UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

☒ **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 No. 1-6571

Merck & Co., Inc.

(Exact name of registrant as specified in its charter)

New Jersey	**22-1918501**
(State or other jurisdiction of incorporation)	(I.R.S. Employer Identification No.)

126 East Lincoln Avenue
Rahway New Jersey 07065
(Address of principal executive offices) (zip code)

(Registrant's telephone number, including area code) **(908) 740-4000**

Not Applicable
(Former name, former address and former fiscal year, if changed since last report.)

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 ($0.50 par value)	MRK	New York Stock Exchange
0.500% Notes due 2024	MRK 24	New York Stock Exchange
1.875% Notes due 2026	MRK/26	New York Stock Exchange
2.500% Notes due 2034	MRK/34	New York Stock Exchange
1.375% Notes due 2036	MRK 36A	New York Stock Exchange

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, smaller reporting company, or an emerging growth company.

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 Exchange Act). Yes ☐ No ☒

The number of shares of common stock outstanding as of the close of business on April 30, 2023: 2,537,435,954

Table of Contents

MERCK & CO., INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENT OF INCOME
(Unaudited, $ in millions except per share amounts)

	Three Months Ended March 31,	
	2023	2022
Sales	$ 14,487	$ 15,901
Costs, Expenses and Other		
Cost of sales	3,926	5,380
Selling, general and administrative	2,479	2,323
Research and development	4,276	2,576
Restructuring costs	67	53
Other (income) expense, net	89	708
	10,837	11,040
Income Before Taxes	3,650	4,861
Taxes on Income	825	554
Net Income	2,825	4,307
Less: Net Income (Loss) Attributable to Noncontrolling Interests	4	(3)
Net Income Attributable to Merck & Co., Inc.	$ 2,821	$ 4,310
Basic Earnings per Common Share Attributable to Merck & Co., Inc. Common Shareholders	$ 1.11	$ 1.70
Earnings per Common Share Assuming Dilution Attributable to Merck & Co., Inc. Common Shareholders	$ 1.11	$ 1.70

MERCK & CO., INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME
(Unaudited, $ in millions)

	Three Months Ended March 31,	
	2023	2022
Net Income Attributable to Merck & Co., Inc.	$ 2,821	$ 4,310
Other Comprehensive (Loss) Income Net of Taxes:		
Net unrealized (loss) gain on derivatives, net of reclassifications	(133)	63
Benefit plan net (loss) gain and prior service (cost) credit, net of amortization	(50)	32
Cumulative translation adjustment	68	(35)
	(115)	60
Comprehensive Income Attributable to Merck & Co., Inc.	$ 2,706	$ 4,370

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

MERCK & CO., INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEET
(Unaudited, $ in millions except per share amounts)

	March 31, 2023	December 31, 2022
Assets		
Current Assets		
Cash and cash equivalents	$ 9,707	$ 12,694
Short-term investments	680	498
Accounts receivable (net of allowance for doubtful accounts of $76 in 2023 and $72 in 2022)	10,415	9,450
Inventories (excludes inventories of $3,284 in 2023 and $2,938 in 2022 classified in Other assets - see Note 7)	5,863	5,911
Other current assets	6,737	7,169
Total current assets	33,402	35,722
Investments	1,290	1,015
Property, Plant and Equipment, at cost, net of accumulated depreciation of $18,256 in 2023 and $17,985 in 2022	21,758	21,422
Goodwill	21,209	21,204
Other Intangibles, Net	19,857	20,269
Other Assets	10,280	9,528
	$ 107,796	$ 109,160
Liabilities and Equity		
Current Liabilities		
Loans payable and current portion of long-term debt	$ 2,672	$ 1,946
Trade accounts payable	3,680	4,264
Accrued and other current liabilities	13,000	14,159
Income taxes payable	1,872	1,986
Dividends payable	1,907	1,884
Total current liabilities	23,131	24,239
Long-Term Debt	28,074	28,745
Deferred Income Taxes	1,442	1,795
Other Noncurrent Liabilities	8,244	8,323
Merck & Co., Inc. Stockholders' Equity		
Common stock, $0.50 par value Authorized - 6,500,000,000 shares Issued - 3,577,103,522 shares in 2023 and 2022	1,788	1,788
Other paid-in capital	44,467	44,379
Retained earnings	62,039	61,081
Accumulated other comprehensive loss	(4,883)	(4,768)
	103,411	102,480
Less treasury stock, at cost: 1,039,651,210 shares in 2023 and 1,039,269,638 shares in 2022	56,577	56,489
Total Merck & Co., Inc. stockholders' equity	46,834	45,991
Noncontrolling Interests	71	67
Total equity	46,905	46,058
	$ 107,796	$ 109,160

The accompanying notes are an integral part of this condensed consolidated financial statement.

MERCK & CO., INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENT OF CASH FLOWS
(Unaudited, $ in millions)

	Three Months Ended March 31,	
	2023	2022
Cash Flows from Operating Activities		
Net income	$ 2,825	$ 4,307
Adjustments to reconcile net income to net cash provided by operating activities:		
Amortization	543	699
Depreciation	448	421
(Income) loss from investments in equity securities, net	(450)	708
Charge for the acquisition of Imago BioSciences, Inc.	1,192	—
Deferred income taxes	(277)	(338)
Share-based compensation	145	120
Other	(197)	143
Net changes in assets and liabilities	(2,890)	(1,299)
Net Cash Provided by Operating Activities	1,339	4,761
Cash Flows from Investing Activities		
Capital expenditures	(1,007)	(984)
Purchases of securities and other investments	(562)	(372)
Proceeds from sales of securities and other investments	500	1
Acquisition of Imago BioSciences, Inc., net of cash acquired	(1,327)	—
Other	37	182
Net Cash Used in Investing Activities	(2,359)	(1,173)
Cash Flows from Financing Activities		
Payments on debt	(1)	(1,250)
Purchases of treasury stock	(149)	—
Dividends paid to stockholders	(1,853)	(1,745)
Proceeds from exercise of stock options	30	12
Other	(81)	(103)
Net Cash Used in Financing Activities	(2,054)	(3,086)
Effect of Exchange Rate Changes on Cash, Cash Equivalents and Restricted Cash	87	(55)
Net (Decrease) Increase in Cash, Cash Equivalents and Restricted Cash	(2,987)	447
Cash, Cash Equivalents and Restricted Cash at Beginning of Year (includes restricted cash of $79 and $71 at January 1, 2023 and 2022, respectively, included in *Other current assets*)	12,773	8,167
Cash, Cash Equivalents and Restricted Cash at End of Period (includes restricted cash of $79 and $58 at March 31, 2023 and 2022, respectively, included in *Other current assets*)	$ 9,786	$ 8,614

The accompanying notes are an integral part of this condensed consolidated financial statement.

1. Basis of Presentation

The accompanying unaudited condensed consolidated financial statements of Merck & Co., Inc. (Merck or the Company) have been prepared pursuant to the rules and regulations for reporting on Form 10-Q. Accordingly, certain information and disclosures required by accounting principles generally accepted in the United States (U.S.) (GAAP) for complete consolidated financial statements are not included herein. These interim statements should be read in conjunction with the audited financial statements and notes thereto included in Merck's Form 10-K filed on February 24, 2023.

The results of operations of any interim period are not necessarily indicative of the results of operations for the full year. In the Company's opinion, all adjustments necessary for a fair statement of these interim statements have been included and are of a normal and recurring nature. Certain reclassifications have been made to prior year amounts to conform to the current year presentation.

Recently Adopted Accounting Standard

In October 2021, the FASB issued amended guidance that requires acquiring entities to recognize and measure contract assets and liabilities in a business combination in accordance with existing revenue recognition guidance. The Company adopted the guidance effective January 1, 2023. The adoption of this guidance did not have an impact on the Company's consolidated financial statements for prior acquisitions; however, the impact in future periods will be dependent upon the contract assets and contract liabilities acquired in future business combinations.

Recently Issued Accounting Standard Not Yet Adopted

In June 2022, the FASB issued guidance related to the fair value measurement of an equity security subject to contractual restrictions that prohibit the sale of the equity security. The new guidance also introduces new disclosure requirements for equity securities subject to contractual sale restrictions that are measured at fair value. The amended guidance is effective for interim and annual periods in 2024 and is to be applied prospectively. Early adoption is permitted for both interim and annual periods. The Company does not expect there to be an impact to its consolidated financial statements upon adoption.

2. Acquisitions, Research Collaborations and Licensing Agreements

The Company continues to pursue acquisitions and the establishment of external alliances such as research collaborations and licensing agreements to complement its internal research capabilities. These arrangements often include upfront payments, as well as expense reimbursements or payments to the third party, and milestone, royalty or profit share arrangements, contingent upon the occurrence of certain future events linked to the success of the asset in development. The Company also reviews its marketed products and pipeline to examine candidates which may provide more value through out-licensing and, as part of its portfolio assessment process, may also divest certain assets. Pro forma financial information for acquired businesses is not presented if the historical financial results of the acquired entity are not significant when compared with the Company's financial results.

In April 2023, Merck announced an agreement to acquire Prometheus Biosciences, Inc. (Prometheus), a clinical-stage biotechnology company pioneering a precision medicine approach for the discovery, development, and commercialization of novel therapeutic and companion diagnostic products for the treatment of immune-mediated diseases. Prometheus' lead candidate, PRA023, is a humanized monoclonal antibody directed to tumor necrosis factor-like ligand 1A, a target associated with both intestinal inflammation and fibrosis. Prometheus is developing PRA023 for the treatment of immune-mediated diseases including ulcerative colitis, Crohn's disease, and other autoimmune conditions. Under the terms of the acquisition agreement, Merck, through a subsidiary, will acquire all of the outstanding shares of Prometheus for $200 per share in cash for a total equity value of approximately $10.8 billion. The acquisition is subject to Prometheus shareholder approval. The closing of the proposed transaction will be subject to certain conditions, including the expiration of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act and other customary conditions. The transaction is expected to close in the third quarter of 2023. If the proposed transaction closes, the Company anticipates it will be accounted for as an asset acquisition, which would result in a charge of approximately $10.3 billion in *Research and development* expenses.

