaccine	mRNA-1893						Worldwide BARDA funded
	Nipah vaccine	mRNA-1215						Worldwide NIH funded
	Systemic secreted & cell surface therapeutics	Relaxin Heart failure	mRNA-0184					Worldwide
		PD-L1 Autoimmune hepatitis	mRNA-6981					Worldwide
	Cancer vaccines & therapeutics	Individualized neoantigen therapy (INT)	mRNA-4157					50-50 global profit sharing with Merck
		KRAS vaccine	mRNA-5671					Worldwide
	Checkpoint vaccine		mRNA-4359					Worldwide
								Worldwide
	Intratumoral immuno-oncology	OX40L/IL-23/IL-36γ (Triplet) Solid tumors/lymphoma	mRNA-2752					Worldwide
		IL-12 Solid tumors	MEDI1191					Worldwide
	Localized regenerative therapeutics	VEGF-A Myocardial ischemia	AZD8601					Worldwide
		Propionic acidemia (PA)	mRNA-3927					Worldwide
	Methylmalonic acidemia (MMA)		mRNA-3705					Worldwide
								Worldwide
	Systemic intracellular therapeutics	Glycogen storage disease type 1a (GSD1a)	mRNA-3745					Worldwide
		Ornithine transcarbamylase deficiency (OTC)	mRNA-3139					Worldwide
	Phenylketonuria (PKU)		mRNA-3283					Worldwide
								Worldwide
	Crigler-Najjar syndrome type 1 (CN-1)		mRNA-3351					Provided to ILCM free of charge
								Vertex to pay milestones and royalties
	Cystic fibrosis (CF)		VX-522					

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-12, interleukin 12; 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; PIV3, human parainfluenza virus 3; RSV, respiratory syncytial virus; VEGF-A, vascular endothelial growth factor A; VZV, varicella-zoster virus.