In February 2023, Merck and Kelun-Biotech (a holding subsidiary of Sichuan Kelun Pharmaceutical Co., Ltd.) closed a license and collaboration agreement expanding their relationship in which Merck gained exclusive rights for the research, development, manufacture and commercialization of up to seven investigational preclinical antibody drug conjugates (ADCs) for the treatment of cancer. Kelun-Biotech retained the right to research, develop, manufacture and commercialize certain licensed and option ADCs for Chinese mainland, Hong Kong and Macau. Merck made an upfront payment of $175 million, which was recorded in *Research and development* expenses in the first quarter of 2023. In addition, Kelun-Biotech is eligible to receive future contingent development-related payments aggregating up to $1.0 billion, $2.8 billion in regulatory milestones, and $5.5 billion in sales-based milestones if Kelun-Biotech does not retain Chinese mainland, Hong Kong and Macau rights for the option ADCs and all candidates achieve regulatory approval. In addition, Kelun-Biotech is eligible to receive tiered royalties ranging from a mid-single-digit rate to a low-double-digit rate on future net sales for any commercialized ADC product. Also, in connection with the agreement, Merck invested $100 million in Kelun-Biotech's Series B preferred shares in January 2023.

In January 2023, Merck acquired Imago BioSciences, Inc. (Imago), a clinical stage biopharmaceutical company developing new medicines for the treatment of myeloproliferative neoplasms and other bone marrow diseases, for $1.35 billion

(including payments to settle share-based equity awards) and also incurred approximately $60 million of transaction costs. Imago's lead candidate bomedemstat, MK-3543 (formerly IMG-7289), is an investigational orally available lysine-specific demethylase 1 inhibitor currently being evaluated in multiple Phase 2 clinical trials for the treatment of essential thrombocythemia, myelofibrosis, and polycythemia vera, in addition to other indications. The transaction was accounted for as an acquisition of an asset since bomedemstat represented substantially all of the fair value of the gross assets acquired (excluding cash and deferred income taxes). Merck recorded net assets of $219 million, as well as *Research and development* expenses of $1.2 billion in the first quarter of 2023 related to the transaction. There are no future contingent payments associated with the acquisition.

3. Collaborative Arrangements

Merck has entered into collaborative arrangements that provide the Company with varying rights to develop, produce and market products together with its collaborative partners. Both parties in these arrangements are active participants and exposed to significant risks and rewards dependent on the commercial success of the activities of the collaboration. Merck's more significant collaborative arrangements are discussed below.

AstraZeneca

In 2017, Merck and AstraZeneca PLC (AstraZeneca) entered into a global strategic oncology collaboration to co-develop and co-commercialize AstraZeneca's Lynparza (olaparib) for multiple cancer types. Independently, Merck and AstraZeneca will develop and commercialize Lynparza in combinations with their respective PD-1 and PD-L1 medicines, *Keytruda* (pembrolizumab) and Imfinzi. The companies are also jointly developing and commercializing AstraZeneca's Koselugo (selumetinib) for multiple indications. Under the terms of the agreement, AstraZeneca and Merck will share the development and commercialization costs for Lynparza and Koselugo monotherapy and non-PD-L1/PD-1 combination therapy opportunities.

Profits from Lynparza and Koselugo product sales generated through monotherapies or combination therapies are shared equally. AstraZeneca is the principal on Lynparza and Koselugo sales transactions. Merck records its share of Lynparza and Koselugo product sales, net of cost of sales and commercialization costs, as alliance revenue and its share of development costs associated with the collaboration as part of *Research and development* expenses. Reimbursements received from AstraZeneca for research and development expenses are recognized as reductions to *Research and development* costs.

As part of the agreement, Merck made an upfront payment to AstraZeneca and also made payments over a multi-year period for certain license options. In addition, the agreement provides for contingent payments from Merck to AstraZeneca related to the successful achievement of sales-based and regulatory milestones.

In the first quarter of 2022, Merck determined it was probable that sales of Lynparza in the future would trigger a $600 million sales-based milestone payment from Merck to AstraZeneca. Accordingly, Merck recorded a $600 million liability (which remained accrued at March 31, 2023) and a corresponding increase to the intangible asset related to Lynparza. Merck also recognized $250 million of cumulative amortization catch-up expense related to the recognition of this milestone in the first quarter of 2022. Also in the first quarter of 2022, Merck made a sales-based milestone payment to AstraZeneca (which had been previously accrued for) of $400 million. Potential future sales-based milestone payments of $2.1 billion have not yet been accrued as they are not deemed by the Company to be probable at this time. In the first quarter of 2023, Merck made a regulatory milestone payment to AstraZeneca (which had been previously accrued for) of $105 million. In 2022, Lynparza received regulatory approvals triggering capitalized milestone payments of $250 million from Merck to AstraZeneca. Potential future regulatory milestone payments of $1.1 billion remain under the agreement.

The intangible asset balance related to Lynparza (which includes capitalized sales-based and regulatory milestone payments) was $1.5 billion at March 31, 2023 and is included in *Other Intangibles, Net*. The amount is being amortized over its estimated useful life through 2028 as supported by projected future cash flows, subject to impairment testing.

Summarized financial information related to this collaboration is as follows:

($ in millions)	Three Months Ended March 31, 2023	Three Months Ended March 31, 2022
Alliance revenue - Lynparza	$ 275	$ 266
Alliance revenue - Koselugo	23	9
Total alliance revenue	$ 298	$ 275
Cost of sales [1]	70	299
Selling, general and administrative	47	44
Research and development	21	26

($ in millions)	March 31, 2023	December 31, 2022
Receivables from AstraZeneca included in *Other current assets*	$ 303	$ 303
Payables to AstraZeneca included in *Accrued and other current liabilities* [2]	21	123
Payables to AstraZeneca included in *Other Noncurrent Liabilities* [2]	600	600

[1] *Represents amortization of capitalized milestone payments. Amount in the first quarter of 2022 includes $250 million of cumulative amortization catch-up expense as noted above.*

[2] *Includes accrued milestone payments.*

Eisai

In 2018, Merck and Eisai Co., Ltd. (Eisai) announced a strategic collaboration for the worldwide co-development and co-commercialization of Lenvima (lenvatinib), an orally available tyrosine kinase inhibitor discovered by Eisai. Under the agreement, Merck and Eisai will develop and commercialize Lenvima jointly, both as monotherapy and in combination with *Keytruda*. Eisai records Lenvima product sales globally (Eisai is the principal on Lenvima sales transactions) and Merck and Eisai share applicable profits equally. Merck records its share of Lenvima product sales, net of cost of sales and commercialization costs, as alliance revenue. Expenses incurred during co-development are shared by the two companies in accordance with the collaboration agreement and reflected in *Research and development* expenses. Certain expenses incurred solely by Merck or Eisai are not shareable under the collaboration agreement, including costs incurred in excess of agreed upon caps and costs related to certain combination studies of *Keytruda* and Lenvima.

Under the agreement, Merck made an upfront payment to Eisai and also made payments over a multi-year period for certain option rights. In addition, the agreement provides for contingent payments from Merck to Eisai related to the successful achievement of sales-based and regulatory milestones.

In the first quarter of 2023, Merck determined it was probable that sales of Lenvima in the future would trigger a $125 million sales-based milestone payment from Merck to Eisai. Accordingly, Merck recorded a $125 million liability and a corresponding increase to the intangible asset related to Lenvima. Merck also recognized $72 million of cumulative amortization catch-up expense related to the recognition of this milestone. In 2022, Merck made sales-based milestone payments to Eisai (which had been previously accrued for) aggregating $600 million (of which $300 million was paid in the first quarter of 2022). Potential future sales-based milestone payments of $2.4 billion have not yet been accrued as they are not deemed by the Company to be probable at this time. In 2022, Lenvima received regulatory approvals triggering capitalized milestone payments of $50 million from Merck to Eisai (of which $25 million was paid in the first quarter of 2022). There are no regulatory milestone payments remaining under the agreement.

The intangible asset balance related to Lenvima (which includes capitalized sales-based and regulatory milestone payments) was $812 million at March 31, 2023 and is included in *Other Intangibles, Net*. The amount is being amortized over its estimated useful life through 2026 as supported by projected future cash flows, subject to impairment testing.

Summarized financial information related to this collaboration is as follows:

($ in millions)	Three Months Ended March 31, 2023	Three Months Ended March 31, 2022
Alliance revenue - Lenvima	$ 232	$ 227
Cost of sales [1]	126	53
Selling, general and administrative	51	31
Research and development	39	57

($ in millions)	March 31, 2023	December 31, 2022
Receivables from Eisai included in *Other current assets*	$ 244	$ 214
Payables to Eisai included in *Accrued and other current liabilities* [2]	125	—

[1] *Represents amortization of capitalized milestone payments. Amount in the first quarter of 2023 includes $72 million of cumulative amortization catch-up expense as noted above.*

[2] *Represents an accrued milestone payment.*

Bayer AG

In 2014, the Company entered into a worldwide clinical development collaboration with Bayer AG (Bayer) to market and develop soluble guanylate cyclase (sGC) modulators including Bayer's Adempas (riociguat). The two companies have implemented a joint development and commercialization strategy. The collaboration also includes development of Bayer's Verquvo (vericiguat), which was approved in the U.S., the European Union (EU) and Japan in 2021, and has since been approved in several other markets. Under the agreement, Bayer commercializes Adempas in the Americas, while Merck commercializes in the rest of the world. For Verquvo, Merck commercializes in the U.S. and Bayer commercializes in the rest of the world. Both companies share in development costs and profits on sales. Merck records sales of Adempas and Verquvo in its marketing territories, as well as alliance revenue. Alliance revenue represents Merck's share of profits from sales of Adempas and Verquvo in Bayer's marketing territories, which are product sales net of cost of sales and commercialization costs. Cost of sales includes Bayer's share of profits from sales in Merck's marketing territories.

In addition, the agreement provided for contingent payments from Merck to Bayer related to the successful achievement of sales-based milestones. In the first quarter of 2022, Merck made the final $400 million sales-based milestone payment under this collaboration to Bayer.

The intangible asset balances related to Adempas (which includes the acquired intangible asset balance, as well as capitalized sales-based milestone payments attributed to Adempas) and Verquvo (which reflects the portion of the final sales-based milestone payment that was attributed to Verquvo) were $613 million and $56 million, respectively, at March 31, 2023 and are included in *Other Intangibles, Net*. The assets are being amortized over their estimated useful lives (through 2027 for Adempas and through 2031 for Verquvo) as supported by projected future cash flows, subject to impairment testing.

Summarized financial information related to this collaboration is as follows:

($ in millions)	Three Months Ended March 31, 2023	Three Months Ended March 31, 2022
Alliance revenue - Adempas/Verquvo	$ 99	$ 72
Net sales of Adempas recorded by Merck	59	61
Net sales of Verquvo recorded by Merck	7	3
Total sales	$ 165	$ 136
Cost of sales [1]	57	50
Selling, general and administrative	33	23
Research and development	25	17

($ in millions)	March 31, 2023	December 31, 2022
Receivables from Bayer included in *Other current assets*	$ 142	$ 143
Payables to Bayer included in *Accrued and other current liabilities*	68	80

[1] *Includes amortization of intangible assets.*

Ridgeback Biotherapeutics LP

In 2020, Merck and Ridgeback Biotherapeutics LP (Ridgeback), a closely held biotechnology company, entered into a collaboration agreement to develop *Lagevrio* (molnupiravir), an investigational orally available antiviral candidate for the treatment of patients with COVID-19. Merck gained exclusive worldwide rights to develop and commercialize *Lagevrio* and

related molecules. Following initial authorizations in certain markets in the fourth quarter of 2021, *Lagevrio* has since received multiple additional authorizations worldwide.

Under the terms of the agreement, Ridgeback received an upfront payment and is eligible to receive future contingent payments dependent upon the achievement of certain developmental and regulatory approval milestones. The agreement also provides for Merck to reimburse Ridgeback for a portion of certain third-party contingent milestone payments and royalties on net sales, which is part of the profit-sharing calculation. Merck is the principal on sales transactions, recognizing sales and related costs, with profit-sharing amounts recorded within *Cost of sales*. Profits from the collaboration are split equally between the partners. Reimbursements from Ridgeback for its share of research and development costs (deducted from Ridgeback's share of profits) are reflected as decreases to *Research and development* expenses.

Summarized financial information related to this collaboration is as follows:

	Three Months Ended March 31,	
($ in millions)	2023	2022
Net sales of *Lagevrio* recorded by Merck	$ 392	$ 3,247
Cost of sales [(1)(2)]	221	1,726
Selling, general and administrative [(2)]	27	35
Research and development [(2)]	16	25

($ in millions)	March 31, 2023	December 31, 2022
Payables to Ridgeback included in *Accrued and other current liabilities* [(3)]	$ 191	$ 348

[(1)] *Includes royalty expense and amortization of capitalized milestone payments.*

[(2)] *Expenses include an allocation for overhead charges.*

[(3)] *Includes accrued royalties. Amount at December 31, 2022 also includes an accrued milestone payment.*

Bristol Myers Squibb

Reblozyl (luspatercept-aamt) is a first-in-class erythroid maturation recombinant fusion protein that is being commercialized through a global collaboration with Bristol Myers Squibb (BMS). Reblozyl is approved in the U.S., Europe and certain other markets for the treatment of anemia in certain rare blood disorders and is also being evaluated for additional indications for hematology therapies. BMS is the principal on sales transactions for Reblozyl; however, Merck co-promotes Reblozyl (and will co-promote all future products approved under this collaboration) in North America, which is reimbursed by BMS. Merck receives a 20% sales royalty from BMS which could increase to a maximum of 24% based on sales levels. This royalty will be reduced by 50% upon the earlier of patent expiry or generic entry on an indication-by-indication basis in each market. Additionally, Merck is eligible to receive future contingent sales-based milestone payments of up to $80 million. Merck recorded alliance revenue related to this collaboration within *Sales* of $43 million in the first quarter of 2023 (consisting of royalties) compared with $52 million in the first quarter of 2022 (consisting of royalties of $32 million and the receipt of a regulatory approval milestone payment of $20 million).

4. Spin-Off of Organon & Co.

On June 2, 2021, Merck completed the spin-off of Organon through a distribution of Organon's publicly traded stock to Company shareholders. In connection with the spin-off, Merck and Organon entered into a separation and distribution agreement and also entered into various other agreements to effect the spin-off and provide a framework for the relationship between Merck and Organon after the spin-off, including a transition services agreement (TSA), manufacturing and supply agreements (MSAs), trademark license agreements, intellectual property license agreements, an employee matters agreement, a tax matters agreement and certain other commercial agreements. Under the TSA, Merck is providing Organon various services and, similarly, Organon is providing Merck various services. The provision of services under the TSA generally will terminate within 25 months following the spin-off; however, the provision of certain services has been extended to 35 months. Merck and Organon also entered into a series of interim operating agreements pursuant to which in various jurisdictions where Merck held licenses, permits and other rights in connection with marketing, import and/or distribution of Organon products prior to the separation, Merck is continuing to market, import and distribute such products until such time as the relevant licenses and permits are transferred to Organon. Under such interim operating agreements and in accordance with the separation and distribution agreement, Merck is continuing operations in the affected markets on behalf of Organon, with Organon receiving all of the economic benefits and burdens of such activities. Additionally, Merck and Organon entered into a number of MSAs pursuant to which Merck is (a) manufacturing and supplying certain active pharmaceutical ingredients for Organon, (b) manufacturing and supplying certain formulated pharmaceutical products for Organon, and (c) packaging and labeling certain finished pharmaceutical products for Organon. Similarly, Organon and Merck entered into a number of MSAs pursuant to which Organon is (a) manufacturing and supplying certain formulated pharmaceutical products for Merck, and (b) packaging and labeling certain finished pharmaceutical products for Merck. The terms of the MSAs range in initial duration from four years to ten years.

The amounts included in the condensed consolidated statement of income for the above MSAs include sales of $94 million and $99 million and related cost of sales of $107 million and $105 million for the first quarter of 2023 and 2022,

respectively. Amounts included in the condensed consolidated statement of income for the TSAs were immaterial for both the first quarter of 2023 and 2022.

The amounts due from Organon under all of the above agreements were $473 million and $511 million at March 31, 2023 and December 31, 2022, respectively, and are reflected in *Other current assets*. The amounts due to Organon under these agreements were $229 million and $345 million at March 31, 2023 and December 31, 2022, respectively, and are included in *Accrued and other current liabilities*.

5. Restructuring

In 2019, Merck approved a global restructuring program (Restructuring Program) as part of a worldwide initiative focused on optimizing the Company's manufacturing and supply network, as well as reducing its global real estate footprint. The actions contemplated under the Restructuring Program are expected to be substantially completed by the end of 2023, with the cumulative pretax costs to be incurred by the Company to implement the program estimated to be approximately $3.7 billion. The Company estimates that approximately 70% of the cumulative pretax costs will result in cash outlays, primarily related to employee separation expense and facility shut-down costs. Approximately 30% of the cumulative pretax costs will be non-cash, relating primarily to the accelerated depreciation of facilities to be closed or divested.

The Company recorded total pretax costs of $97 million and $127 million in the first quarter of 2023 and 2022, respectively, related to restructuring program activities. Since inception of the Restructuring Program through March 31, 2023, Merck has recorded total pretax accumulated costs of approximately $3.4 billion. For the full year of 2023, the Company expects to record charges of approximately $400 million related to the Restructuring Program. For segment reporting, restructuring charges are unallocated expenses.

The following tables summarize the charges related to restructuring program activities by type of cost:

	Three Months Ended March 31, 2023			
($ in millions)	Separation Costs	Accelerated Depreciation	Other	Total
Cost of sales	$ —	$ 21	$ 8	$ 29
Selling, general and administrative	—	—	1	1
Restructuring costs	41	—	26	67
	$ 41	$ 21	$ 35	$ 97

	Three Months Ended March 31, 2022			
($ in millions)	Separation Costs	Accelerated Depreciation	Other	Total
Cost of sales	$ —	$ 18	$ 28	$ 46
Selling, general and administrative	—	4	17	21
Research and development	—	7	—	7
Restructuring costs	26	—	27	53
	$ 26	$ 29	$ 72	$ 127

Separation costs are associated with actual headcount reductions, as well as involuntary headcount reductions which were probable and could be reasonably estimated.

Accelerated depreciation costs primarily relate to manufacturing, research and administrative facilities and equipment to be sold or closed as part of the program. Accelerated depreciation costs represent the difference between the depreciation expense to be recognized over the revised useful life of the asset, based upon the anticipated date the site will be closed or divested or the equipment disposed of, and depreciation expense as determined utilizing the useful life prior to the restructuring actions. All the sites have and will continue to operate up through the respective closure dates and, since future undiscounted cash flows are sufficient to recover the respective book values, Merck is recording accelerated depreciation over the revised useful life of the site assets. Anticipated site closure dates, particularly related to manufacturing locations, have been and may continue to be adjusted to reflect changes resulting from regulatory or other factors.

Other activity in 2023 and 2022 includes asset abandonment, facility shut-down and other related costs, as well as pretax gains and losses resulting from the sales of facilities and related assets. Additionally, other activity includes certain employee-related costs associated with pension and other postretirement benefit plans (see Note 10) and share-based compensation.

The following table summarizes the charges and spending relating to restructuring program activities for the three months ended March 31, 2023:

($ in millions)	Separation Costs	Accelerated Depreciation	Other	Total
Restructuring reserves January 1, 2023	$ 479	$ —	$ 34	$ 513
Expenses	41	21	35	97
(Payments) receipts, net	(47)	—	(27)	(74)
Non-cash activity	—	(21)	(9)	(30)
Restructuring reserves March 31, 2023 [(1)]	$ 473	$ —	$ 33	$ 506

[(1)] *The remaining cash outlays are expected to be largely completed by the end of 2025.*

6. Financial Instruments

Derivative Instruments and Hedging Activities

The Company manages the impact of foreign exchange rate movements and interest rate movements on its earnings, cash flows and fair values of assets and liabilities through operational means and through the use of various financial instruments, including derivative instruments.

A significant portion of the Company's revenues and earnings in foreign affiliates is exposed to changes in foreign exchange rates. The objectives of and accounting related to the Company's foreign currency risk management program, as well as its interest rate risk management activities are discussed below.

Foreign Currency Risk Management

The Company has established revenue hedging, balance sheet risk management and net investment hedging programs to protect against volatility of future foreign currency cash flows and changes in fair value caused by changes in foreign exchange rates.

The objective of the revenue hedging program is to reduce the variability caused by changes in foreign exchange rates that would affect the U.S. dollar value of future cash flows derived from foreign currency denominated sales, primarily the euro, Japanese yen and Chinese renminbi. To achieve this objective, the Company will hedge a portion of its forecasted foreign currency denominated third-party and intercompany distributor entity sales (forecasted sales) that are expected to occur over its planning cycle, typically no more than two years into the future. The Company will layer in hedges over time, increasing the portion of forecasted sales hedged as it gets closer to the expected date of the forecasted sales. The portion of forecasted sales hedged is based on assessments of cost-benefit profiles that consider natural offsetting exposures, revenue and exchange rate volatilities and correlations, and the cost of hedging instruments. The Company manages its anticipated transaction exposure principally with purchased local currency put options, forward contracts, and purchased collar options.