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

- **Infectious disease vaccines:** Our infectious vaccines modality currently includes 32 development programs, 25 of which have entered into clinical trials. Our original COVID-19 vaccine (Spikevax/mRNA-1273) has been approved or authorized for individuals 18 years and older in more than 70 countries and for adolescent and pediatric populations in more than 50 countries. Our bivalent BA.1 Omicron-targeting vaccine (mRNA-1273.214) and BA.4/BA.5 Omicron-targeting vaccine (mRNA-1273.222) are sold commercially in various countries. We have ongoing Phase 3 studies for our flu vaccine (mRNA-1010), RSV vaccine in older adults (mRNA-1345), next-generation COVID-19 vaccine (mRNA-1283) and CMV vaccine (mRNA-1647). We have ongoing Phase 2 trials for flu vaccines (mRNA-1020, mRNA-1030, mRNA-1011 and mRNA-1012) and our Zika vaccine (mRNA-1893). We have ongoing Phase 1 trials for our RSV vaccine in pediatrics (mRNA-1345), combined COVID and flu vaccine (mRNA-1073), next-generation combined COVID and flu vaccine (mRNA-1083), combined COVID, flu and RSV vaccine (mRNA-1230), combined flu and RSV vaccine (mRNA-1045), hMPV/PIV3 vaccine (mRNA-1653), pediatric RSV and hMPV vaccine (mRNA-1365), EBV vaccine to prevent infectious mononucleosis (mRNA-1189), EBV vaccine to address EBV sequelae (mRNA-1195), VZV vaccine (mRNA-1468), HIV vaccines (mRNA-1644 and mRNA-1574) and Nipah vaccine (mRNA-1215). Our seven preclinical programs within our infectious disease vaccines modality are for an endemic HCoV vaccine (mRNA-1287), pandemic flu vaccine (mRNA-1018), HSV vaccine (mRNA-1608), norovirus vaccines (mRNA-1403 and mRNA-1405) and Lyme vaccines (mRNA-1975 and mRNA-1982).
- **Systemic secreted and cell surface therapeutics:** We have two systemic secreted and cell surface therapeutics development candidates in our pipeline. Our secreted programs include Relaxin (mRNA-0184) for cardiac disorders, currently in a Phase 1 trial, and PD-L1 (mRNA-6981) for autoimmune hepatitis, currently in preclinical development.
- **Cancer vaccines and therapeutics:** We are currently developing three programs within our cancer vaccines and therapeutics modality. Our individualized neoantigen therapy program (mRNA-4157) is being developed in collaboration with Merck and met its primary endpoint in a randomized Phase 2 trial. We and Merck plan to discuss results with regulatory authorities and to initiate a Phase 3 study in adjuvant melanoma in 2023 and rapidly expand to additional tumor types, including non-small cell lung cancer (NSCLC). Our second program within this modality is a KRAS vaccine (mRNA-5671). We have retained all rights to our KRAS vaccine from Merck and we are evaluating next steps for the program. Our third program is our checkpoint vaccine (mRNA-4359), which is currently in a Phase 1 clinical trial.
- **Intratumoral immuno-oncology:** We have two programs in this modality. Our first program, OX40L/IL-23/IL-36 γ (Triplet) (mRNA-2752), is currently in a Phase 1 study that is designed as an open-label, multicenter study of intratumoral injections of Triplet (mRNA-2752) alone or in combination with durvalumab (anti-PD-L1). Our second program, IL-12 (MEDI1191), was developed in collaboration with AstraZeneca. In August 2022, AstraZeneca notified us that it was terminating the development of the IL-12 program (MEDI1191) and that they were returning the rights to the program to us. We are evaluating next steps for the program.
- **Localized regenerative therapeutics:** Our localized VEGF-A program, AZD8601, which was developed in collaboration with AstraZeneca, has advanced through a Phase 2 trial. After a portfolio review, AstraZeneca has returned the rights to AZD8601 to us. We are evaluating next steps for the program.
- **Systemic intracellular therapeutics:** We have six systemic intracellular therapeutics development candidates in our pipeline. Our intracellular programs address propionic acidemia, or PA (mRNA-3927), methylmalonic acidemia (MMA) (mRNA-3705), glycogen storage disorder type 1a (GSD1a) (mRNA-3745), ornithine transcarbamylase deficiency (OTC) (mRNA-3139), phenylketonuria (PKU) (mRNA-3283), and Crigler-Najjar Syndrome Type 1 (CN-1) (mRNA-3351). We have an ongoing Phase 2 clinical trial for PA (mRNA-3927), and ongoing Phase 1 clinical trials for MMA (mRNA-3705) and GSD1a (mRNA-3745). OTC (mRNA-3139), PKU (mRNA-3283) and CN-1 (mRNA-3351) are currently in preclinical development. We have entered into a collaboration agreement with the Institute for Life Changing Medicines (ILCM) to license mRNA-3351 to ILCM with no upfront fees, and without any downstream payments. ILCM will be responsible for the clinical development of mRNA-3351.
- **Inhaled pulmonary therapeutics:** We have one inhaled pulmonary therapeutic development candidate in our pipeline. Our program addresses cystic fibrosis, or CF (VX-522), in collaboration partnership with Vertex Pharmaceuticals, as described above. VX-522 is currently in a Phase 1 clinical trial. Moderna has licensed worldwide commercial rights to VX-522 to Vertex.

Results of operations

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

	Three Months Ended March 31,		Change 2023 vs. 2022	
	2023	2022	\$	%
Revenue:				
Product revenue	\$ 1,828	\$ 5,925	\$ (4,097)	(69)%
Other revenue	34	141	(107)	(76)%
Total revenue	1,862	6,066	(4,204)	(69)%
Operating Expenses:				
Cost of sales	792	1,017	(225)	(22)%
Research and development	1,131	554	577	104%
Selling, general and administrative	305	268	37	14%
Total operating expenses	2,228	1,839	389	21%
(Loss) income from operations	(366)	4,227	(4,593)	(109)%
Interest income	109	15	94	627%
Other expense, net	(48)	(13)	(35)	269%
(Loss) income before income taxes	(305)	4,229	(4,534)	(107)%
(Benefit from) provision for income taxes	(384)	572	(956)	(167)%
Net income	\$ 79	\$ 3,657	\$ (3,578)	(98)%

Revenue

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

	Three Months Ended March 31,	
	2023	2022
United States	\$ 1	\$ 945
Europe	576	2,076
Rest of world ⁽¹⁾	1,251	2,904
Total	\$ 1,828	\$ 5,925

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

As of March 31, 2023, our original COVID-19 vaccine (mRNA-1273) and Omicron-targeting bivalent boosters (mRNA-1273.214 and mRNA-1273.222) were our only commercial products authorized for use.