The fair values of these derivative contracts are recorded as either assets (gain positions) or liabilities (loss positions) in the Condensed Consolidated Balance Sheet. Changes in the fair value of derivative contracts are recorded each period in either current earnings or *Other comprehensive income* (*OCI*), depending on whether the derivative is designated as part of a hedge transaction and, if so, the type of hedge transaction. For derivatives that are designated as cash flow hedges, the unrealized gains or losses on these contracts are recorded in *Accumulated Other Comprehensive Loss* (*AOCL)* and reclassified into *Sales* when the hedged anticipated revenue is recognized. For those derivatives which are not designated as cash flow hedges, but serve as economic hedges of forecasted sales, unrealized gains or losses are recorded in *Sales* each period. The cash flows from both designated and non-designated contracts are reported as operating activities in the Condensed Consolidated Statement of Cash Flows. The Company does not enter into derivatives for trading or speculative purposes.

The Company manages operating activities and net asset positions at each local subsidiary in order to mitigate the effects of exchange on monetary assets and liabilities. Monetary assets and liabilities denominated in a currency other than the functional currency of a given subsidiary are remeasured at spot rates in effect on the balance sheet date with the effects of changes in spot rates reported in *Other (income) expense, net*. The Company also uses a balance sheet risk management program to mitigate the exposure of such assets and liabilities from the effects of volatility in foreign exchange. Merck principally utilizes forward exchange contracts to offset the effects of exchange in developed country currencies, primarily the euro, Japanese yen, British pound, Canadian dollar, Australian dollar and Swiss franc. For exposures in developing country currencies, including the Chinese renminbi, the Company will enter into forward contracts to offset the effects of exchange on exposures when it is deemed economical to do so based on a cost-benefit analysis that considers the magnitude of the exposure, the volatility of the exchange rate and the cost of the hedging instrument. The forward contracts are not designated as hedges and are marked to market through *Other (income) expense, net*. Accordingly, fair value changes in the forward contracts help mitigate the changes in the value of the remeasured assets and liabilities attributable to changes in foreign currency exchange rates, except to the extent of the spot-forward differences. These differences are not significant due to the short-term nature of the contracts, which typically have average maturities at inception of less than six months. The cash flows from these contracts are reported as operating activities in the Condensed Consolidated Statement of Cash Flows.

The Company also uses forward exchange contracts to hedge a portion of its net investment in foreign operations against movements in exchange rates. The forward contracts are designated as hedges of the net investment in a foreign operation. The unrealized gains or losses on these contracts are recorded in foreign currency translation adjustment within *OCI*

and remain in *AOCL* until either the sale or complete or substantially complete liquidation of the subsidiary. The Company excludes certain portions of the change in fair value of its derivative instruments from the assessment of hedge effectiveness (excluded components). Changes in fair value of the excluded components are recognized in *OCI*. The Company recognizes in earnings the initial value of the excluded components on a straight-line basis over the life of the derivative instrument, rather than using the mark-to-market approach. The cash flows from these contracts are reported as investing activities in the Condensed Consolidated Statement of Cash Flows.

Foreign exchange risk is also managed through the use of foreign currency debt. The Company's senior unsecured euro-denominated notes have been designated as, and are effective as, economic hedges of the net investment in a foreign operation. Accordingly, foreign currency transaction gains or losses due to spot rate fluctuations on the euro-denominated debt instruments are included in foreign currency translation adjustment within *OCI*.

The effects of the Company's net investment hedges on *OCI* and the Consolidated Statement of Income are shown below:

	Amount of Pretax (Gain) Loss Recognized in Other Comprehensive Income [1]		Amount of Pretax (Gain) Loss Recognized in *Other (income) expense, net* for Amounts Excluded from Effectiveness Testing	
	Three Months Ended March 31,		Three Months Ended March 31,	
($ in millions)	2023	2022	2023	2022
Net Investment Hedging Relationships				
Foreign exchange contracts	$ 1	$ (16)	$ 1	$ (1)
Euro-denominated notes	52	(53)	—	—

[1] *No amounts were reclassified from AOCL into income related to the sale of a subsidiary.*

Interest Rate Risk Management

The Company may use interest rate swap contracts on certain investing and borrowing transactions to manage its net exposure to interest rate changes and to reduce its overall cost of borrowing. The Company does not use leveraged swaps and, in general, does not leverage any of its investment activities that would put principal at risk. In March 2023, the Company entered into five forward starting swaps and in April 2023 entered into two additional forward starting swaps, each with a notional amount of $100 million.

Presented in the table below is the fair value of derivatives on a gross basis segregated between those derivatives that are designated as hedging instruments and those that are not designated as hedging instruments:

		March 31, 2023			December 31, 2022		
		Fair Value of Derivative		U.S. Dollar Notional	Fair Value of Derivative		U.S. Dollar Notional
($ in millions)		Asset	Liability		Asset	Liability	
Derivatives Designated as Hedging Instruments	*Balance Sheet Caption*						
Interest rate swap contracts	Other Assets	$ 1	$ —	$ 300	$ —	$ —	$ —
Interest rate swap contracts	Other Noncurrent Liabilities	—	1	200	—	—	—
Foreign exchange contracts	Other current assets	104	—	4,253	220	—	4,824
Foreign exchange contracts	Other Assets	32	—	1,756	27	—	1,609
Foreign exchange contracts	Accrued and other current liabilities	—	116	3,444	—	101	2,691
Foreign exchange contracts	Other Noncurrent Liabilities	—	2	120	—	1	91
		$ 137	$ 119	$ 10,073	$ 247	$ 102	$ 9,215
Derivatives Not Designated as Hedging Instruments	*Balance Sheet Caption*						
Foreign exchange contracts	Other current assets	$ 121	$ —	$ 9,507	$ 186	$ —	$ 8,540
Foreign exchange contracts	Other Assets	1	—	65	—	—	—
Foreign exchange contracts	Accrued and other current liabilities	—	164	10,592	—	307	10,926
Foreign exchange contracts	Other Noncurrent Liabilities	—	1	124	—	—	—
		$ 122	$ 165	$ 20,288	$ 186	$ 307	$ 19,466
		$ 259	$ 284	$ 30,361	$ 433	$ 409	$ 28,681

As noted above, the Company records its derivatives on a gross basis in the Condensed Consolidated Balance Sheet. The Company has master netting agreements with several of its financial institution counterparties (see *Concentrations of Credit Risk* below). The following table provides information on the Company's derivative positions subject to these master netting arrangements as if they were presented on a net basis, allowing for the right of offset by counterparty and cash collateral exchanged per the master agreements and related credit support annexes:

	March 31, 2023		December 31, 2022	
($ in millions)	Asset	Liability	Asset	Liability
Gross amounts recognized in the condensed consolidated balance sheet	$ 259	$ 284	$ 433	$ 409
Gross amounts subject to offset in master netting arrangements not offset in the condensed consolidated balance sheet	(148)	(148)	(220)	(220)
Cash collateral received/posted	(13)	—	(66)	(19)
Net amounts	$ 98	$ 136	$ 147	$ 170

The table below provides information regarding the location and amount of pretax gains and losses of derivatives designated in fair value or cash flow hedging relationships:

	Three Months Ended March 31,					
($ in millions)	2023	2022	2023	2022	2023	2022
Financial Statement Caption in which Effects of Fair Value or Cash Flow Hedges are Recorded	Sales		Other (income) expense, net [1]		Other comprehensive income (loss)	
	$ 14,487	$ 15,901	$ 89	$ 708	$ (115)	$ 60
(Gain) loss on fair value hedging relationships:						
Interest rate swap contracts						
Hedged items	—	—	—	(10)	—	—
Derivatives designated as hedging instruments	—	—	—	4	—	—
Impact of cash flow hedging relationships:						
Foreign exchange contracts						
Amount of (loss) gain recognized in *OCI* on derivatives	—	—	—	—	(66)	148
Increase in *Sales* as a result of *AOCL* reclassifications	101	67	—	—	(101)	(67)
Interest rate contracts						
Amount of gain recognized in *Other (income) expense, net* on derivatives	—	—	(1)	(1)	—	—
Amount of loss recognized in *OCI* on derivatives	—	—	—	—	(1)	(1)

[1] *Interest expense is a component of* Other (income) expense, net.

The table below provides information regarding the income statement effects of derivatives not designated as hedging instruments:

		Amount of Derivative Pretax (Gain) Loss Recognized in Income	
		Three Months Ended March 31,	
($ in millions)		2023	2022
Derivatives Not Designated as Hedging Instruments	*Income Statement Caption*		
Foreign exchange contracts [1]	Other (income) expense, net	$ 13	$ 28
Foreign exchange contracts [2]	Sales	2	(2)

[1] *These derivative contracts primarily mitigate changes in the value of remeasured foreign currency denominated monetary assets and liabilities attributable to changes in foreign currency exchange rates.*

[2] *These derivative contracts serve as economic hedges of forecasted transactions.*

At March 31, 2023, the Company estimates $71 million of pretax net unrealized losses on derivatives maturing within the next 12 months that hedge foreign currency denominated sales over that same period will be reclassified from *AOCL* to *Sales*. The amount ultimately reclassified to *Sales* may differ as foreign exchange rates change. Realized gains and losses are ultimately determined by actual exchange rates at maturity.

Investments in Debt and Equity Securities

Information on investments in debt and equity securities is as follows:

	March 31, 2023				December 31, 2022			
	Amortized Cost	Gross Unrealized		Fair Value	Amortized Cost	Gross Unrealized		Fair Value
($ in millions)		Gains	Losses			Gains	Losses	
Commercial paper	$ 663	$ —	$ —	$ 663	$ 498	$ —	$ —	$ 498
U.S. government and agency securities	92	—	—	92	68	—	—	68
Corporate notes and bonds	4	—	—	4	3	—	—	3
Foreign government bonds	1	—	—	1	—	—	—	—
Total debt securities	$ 760	$ —	$ —	$ 760	$ 569	$ —	$ —	$ 569
Publicly traded equity securities [(1)]				1,585				1,284
Total debt and publicly traded equity securities				$ 2,345				$ 1,853

[(1)] *Unrealized net gains of $338 million were recorded in* Other (income) expense, net *in the first quarter of 2023 on equity securities still held at March 31, 2023. Unrealized net losses of $225 million were recorded in* Other (income) expense, net *in the first quarter of 2022 on equity securities still held at March 31, 2022.*

At March 31, 2023 and March 31, 2022, the Company also had $942 million and $643 million, respectively, of equity investments without readily determinable fair values included in *Other Assets*. The Company records unrealized gains on these equity investments based on favorable observable price changes from transactions involving similar investments of the same investee and records unrealized losses based on unfavorable observable price changes, which are included in *Other (income) expense, net*. During the first quarter of 2023, the Company recorded unrealized gains of $1 million and unrealized losses of $21 million related to certain of these equity investments still held at March 31, 2023. During the first quarter of 2022, the Company recorded unrealized gains of $14 million related to certain of these investments still held at March 31, 2022. Cumulative unrealized gains and cumulative unrealized losses based on observable price changes for investments in equity investments without readily determinable fair values still held at March 31, 2023 were $287 million and $40 million, respectively.

At March 31, 2023 and March 31, 2022, the Company also had $725 million and $1.2 billion, respectively, recorded in *Other Assets* for equity securities held through ownership interests in investment funds. (Gains) losses recorded in *Other (income) expense, net* relating to these investment funds were $(132) million and $509 million for the first quarter of 2023 and 2022, respectively.

Fair Value Measurements

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. The Company uses a fair value hierarchy which maximizes the use of observable inputs and minimizes the use of unobservable inputs when measuring fair value. There are three levels of inputs used to measure fair value with Level 1 having the highest priority and Level 3 having the lowest:

Level 1 - Quoted prices (unadjusted) in active markets for identical assets or liabilities;

Level 2 - Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities;

Level 3 - Unobservable inputs that are supported by little or no market activity. Level 3 assets or liabilities are those whose values are determined using pricing models, discounted cash flow methodologies, or similar techniques with significant unobservable inputs, as well as assets or liabilities for which the determination of fair value requires significant judgment or estimation.

If the inputs used to measure the financial assets and liabilities fall within more than one level described above, the categorization is based on the lowest level input that is significant to the fair value measurement of the instrument.

Financial Assets and Liabilities Measured at Fair Value on a Recurring Basis

Financial assets and liabilities measured at fair value on a recurring basis are summarized below:

	Fair Value Measurements Using				Fair Value Measurements Using			
	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3	Total
($ in millions)	March 31, 2023				December 31, 2022			
Assets								
Investments								
Commercial paper	$ —	$ 663	$ —	$ 663	$ —	$ 498	$ —	$ 498
U.S. government and agency securities	—	22	—	22	—	—	—	—
Foreign government bonds	—	1	—	1	—	—	—	—
Publicly traded equity securities	1,284	—	—	1,284	1,015	—	—	1,015
	1,284	686	—	1,970	1,015	498	—	1,513
Other assets [1]								
U.S. government and agency securities	70	—	—	70	68	—	—	68
Corporate notes and bonds	4	—	—	4	3	—	—	3
Publicly traded equity securities	301	—	—	301	269	—	—	269
	375	—	—	375	340	—	—	340
Derivative assets [2]								
Purchased currency options	—	139	—	139	—	215	—	215
Forward exchange contracts	—	119	—	119	—	218	—	218
Interest rate swap contracts	—	1	—	1	—	—	—	—
	—	259	—	259	—	433	—	433
Total assets	$ 1,659	$ 945	$ —	$ 2,604	$ 1,355	$ 931	$ —	$ 2,286
Liabilities								
Other liabilities								
Contingent consideration	$ —	$ —	$ 353	$ 353	$ —	$ —	$ 456	$ 456
Derivative liabilities [2]								
Forward exchange contracts	—	276	—	276	—	402	—	402
Written currency options	—	7	—	7	—	7	—	7
Interest rate swap contracts	—	1	—	1	—	—	—	—
	—	284	—	284	—	409	—	409
Total liabilities	$ —	$ 284	$ 353	$ 637	$ —	$ 409	$ 456	$ 865

[1] *Investments included in other assets are restricted as to use, including for the payment of benefits under employee benefit plans.*

[2] *The fair value determination of derivatives includes the impact of the credit risk of counterparties to the derivatives and the Company's own credit risk, the effects of which were not significant.*

As of March 31, 2023 and December 31, 2022, *Cash and cash equivalents* included $8.8 billion and $11.3 billion of cash equivalents, respectively (which would be considered Level 2 in the fair value hierarchy).

Contingent Consideration

Summarized information about the changes in the fair value of liabilities for contingent consideration associated with business combinations is as follows:

($ in millions)	2023	2022
Fair value January 1	$ 456	$ 777
Changes in estimated fair value [1]	14	(84)
Payments	(117)	(119)
Other	—	(2)
Fair value March 31 [2]	$ 353	$ 572

[1] *Recorded in* Cost of sales, Research and development *expenses, and* Other (income) expense, net. *Includes cumulative translation adjustments.*

[2] *At March 31, 2023, $263 million of the liabilities relate to the termination of the Sanofi Pasteur MSD joint venture in 2016. As part of the termination, Merck recorded a liability for contingent future royalty payments of 11.5% on net sales of all Merck products that were previously sold by the joint venture through December 31, 2024. The fair value of this liability is determined utilizing the estimated amount and timing of projected cash flows using a risk-adjusted discount rate to present value the cash flows. Balance at March 31, 2023 includes $127 million recorded as a current liability for amounts expected to be paid within the next 12 months.*

The payments of contingent consideration in both periods relate to the Sanofi Pasteur MSD liabilities described above.

Other Fair Value Measurements

Some of the Company's financial instruments, such as cash and cash equivalents, receivables and payables, are reflected in the balance sheet at carrying value, which approximates fair value due to their short-term nature.

The estimated fair value of loans payable and long-term debt (including current portion) at March 31, 2023, was $28.2 billion compared with a carrying value of $30.7 billion and at December 31, 2022, was $26.7 billion compared with a carrying value of $30.7 billion. Fair value was estimated using recent observable market prices and would be considered Level 2 in the fair value hierarchy.

Concentrations of Credit Risk

On an ongoing basis, the Company monitors concentrations of credit risk associated with corporate and government issuers of securities and financial institutions with which it conducts business. Credit exposure limits are established to limit a concentration with any single issuer or institution. Cash and investments are placed in instruments that meet high credit quality standards as specified in the Company's investment policy guidelines.

The majority of the Company's accounts receivable arise from product sales in the U.S., Europe and China and are primarily due from drug wholesalers and retailers, hospitals and government agencies. The Company monitors the financial performance and creditworthiness of its customers so that it can properly assess and respond to changes in their credit profile. The Company also continues to monitor global economic conditions, including the volatility associated with international sovereign economies, and associated impacts on the financial markets and its business.

The Company has accounts receivable factoring agreements with financial institutions in certain countries to sell accounts receivable. The Company factored $2.4 billion and $2.5 billion of accounts receivable as of March 31, 2023 and December 31, 2022, respectively, under these factoring arrangements, which reduced outstanding accounts receivable. The cash received from the financial institutions is reported within operating activities in the Condensed Consolidated Statement of Cash Flows. In certain of these factoring arrangements, for ease of administration, the Company will collect customer payments related to the factored receivables, which it then remits to the financial institutions. As of March 31, 2023 and December 31, 2022, the Company had collected $31 million and $67 million, respectively, on behalf of the financial institutions, which is reflected as restricted cash in *Other current assets* and the related obligation to remit the cash within *Accrued and other current liabilities*. The Company remitted the cash to the financial institutions in April 2023 and January 2023, respectively. The net cash flows related to these collections are reported as financing activities in the Condensed Consolidated Statement of Cash Flows. The cost of factoring such accounts receivable was *de minimis*.

Derivative financial instruments are executed under International Swaps and Derivatives Association master agreements. The master agreements with several of the Company's financial institution counterparties also include credit support annexes. These annexes contain provisions that require collateral to be exchanged depending on the value of the derivative assets and liabilities, the Company's credit rating, and the credit rating of the counterparty. Cash collateral received by the Company from various counterparties was $13 million and $66 million at March 31, 2023 and December 31, 2022, respectively. The obligation to return such collateral is recorded in *Accrued and other current liabilities*. Cash collateral advanced by the Company to various counterparties was $19 million at December 31, 2022.

7. Inventories

Inventories consisted of:

($ in millions)	March 31, 2023	December 31, 2022
Finished goods	$ 1,883	$ 1,841
Raw materials and work in process	7,348	7,063
Supplies	266	238
Total (approximates current cost)	9,497	9,142
Decrease to LIFO cost	(350)	(293)
	$ 9,147	$ 8,849
Recognized as:		
Inventories	$ 5,863	$ 5,911
Other Assets	3,284	2,938

Amounts recognized as *Other Assets* are comprised almost entirely of raw materials and work in process inventories. At March 31, 2023 and December 31, 2022, these amounts included $2.7 billion and $2.4 billion, respectively, of inventories not expected to be sold within one year. In addition, these amounts included $590 million and $516 million at March 31, 2023 and December 31, 2022, respectively, of inventories produced in preparation for product launches.

8. Contingencies

The Company is involved in various claims and legal proceedings of a nature considered normal to its business, including product liability, intellectual property, and commercial litigation, as well as certain additional matters including governmental and environmental matters. In the opinion of the Company, it is unlikely that the resolution of these matters will be material to the Company's financial condition, results of operations or cash flows.

Given the nature of the litigation discussed below and the complexities involved in these matters, the Company is unable to reasonably estimate a possible loss or range of possible loss for such matters until the Company knows, among other factors, (i) what claims, if any, will survive dispositive motion practice, (ii) the extent of the claims, including the size of any potential class, particularly when damages are not specified or are indeterminate, (iii) how the discovery process will affect the litigation, (iv) the settlement posture of the other parties to the litigation and (v) any other factors that may have a material effect on the litigation.

The Company records accruals for contingencies when it is probable that a liability has been incurred and the amount can be reasonably estimated. These accruals are adjusted periodically as assessments change or additional information becomes available. For product liability claims, a portion of the overall accrual is actuarially determined and considers such factors as past experience, number of claims reported and estimates of claims incurred but not yet reported. Individually significant contingent losses are accrued when probable and reasonably estimable. Legal defense costs expected to be incurred in connection with a loss contingency are accrued when probable and reasonably estimable.

The Company's decision to obtain insurance coverage is dependent on market conditions, including cost and availability, existing at the time such decisions are made. The Company has evaluated its risks and has determined that the cost of obtaining product liability insurance outweighs the likely benefits of the coverage that is available and, as such, has no insurance for most product liabilities.