As of March 31, 2023, we had deferred revenue of \$1.8 billion associated with customer deposits received or billable under supply agreements for delivery of our COVID-19 vaccines in 2023. We believe that the COVID-19 vaccine market continues to shift to an endemic seasonal market and our product sales will decline significantly in 2023 compared to 2022. In addition, we anticipate greater seasonality for sales, with greater demand in the fall/winter season in each hemisphere as countries seek to provide booster vaccinations to their populations.

Other than 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 Gates Foundation and from strategic alliances with Merck & Co., Inc (Merck) and Vertex Pharmaceuticals Incorporated and Vertex Pharmaceuticals (Europe) Limited (together, Vertex) to discover, develop, and commercialize potential mRNA medicines.

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

	Three Months Ended March 31,	
	2023	2022
Grant revenue	\$ 24	\$ 126
Collaboration revenue	10	15
Total other revenue	\$ 34	\$ 141

Total revenue decreased by \$4.2 billion, or 69%, for the three months ended March 31, 2023, compared to the same period in 2022, mainly due to a decrease in product sales of our COVID-19 vaccines. Product revenue decreased by \$4.1 billion, or 69%, for the three months ended March 31, 2023, compared to the same period in 2022, primarily driven by lower sales volume in 2023. Other revenue decreased by \$107 million, or 76%, for the three months ended March 31, 2023, compared to the same period in 2022, largely due to a decrease in grant revenue under our agreement with BARDA for the development of our mRNA-1273 vaccine.

Operating expenses

Cost of sales

Cost of sales for the three months ended March 31, 2023 was \$792 million, including third-party royalties of \$86 million, inventory write-downs of \$148 million, unutilized manufacturing capacity of \$135 million, and losses on firm purchase commitments and related cancellation fees of \$95 million. Cost of sales for the three months ended March 31, 2023 decreased by \$225 million, or 22%, compared to the same period in 2022. Cost of sales as a percentage of product sales for the three months ended March 31, 2023 was 43%, compared to 17% for the same period in 2022. The decrease in cost of sales in 2023 was primarily driven by lower sales volume. The increase in cost of sales as a percentage of product sales in 2023 was mainly due to the aforementioned charges, other than royalties, over lower product sales, as well as higher manufacturing cost per unit and unutilized capacity. The increased manufacturing cost per unit was largely driven by lower product sales to absorb fixed manufacturing costs, as well as a shift from multi-dose vials to single-dose presentations. The increase in unutilized manufacturing capacity was driven by lower production volume, due to increased product seasonality and a decline in product demand.

We expect our manufacturing costs to increase as we move from a pandemic market to an endemic market, characterized by greater seasonality, for our COVID-19 vaccines in 2023. We expect that this shift will cause our cost of sales for the full year of 2023 to represent a higher percentage of our product sales than the percentage experienced in 2022. Our per unit manufacturing cost in 2023 is expected to be significantly higher than the prior year; we may continue to experience significant unutilized capacity charges and inventory write-downs in 2023 (please refer to [Note 9](#) to our condensed consolidated financial statements for inventory related charges).

Research and development expenses

Research and development expenses increased by \$577 million, or 104%, for the three months ended March 31, 2023, compared to the same period in 2022. The increase was primarily attributable to increases in clinical trial expenses of \$281 million, manufacturing costs for clinical trial materials of \$108 million, personnel-related costs and stock-based compensation of \$98 million, and preclinical research expenses, including collaboration upfront fees, of \$43 million. These increases for the three month period in 2023 were largely driven by increased clinical development, particularly for our RSV, flu and CMV programs, increased headcount and our recently announced collaboration agreements with Life Edit and Generation Bio.

We expect that research and development expenses will increase in 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, our RSV, flu and CMV vaccine programs, as well as our individualized neoantigen therapy (personalized cancer vaccine) program, which currently has an ongoing multiple-arm Phase 1 trial and an ongoing randomized Phase 2 trial.