Product Liability Litigation

Gardasil/Gardasil 9

Merck is a defendant in product liability lawsuits in the U.S. involving *Gardasil* (Human Papillomavirus Quadrivalent [Types 6, 11, 16 and 18] Vaccine, Recombinant) and *Gardasil* 9 (Human Papillomavirus 9-valent Vaccine, Recombinant). As of March 31, 2023, approximately 95 cases were filed and pending against Merck in either federal or state court. In these actions, plaintiffs allege, among other things, that they suffered various personal injuries after vaccination with *Gardasil* or *Gardasil* 9, with postural orthostatic tachycardia syndrome as a predominate alleged injury. In August 2022, the Judicial Panel on Multidistrict Litigation ordered that *Gardasil/Gardasil* 9 product liability cases pending in federal courts nationwide be transferred to Judge Robert J. Conrad in the Western District of North Carolina for coordinated pre-trial proceedings. There are fewer than 15 product liability cases pending outside the U.S., including one purported class action in Colombia.

Governmental Proceedings

As previously disclosed, from time to time, the Company's subsidiaries in China receive inquiries regarding their operations from various Chinese governmental agencies. Some of these inquiries may be related to matters involving other multinational pharmaceutical companies, as well as Chinese entities doing business with such companies. The Company's policy is to cooperate with these authorities and to provide responses as appropriate.

As previously disclosed, from time to time, the Company receives inquiries and is the subject of preliminary investigation activities from competition and other governmental authorities in markets outside the U.S. These authorities may include regulators, administrative authorities, and law enforcement and other similar officials, and these preliminary investigation activities may include site visits, formal or informal requests or demands for documents or materials, inquiries or interviews and similar matters. Certain of these preliminary inquiries or activities may lead to the commencement of formal proceedings. Should those proceedings be determined adversely to the Company, monetary fines and/or remedial undertakings may be required.

Commercial and Other Litigation

Zetia Antitrust Litigation

As previously disclosed, Merck, Merck Sharp & Dohme, LLC. (MSD), Schering Corporation, Schering-Plough Corporation, and MSP Singapore Company LLC (collectively, the Merck Defendants) are defendants in a number of lawsuits filed in 2018 on behalf of direct and indirect purchasers of Zetia alleging violations of federal and state antitrust laws, as well as other state statutory and common law causes of action. The cases were consolidated in a federal multidistrict litigation (the Zetia MDL) before Judge Rebecca Beach Smith in the Eastern District of Virginia.

In November 2019, the direct purchaser plaintiffs and the indirect purchaser plaintiffs filed motions for class certification. In August 2020, the district court granted in part the direct purchasers' motion for class certification and certified a class of 35 direct purchasers. In August 2021, the Fourth Circuit vacated the district court's class certification order and remanded for further proceedings consistent with the court's ruling. In September 2021, the direct purchaser plaintiffs filed a renewed motion for class certification. In April 2022, the district court denied the direct purchaser plaintiffs' renewed motion for class certification. In August 2021, the district court granted certification of a class of indirect purchasers.

In 2020 and 2021, United Healthcare Services, Inc., Humana Inc., Centene Corporation and others, and Kaiser Foundation Health Plan, Inc. (collectively, the Insurer Plaintiffs), each filed a lawsuit in a jurisdiction outside of the Eastern District of Virginia against the Merck Defendants and others, making similar allegations as those made in the Zetia MDL, as well as additional allegations about Vytorin. These cases have been transferred to the Eastern District of Virginia to proceed with the Zetia MDL and remain pending.

In February 2022, the Insurer Plaintiffs filed amended complaints. In March 2022, the Merck Defendants, jointly with other defendants, moved to dismiss certain aspects of the Insurer Plaintiffs' complaints, including any claims for Vytorin damages. That motion to dismiss the Vytorin-related claims is still pending.

In April 2022, the direct purchaser plaintiffs moved for an order setting a deadline for direct purchasers of Zetia not currently parties to the case to file cases against defendants in order for those cases to be coordinated for trial with the existing direct purchaser plaintiffs and other MDL plaintiff groups. The court granted that motion, setting a deadline of June 30, 2022 for unnamed direct purchasers to file claims. On June 30, 2022, 23 new entities, many related, brought new complaints against defendants or otherwise sought to intervene.

On February 10, 2023, the district court denied the Merck Defendants' and Glenmark Defendants' motions for summary judgment. In April 2023, the Merck Defendants reached settlements with the direct purchaser and retailer plaintiffs and a proposed settlement, subject to court approval, with the indirect purchaser class. Under these agreements, Merck will pay $572.5 million to resolve the direct purchaser, retailer, and indirect purchaser plaintiffs' claims, which was recorded as an expense in the Company's first quarter 2023 financial results.

RotaTeq Antitrust Litigation

On March 3, 2023, the Mayor and City Council of Baltimore filed a putative class action against MSD in the Eastern District of Pennsylvania on behalf of all third-party payors in 35 states that indirectly purchased, paid, and/or provided reimbursement for some or all of the purchase price of *RotaTeq* (Rotavirus Vaccine, Live Oral, Pentavalent), other than for resale, from March 3, 2019 to the present. Plaintiff alleges that MSD violated federal and state antitrust laws and state consumer protection laws. Plaintiff alleges that MSD has implemented an anticompetitive vaccine bundling scheme whereby MSD leverages its alleged monopoly power in certain pediatric vaccine markets to maintain its alleged monopoly power in the U.S. market for rotavirus vaccines in order to charge supracompetitive prices for *RotaTeq*. Plaintiff seeks permanent injunctive relief and unspecified monetary damages on purchases of *RotaTeq*, trebled, and fees and costs.

Bravecto Litigation

As previously disclosed, in January 2020, the Company was served with a complaint in the U.S. District Court for the District of New Jersey. Following motion practice, the plaintiffs filed a second amended complaint on July 1, 2021, seeking to certify a nationwide class action of purchasers or users of *Bravecto* (fluralaner) products in the U.S. or its territories between May 1, 2014 and July 1, 2021. Plaintiffs contend *Bravecto* causes neurological events in dogs and cats and alleges violations of the New Jersey Consumer Fraud Act, Breach of Warranty, Product Liability, and related theories. The Company moved to dismiss or, alternatively, to strike the class allegations from the second amended complaint, and that motion is pending. A similar case was filed in Quebec, Canada in May 2019. The Superior Court certified a class of dog owners in Quebec who gave *Bravecto* Chew to their dogs between February 16, 2017 and November 2, 2018 whose dogs experienced one of the conditions in the post-marketing adverse reactions section of the labeling approved on November 2, 2018. The Company and plaintiffs each appealed the class certification decision. The Court of Appeal of Quebec heard the appeal in February 2022 and issued a decision in April 2022 allowing both parties' appeals in part. The Court of Appeal amended the class period to start on July 2, 2014, allowed a second plaintiff to serve as a class representative, and modified the list of conditions in the class definition by adding "death" and removing "lack of efficacy." The Court of Appeal also added to the list of questions to be considered by the trial court the questions of whether the Consumer Protection Act of Quebec applies to the sale of a veterinary product and, if so, whether it was breached. The Company sought leave to appeal to the Supreme Court of Canada, which was denied. The case is proceeding in the Superior Court.

Patent Litigation

From time to time, generic manufacturers of pharmaceutical products file abbreviated New Drug Applications (NDAs) with the FDA seeking to market generic forms of the Company's products prior to the expiration of relevant patents owned by the Company. To protect its patent rights, the Company may file patent infringement lawsuits against such generic companies. Similar lawsuits defending the Company's patent rights may exist in other countries. The Company intends to vigorously defend its patents, which it believes are valid, against infringement by companies attempting to market products prior to the expiration of such patents. As with any litigation, there can be no assurance of the outcomes, which, if adverse, could result in significantly shortened periods of exclusivity for these products and, with respect to products acquired through acquisitions accounted for as business combinations, potentially significant intangible asset impairment charges.

Bridion — As previously disclosed, between January and November 2020, the Company received multiple Paragraph IV Certification Letters under the Hatch-Waxman Act notifying the Company that generic drug companies have filed applications to the FDA seeking pre-patent expiry approval to sell generic versions of *Bridion* (sugammadex) Injection. In March, April and December 2020, the Company filed patent infringement lawsuits in the U.S. District Courts for the District of New Jersey and the Northern District of West Virginia against those generic companies. All actions in the District of New Jersey have been consolidated. These lawsuits, which assert one or more patents covering sugammadex and methods of using sugammadex, automatically stay FDA approval of the generic applications until June 2023 or until adverse court decisions, if any, whichever

may occur earlier. The West Virginia case was jointly dismissed with prejudice on August 8, 2022 in favor of proceeding in New Jersey. The remaining defendants in the New Jersey action have stipulated to infringement of the asserted claims and have stated they are withdrawing all remaining claims and defenses other than a defense seeking to shorten the patent term extension of the sugammadex patent to December 2022. The U.S. District Court for the District of New Jersey held a one-day trial on December 19, 2022 on this remaining patent term extension calculation defense. The court ordered post-trial briefing on this defense and held closing arguments on February 3, 2023.

The Company has settled with five generic companies providing that these generic companies can bring their generic versions of *Bridion* to the market in January 2026 (which may be delayed by any applicable pediatric exclusivity) or earlier under certain circumstances. The Company has agreed to stay the lawsuit filed against two generic companies, which in exchange agreed to be bound by a judgment on the merits of the consolidated action in the District of New Jersey. One of the generic companies in the consolidated action requested dismissal of the action against it and the Company did not oppose this request, which was subsequently granted by the court. The Company does not expect this company to bring its generic version of *Bridion* to the market before January 2026 or later, depending on any applicable pediatric exclusivity, unless the Company receives an adverse court decision.

Januvia, Janumet, Janumet XR — As previously disclosed, the FDA granted pediatric exclusivity with respect to *Januvia* (sitagliptin), *Janumet* (sitagliptin/metformin HCl), and *Janumet XR* (sitagliptin and metformin HCl extended-release), which provides a further six months of exclusivity in the U.S. beyond the expiration of all patents listed in the FDA's Orange Book. Adding this exclusivity to the term of the key patent protection extended exclusivity on these products to January 2023. However, *Januvia*, *Janumet*, and *Janumet XR* contain sitagliptin phosphate monohydrate and the Company has another patent covering certain phosphate salt and polymorphic forms of sitagliptin that expires in May 2027, including pediatric exclusivity (2027 salt/polymorph patent). In 2019, Par Pharmaceutical filed suit against the Company in the U.S. District Court for the District of New Jersey, seeking a declaratory judgment of invalidity of the 2027 salt/polymorph patent. In response, the Company filed a patent infringement lawsuit in the U.S. District Court for the District of Delaware against Par Pharmaceutical and additional companies that also indicated an intent to market generic versions of *Januvia*, *Janumet*, and *Janumet XR* following expiration of key patent protection, but prior to the expiration of the 2027 salt/polymorph patent, and a later granted patent owned by the Company covering the *Janumet* formulation where its term plus the pediatric exclusivity ends in 2029. The Company also filed a patent infringement lawsuit against Mylan in the Northern District of West Virginia. The Judicial Panel on Multidistrict Litigation entered an order transferring the Company's lawsuit against Mylan to the U.S. District Court for the District of Delaware for coordinated and consolidated pretrial proceedings with the other cases pending in that district.

Prior to the beginning of the scheduled October 2021 trial in the U.S. District Court for the District of Delaware on invalidity issues, the Company settled with all defendants scheduled to participate in that trial. In the Company's case against Mylan, a bench trial was held in December 2021 in the U.S. District Court for the Northern District of West Virginia, and the closing arguments were held in April 2022. In September 2022, the District Court for the Northern District of West Virginia issued a decision in the Company's favor, upholding all asserted patent claims. Mylan (now Viatris) appealed to the U.S. Court of Appeals for the Federal Circuit. The parties have now settled the matter, and Mylan has agreed to voluntarily dismiss the appeal following entry of an amended final judgment by the district court.

Additionally, in 2019, Mylan filed a petition for *inter partes* review (IPR) at the U.S. Patent and Trademark Office (USPTO) seeking invalidity of some, but not all, of the claims of the 2027 salt/polymorph patent. The USPTO instituted IPR proceedings in May 2020, finding a reasonable likelihood that the challenged claims are not valid. A trial was held in February 2021 and a final decision was rendered in May 2021, holding that all of the challenged claims were not invalid. Mylan appealed the USPTO's decision to the U.S. Court of Appeals for the Federal Circuit, and a hearing was held in August 2022. In September 2022, the U.S. Court of Appeals for the Federal Circuit ruled in the Company's favor, upholding the USPTO's decision. Mylan submitted a combined petition for panel rehearing and rehearing en banc, for which the Company was invited by the court to provide a response. On February 3, 2023, the court issued a per curiam decision denying both rehearing requests.

In total, the Company has settled with 25 generic companies providing that these generic companies can bring their generic versions of *Januvia* and *Janumet* to the market in May 2026 or earlier under certain circumstances, and their generic versions of *Janumet XR* to the market in July 2026 or earlier under certain circumstances.

In March 2021, the Company filed a patent infringement lawsuit in the U.S. District Court for the District of Delaware against Zydus Worldwide DMCC, Zydus Pharmaceuticals (USA) Inc., and Cadila Healthcare Ltd. (collectively, Zydus). In that lawsuit, the Company alleged infringement of the 2027 salt/polymorph patent based on the filing of Zydus's NDA seeking approval of its sitagliptin tablets. In December 2022, the parties reached settlement that included dismissal of the case without prejudice enabling Zydus to seek final approval of a non-automatically substitutable product containing a different form of sitagliptin than that used in *Januvia*.

In January 2023, the Company received a Paragraph IV Certification Letter under the Hatch-Waxman Act notifying the Company that Zydus has filed a NDA seeking approval of sitagliptin/metformin HCl tablets and certifying that no valid or enforceable claim of any of the patents listed in FDA's Orange Book for *Janumet* will be infringed by the proposed Zydus product. In March 2023, the parties reached settlement enabling Zydus to seek final approval of a non-automatically substitutable product containing a different form of sitagliptin than that used in *Janumet.*

As a result of these favorable court rulings and settlement agreements related to the later expiring patent directed to the specific sitagliptin salt form of the products, the Company expects that *Januvia* and *Janumet* will not lose market exclusivity in

the U.S. until May 2026 and *Janumet XR* will not lose market exclusivity in the U.S. until July 2026, although another non-automatically substitutable form of sitagliptin is likely to be available prior to 2026.

Supplementary Protection Certificates (SPCs) for *Janumet* expired between April 7 and 10, 2023, for the majority of European countries. Prior to expiration, generic companies sought revocation of the *Janumet* SPCs in a number of European countries. In February 2022, a Finnish court referred certain questions to the Court of Justice of the European Union (CJEU) that could determine the validity of the *Janumet* SPCs in Europe, for which an oral hearing was held on March 8, 2023, and an Advocate General Opinion is expected on July 13, 2023. If the CJEU renders a decision that negatively impacts the validity of the *Janumet* SPCs throughout Europe, generic companies that were prevented from launching products during the SPC period in certain European countries may have an action for damages. Those countries include Belgium, Czech Republic, Ireland, Finland, France, Slovakia and Switzerland. If the *Janumet* SPCs are ultimately upheld, the Company has reserved its rights related to the pursuit of damages for those countries where a generic launched prior to expiry of the *Janumet* SPC.

Keytruda — The Company filed a complaint against The Johns Hopkins University (JHU) on November 29, 2022, in the District Court of Maryland. This action concerns patents emerging from a joint research collaboration between Merck and JHU regarding the use of pembrolizumab, which Merck sells under the trade name *Keytruda*. Merck and JHU partnered to design and conduct a clinical study administering *Keytruda* to cancer patients having tumors that had the genetic biomarker known as microsatellite instability-high (MSI-H). After the conclusion of the study, JHU secured U.S. patents citing the joint research study. Merck alleges that JHU has breached the collaboration agreement by filing and obtaining these patents without informing or involving Merck and then licensing the patents to others. Merck therefore brought this action for breach of contract; declaratory judgment of noninfringement; and promissory estoppel. JHU answered the complaint on April 13, 2023, denying Merck's claims, and counterclaiming for willful infringement of five issued U.S. patents, including a demand for damages.

Lynparza — In December 2022, AstraZeneca Pharmaceuticals LP received a Paragraph IV Certification Letter under the Hatch-Waxman Act notifying AstraZeneca that Natco Pharma Limited (Natco) has filed an application to the FDA seeking pre-patent expiry approval to sell generic versions of Lynparza (olaparib) tablet. In February 2023, AstraZeneca and the Company filed a patent infringement lawsuit in the U.S. District Court for the District of New Jersey against Natco. This lawsuit, which asserts one or more patents covering olaparib, automatically stays FDA approval of the generic application until June 2025 or until an adverse court decision, if any, whichever may occur earlier.

Other Litigation

There are various other pending legal proceedings involving the Company, principally product liability and intellectual property lawsuits. While it is not feasible to predict the outcome of such proceedings, in the opinion of the Company, either the likelihood of loss is remote or any reasonably possible loss associated with the resolution of such proceedings is not expected to be material to the Company's financial condition, results of operations or cash flows either individually or in the aggregate.

Legal Defense Reserves

Legal defense costs expected to be incurred in connection with a loss contingency are accrued when probable and reasonably estimable. Some of the significant factors considered in the review of these legal defense reserves are as follows: the actual costs incurred by the Company; the development of the Company's legal defense strategy and structure in light of the scope of its litigation; the number of cases being brought against the Company; the costs and outcomes of completed trials and the most current information regarding anticipated timing, progression, and related costs of pre-trial activities and trials in the associated litigation. The amount of legal defense reserves as of March 31, 2023 and December 31, 2022 of approximately $225 million and $230 million, respectively, represents the Company's best estimate of the minimum amount of defense costs to be incurred in connection with its outstanding litigation; however, events such as additional trials and other events that could arise in the course of its litigation could affect the ultimate amount of legal defense costs to be incurred by the Company. The Company will continue to monitor its legal defense costs and review the adequacy of the associated reserves and may determine to increase the reserves at any time in the future if, based upon the factors set forth, it believes it would be appropriate to do so.

9. Equity

	Three Months Ended March 31,								
	Common Stock		Other Paid-In Capital	Retained Earnings	Accumulated Other Comprehensive Loss	Treasury Stock		Non-controlling Interests	Total
($ and shares in millions except per share amounts)	Shares	Par Value				Shares	Cost		
Balance at January 1, 2022	3,577	$ 1,788	$ 44,238	$ 53,696	$ (4,429)	1,049	$ (57,109)	$ 73	$ 38,257
Net income attributable to Merck & Co., Inc.	—	—	—	4,310	—	—	—	—	4,310
Other comprehensive income, net of taxes	—	—	—	—	60	—	—	—	60
Cash dividends declared on common stock ($0.69 per share)	—	—	—	(1,754)	—	—	—	—	(1,754)
Share-based compensation plans and other	—	—	37	—	—	—	46	—	83
Net loss attributable to noncontrolling interests	—	—	—	—	—	—	—	(3)	(3)
Balance at March 31, 2022	3,577	$ 1,788	$ 44,275	$ 56,252	$ (4,369)	1,049	$ (57,063)	$ 70	$ 40,953
Balance at January 1, 2023	3,577	$ 1,788	$ 44,379	$ 61,081	$ (4,768)	1,039	$ (56,489)	$ 67	$ 46,058
Net income attributable to Merck & Co., Inc.	—	—	—	2,821	—	—	—	—	2,821
Other comprehensive loss, net of taxes	—	—	—	—	(115)	—	—	—	(115)
Cash dividends declared on common stock ($0.73 per share)	—	—	—	(1,863)	—	—	—	—	(1,863)
Treasury stock shares purchased	—	—	—	—	—	1	(149)	—	(149)
Share-based compensation plans and other	—	—	88	—	—	—	61	—	149
Net income attributable to noncontrolling interests	—	—	—	—	—	—	—	4	4
Balance at March 31, 2023	3,577	$ 1,788	$ 44,467	$ 62,039	$ (4,883)	1,040	$ (56,577)	$ 71	$ 46,905

10. Pension and Other Postretirement Benefit Plans

The Company has defined benefit pension plans covering eligible employees in the U.S. and in certain of its international subsidiaries. The net periodic benefit cost (credit) of such plans consisted of the following components:

	Three Months Ended March 31,			
	2023		2022	
($ in millions)	U.S.	International	U.S.	International
Service cost	$ 76	$ 49	$ 99	$ 75
Interest cost	133	74	103	38
Expected return on plan assets	(187)	(128)	(196)	(101)
Amortization of unrecognized prior service credit	—	(3)	(8)	(4)
Net (gain) loss amortization	—	(1)	56	25
Curtailments	2	—	3	—
Settlements	21	—	1	—
	$ 45	$ (9)	$ 58	$ 33

The Company provides medical benefits, principally to its eligible U.S. retirees and similar benefits to their dependents, through its other postretirement benefit plans. The net credit of such plans consisted of the following components:

	Three Months Ended March 31,	
($ in millions)	2023	2022
Service cost	$ 8	$ 12
Interest cost	16	11
Expected return on plan assets	(16)	(21)
Amortization of unrecognized prior service credit	(12)	(14)
Net gain amortization	(11)	(11)
	$ (15)	$ (23)

In connection with restructuring actions (see Note 5), termination charges were recorded on pension plans related to expanded eligibility for certain employees exiting Merck. Also, in connection with these restructuring activities, curtailments were recorded on certain pension plans. In addition, lump sum payments to U.S. pension plan participants triggered a partial settlement resulting in a charge of $21 million in the first quarter of 2023. This partial settlement triggered a remeasurement of some of the Company's U.S. pension plans. The remeasurement, which was calculated using discount rates and asset values as of March 31, 2023, resulted in a net increase of $44 million to net pension liabilities and also resulted in a related adjustment to *AOCL*.