Selling, general and administrative expenses

Selling, general and administrative expenses increased by \$37 million, or 14%, for the three months ended March 31, 2023, compared to the same period in 2022. The increase was mainly due to increases in outside services of \$50 million, personnel-related costs and stock-based compensation of \$41 million, partially offset by an endowment to the Moderna Charitable Foundation (the Foundation) of \$50 million contributed in 2022. These increases for the three month period in 2023 were primarily driven by our commercialization-related activities, increased headcount and digital- and technology-related spend to support the corporate expansion.

We expect that selling, general and administrative expenses will increase in 2023, as compared to 2022, as we continue to build out our global commercial, regulatory, sales and marketing infrastructure, and continue to expand the number of programs and our business operations.

Interest income

Interest income increased by \$94 million for the three months ended March 31, 2023, compared to the same period in 2022. The increases in interest income from our investments in marketable securities for the three month period in 2023 were mainly driven by an overall higher interest rate environment.

Other expense, net

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

	Three Months Ended March 31,		Change 2023 vs. 2022	
	2023	2022	\$	%
Loss on investments	\$ (35)	\$ (6)	\$ (29)	(483)%
Interest expense	(9)	(6)	(3)	50%
Other expense, net	(4)	(1)	(3)	300%
Total other expense, net	<u>\$ (48)</u>	<u>\$ (13)</u>	<u>\$ (35)</u>	269%

Total other expense, net increased by \$35 million, or 269%, for the three months ended March 31, 2023, compared to the same period in 2022. The increase in other expense, net for the three months ended March 31, 2023 was primarily due to losses on equity investments and available-for-sale debt securities. 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 benefit of \$384 million for the three months ended March 31, 2023. Income taxes decreased by \$956 million, or 167%, for the three months ended March 31, 2023, compared to the same period in 2022, primarily due to a significant decrease in income. As a result, the 2023 effective tax rate will not be comparable to the prior year.

Liquidity and capital resources

The following table summarizes our cash, cash equivalents, investments and working capital as of March 31, 2023 and December 31, 2022 (in millions):

	March 31, 2023	December 31, 2022
Financial assets:		
Cash and cash equivalents	\$ 3,441	\$ 3,205
Investments	5,482	6,697
Investments, non-current	7,442	8,318
Total	<u>\$ 16,365</u>	<u>\$ 18,220</u>
Working capital:		
Current assets	\$ 12,122	\$ 13,431
Current liabilities	3,499	4,923
Total	<u>\$ 8,623</u>	<u>\$ 8,508</u>

Our cash, cash equivalents and investments are invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation. Investments, consisting primarily of government and corporate debt securities, are stated at fair value. Cash, cash equivalents and investments as of March 31, 2023 decreased by \$1.9 billion, or 10%, compared to December 31, 2022. During the three months ended March 31, 2023, we had a net cash outflow from operating activities of \$1.2 billion, repurchases of our common stock of \$526 million, purchases of property and equipment of \$113 million, and a business acquisition, net of cash acquired of \$85 million, partially offset by unrealized gains on available-for-sale debt securities of \$122 million.

Working capital, which is current assets less current liabilities, as of March 31, 2023 increased by \$115 million, or 1%, compared to December 31, 2022, primarily due to a decrease in short-term deferred revenue of \$819 million, mainly driven by revenue recognized from deferred revenue in excess of customer deposits received, and a decrease in accrued liabilities of \$488 million. This was partially offset by a decrease in short-term investments of \$1.2 billion, primarily to fund our operating activities and repurchases of common stock.

As of March 31, 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):

	Three Months Ended March 31,	
	2023	2022
Net cash provided by (used in):		
Operating activities	\$ (1,225)	\$ 2,763
Investing activities	2,011	(3,921)
Financing activities	(542)	(642)
Net increase (decrease) in cash, cash equivalents and restricted cash	\$ 244	\$ (1,800)

Operating activities

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

Beginning in the third quarter of 2020, we entered into supply agreements with the U.S. Government and other international organizations for the supply of our COVID-19 vaccines and received upfront deposits. As of March 31, 2023, we had \$1.8 billion in deferred revenue related to customer deposits received or billable.

Net cash used in operating activities for the three months ended March 31, 2023 was \$1.2 billion and consisted of net income of \$79 million, a net change in assets and liabilities, net of acquisition of business, of \$1.1 billion and non-cash adjustments of \$160 million. Non-cash items primarily included deferred income taxes of \$310 million, depreciation and amortization of \$78 million, and stock-based compensation of \$75 million. The net change in assets and liabilities was mainly due to a decrease in deferred revenue of \$819 million, a decrease in accrued liabilities of \$495 million, an increase in prepaid expenses and other assets of \$212 million and a decrease in accounts payable of \$117 million, partially offset by a decrease in accounts receivable of \$272 million, and a decrease in inventory of \$216 million.

Net operating cash flows decreased by \$4.0 billion, or 144%, during the three months ended March 31, 2023, compared to the same period in 2022, primarily attributable to a decrease in net income of \$3.6 billion.

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 three months ended March 31, 2023 was \$2.0 billion, which primarily included proceeds from sales of marketable securities of \$2.0 billion and proceeds from maturities of marketable securities of \$1.4 billion, partially offset by purchases of marketable securities of \$1.1 billion, purchases of property and equipment of \$113 million, and a business acquisition, net of cash acquired of \$85 million.

Net investing cash flows increased by \$5.9 billion, or 151%, during the three months ended March 31, 2023, compared to the same period in 2022, primarily reflecting timing differences related to purchases, sales, and maturities of marketable debt securities and changes in our investment portfolio mix.

Financing activities

Net cash used in financing activities for the three months ended March 31, 2023 was \$542 million, primarily due to repurchases of common stock of \$526 million.

Net cash used in financing activities decreased by \$100 million, or 16%, during the three months ended March 31, 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 March 31, 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 have retained earnings of \$18.4 billion as of March 31, 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 expect our expenses to increase in connection with our ongoing activities, particularly as we continue research and development of our development candidates and clinical activities for our investigational medicines. We also expect our expenses to increase associated with manufacturing costs, including our arrangements with our international supply and manufacturing partners. Our ongoing work on our RSV, seasonal flu, 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, late-stage clinical development, and buildout of global commercial, regulatory, sales and marketing infrastructure will require significant cash outflows during 2023, 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 March 31, 2023, together with cash expected to be generated from operations, will be sufficient to enable us to fund our projected operations, capital expenditures and stock repurchases through at least the next 12 months from the issuance of these financial statements included in this Form 10-Q. We are subject to all the risks related to the development and commercialization of novel medicines, and we may encounter unforeseen expenses, difficulties, complications, delays, and other unknown factors, which may adversely affect our business. Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect.

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 March 31, 2023 compared to those disclosed in our 2022 Form 10-K.

Contractual Obligations

As of March 31, 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 months ended March 31, 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 March 31, 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 March 31, 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 March 31, 2023, which have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls

Our management, including our Chief Executive Officer and Chief Financial Officer, believes that our disclosure controls and procedures and internal control over financial reporting are designed to provide reasonable assurance of achieving their objectives and are effective at the reasonable assurance level. However, our management does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent all errors and all fraud. A control system, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. These inherent limitations include the realities that judgments in decision making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by the collusion of two or more people or by a management override of the controls. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

PART II

Item 1. Legal Proceedings

We are involved in various claims and legal proceedings of a nature considered ordinary course in our business, including the intellectual property litigation described in our 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.

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

The following table provides information with respect to the shares of common stock repurchased by us during the three months ended March 31, 2023:

Period	Total Number of Shares Purchased	Average Price Paid per Share ⁽¹⁾	Total Number of Shares Purchased as Part of Publicly Announced Program	Approximate Dollar Value of Shares that May Yet Be Purchased Under the Program (in millions) ⁽²⁾
January 1 - January 31, 2023	—	\$ —	22,701,168	\$ 2,814
February 1 - February 28, 2023	—	\$ —	22,701,168	\$ 2,814
March 1 - March 31, 2023	3,618,461	\$ 145.31	26,319,629	\$ 2,291
Total	<u>3,618,461</u>			

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

⁽²⁾ On February 22, 2022, our Board of Directors authorized a share repurchase program for our common stock of up to \$3.0 billion, with no expiration date. This share repurchase program was increased by the Board of Directors by an additional \$3.0 billion on August 1, 2022, also with no expiration date.

Refer to [Note 14](#) to condensed consolidated financial statements for information regarding our share repurchase programs.

Item 6. Exhibits

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

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:
May 4, 2023

By: /s/ Stéphane Bancel

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

Date:
May 4, 2023

By: /s/ James M. Mock

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