The components of net periodic benefit cost (credit) other than the service cost component are included in *Other (income) expense, net* (see Note 11), with the exception of certain amounts for termination benefits and curtailments which are recorded in *Restructuring costs* if the event giving rise to the termination benefits or curtailment is related to restructuring actions.

11. Other (Income) Expense, Net

Other (income) expense, net, consisted of:

($ in millions)	Three Months Ended March 31, 2023	Three Months Ended March 31, 2022
Interest income	$ (112)	$ (7)
Interest expense	242	243
Exchange losses	61	39
(Income) loss from investments in equity securities, net [1]	(450)	708
Net periodic defined benefit plan (credit) cost other than service cost	(115)	(121)
Other, net	463	(154)
	$ 89	$ 708

[1] *Includes net realized and unrealized gains and losses from investments in equity securities either owned directly or through ownership interests in investment funds. Unrealized gains and losses from investments that are directly owned are determined at the end of the reporting period, while gains and losses from ownership interests in investment funds are accounted for on a one quarter lag.*

Other, net (as reflected in the table above) in the first quarter of 2023 includes a $572.5 million charge related to settlements with certain plaintiffs in the Zetia antitrust litigation (see Note 8).

Interest paid for the three months ended March 31, 2023 and 2022 was $208 million and $211 million, respectively.

12. Taxes on Income

The effective income tax rates were 22.6% and 11.4% for the first quarter of 2023 and 2022, respectively. The effective income tax rate for the first quarter of 2023 reflects the unfavorable discrete impact of a charge for the acquisition of Imago for which no tax benefit was recognized, as well as higher foreign taxes, the impact of the R&D capitalization provision of the Tax Cuts and Jobs Act of 2017 on the Company's U.S. global intangible low-taxed income inclusion, and net unrealized gains from investments in equity securities, which were taxed at the U.S. tax rate, partially offset by higher foreign tax credits. The effective income tax rate in the first quarter of 2022 includes the favorable impact of net unrealized losses from investments in equity securities, which were taxed at the U.S. tax rate.

13. Earnings Per Share

The calculations of earnings per share are as follows:

($ and shares in millions except per share amounts)	Three Months Ended March 31, 2023	Three Months Ended March 31, 2022
Net Income Attributable to Merck & Co., Inc.	$ 2,821	$ 4,310
Average common shares outstanding	2,538	2,528
Common shares issuable [1]	13	9
Average common shares outstanding assuming dilution	2,551	2,537
Basic Earnings per Common Share Attributable to Merck & Co., Inc. Common Shareholders	$ 1.11	$ 1.70
Earnings per Common Share Assuming Dilution Attributable to Merck & Co., Inc. Common Shareholders	$ 1.11	$ 1.70

[1] *Issuable primarily under share-based compensation plans.*

For the first quarter of 2023 and 2022, 1 million and 7 million, respectively, of common shares issuable under share-based compensation plans were excluded from the computation of earnings per common share assuming dilution because the effect would have been antidilutive.

14. Other Comprehensive Income (Loss)

Changes in each component of other comprehensive income (loss) are as follows:

	Three Months Ended March 31,			
($ in millions)	Derivatives	Employee Benefit Plans	Foreign Currency Translation Adjustment	Accumulated Other Comprehensive Loss
Balance January 1, 2022, net of taxes	$ 144	$ (2,743)	$ (1,830)	$ (4,429)
Other comprehensive income (loss) before reclassification adjustments, pretax	148	1	(18)	131
Tax	(31)	(2)	(17)	(50)
Other comprehensive income (loss) before reclassification adjustments, net of taxes	117	(1)	(35)	81
Reclassification adjustments, pretax	(68) [1]	45 [2]	—	(23)
Tax	14	(12)	—	2
Reclassification adjustments, net of taxes	(54)	33	—	(21)
Other comprehensive income (loss), net of taxes	63	32	(35)	60
Balance March 31, 2022, net of taxes	$ 207	$ (2,711)	$ (1,865)	$ (4,369)
Balance January 1, 2023, net of taxes	$ 73	$ (2,408)	$ (2,433)	$ (4,768)
Other comprehensive income (loss) before reclassification adjustments, pretax	(66)	(47)	79	(34)
Tax	14	2	(20)	(4)
Other comprehensive income (loss) before reclassification adjustments, net of taxes	(52)	(45)	59	(38)
Reclassification adjustments, pretax	(102) [1]	(7) [2]	9	(100)
Tax	21	2	—	23
Reclassification adjustments, net of taxes	(81)	(5)	9	(77)
Other comprehensive income (loss), net of taxes	(133)	(50)	68	(115)
Balance March 31, 2023, net of taxes	$ (60)	$ (2,458)	$ (2,365)	$ (4,883)

[1] *Primarily relates to foreign currency cash flow hedges that were reclassified from* AOCL *to* Sales.

[2] *Includes net amortization of prior service cost, actuarial gains and losses, settlements and curtailments included in net periodic benefit cost (see Note 10).*

15. Segment Reporting

The Company's operations are principally managed on a product basis and include two operating segments, Pharmaceutical and Animal Health, both of which are reportable segments.

The Pharmaceutical segment includes human health pharmaceutical and vaccine products. Human health pharmaceutical products consist of therapeutic and preventive agents, generally sold by prescription, for the treatment of human disorders. The Company sells these human health pharmaceutical products primarily to drug wholesalers and retailers, hospitals, government agencies and managed health care providers such as health maintenance organizations, pharmacy benefit managers and other institutions. Human health vaccine products consist of preventive pediatric, adolescent and adult vaccines. The Company sells these human health vaccines primarily to physicians, wholesalers, physician distributors and government entities. A large component of pediatric and adolescent vaccine sales are made to the U.S. Centers for Disease Control and Prevention Vaccines for Children program, which is funded by the U.S. government. Additionally, the Company sells vaccines to the Federal government for placement into vaccine stockpiles.

The Animal Health segment discovers, develops, manufactures and markets a wide range of veterinary pharmaceutical and vaccine products, as well as health management solutions and services, for the prevention, treatment and control of disease in all major livestock and companion animal species. The Company also offers an extensive suite of digitally connected identification, traceability and monitoring products. The Company sells its products to veterinarians, distributors, animal producers, farmers and pet owners.

Sales of the Company's products were as follows:

	Three Months Ended March 31,					
	2023			2022		
($ in millions)	U.S.	Int'l	Total	U.S.	Int'l	Total
Pharmaceutical:						
Oncology						
Keytruda	$ 3,485	$ 2,310	$ 5,795	$ 2,779	$ 2,030	$ 4,809
Alliance revenue-Lynparza [(1)]	142	133	275	141	125	266
Alliance revenue-Lenvima [(1)]	153	79	232	156	71	227
Alliance revenue-Reblozyl [(2)]	30	12	43	27	25	52
Welireg	41	1	42	18	—	18
Vaccines						
Gardasil/Gardasil 9	416	1,556	1,972	418	1,042	1,460
ProQuad/M-M-R II*/Varivax*	421	107	528	371	99	470
RotaTeq	180	117	297	175	41	216
Vaxneuvance	94	13	106	5	—	5
Pneumovax 23	40	56	96	118	55	173
Vaqta	30	10	40	29	7	36
Hospital Acute Care						
Bridion	276	210	487	195	199	395
Prevymis	54	75	129	40	54	94
Primaxin	4	76	80	1	58	58
Dificid	62	3	65	49	3	52
Noxafil	14	46	60	10	48	57
Zerbaxa	27	23	50	18	12	30
Cardiovascular						
Alliance revenue-Adempas/Verquvo [(3)]	83	16	99	71	1	72
Adempas	—	59	59	—	61	61
Virology						
Lagevrio	(2)	394	392	1,523	1,723	3,247
Isentress/Isentress HD	52	71	123	61	97	158
Neuroscience						
Belsomra	16	40	56	20	48	69
Immunology						
Simponi	—	180	180	—	186	186
Remicade	—	51	51	—	61	61
Diabetes						
Januvia	271	280	551	325	454	779
Janumet	56	272	329	63	391	454
Other pharmaceutical [(4)]	172	414	584	160	443	602
Total Pharmaceutical segment sales	6,117	6,604	12,721	6,773	7,334	14,107
Animal Health:						
Livestock	174	676	849	171	661	832
Companion Animals	308	334	642	302	348	650
Total Animal Health segment sales	482	1,010	1,491	473	1,009	1,482
Total segment sales	6,599	7,614	14,212	7,246	8,343	15,589
Other [(5)]	60	214	275	93	220	312
	$ 6,659	$ 7,828	$ 14,487	$ 7,339	$ 8,563	$ 15,901

U.S. plus international may not equal total due to rounding.

[(1)] *Alliance revenue for Lynparza and Lenvima represents Merck's share of profits, which are product sales net of cost of sales and commercialization costs (see Note 3).*

[(2)] *Alliance revenue for Reblozyl represents royalties and, for 2022, also includes the receipt of a regulatory approval milestone payment (see Note 3).*

[(3)] *Alliance revenue for Adempas/Verquvo represents Merck's share of profits from sales in Bayer's marketing territories, which are product sales net of cost of sales and commercialization costs (see Note 3).*

[(4)] *Other pharmaceutical primarily reflects sales of other human health pharmaceutical products, including products within the franchises not listed separately.*

[(5)] *Other is primarily comprised of miscellaneous corporate revenue, including revenue hedging activities which increased sales by $99 million and $69 million for the three months ended March 31, 2023 and 2022, respectively, as well as revenue from third-party manufacturing arrangements (including sales to Organon). Other for the three months ended March 31, 2023 and 2022 also includes $51 million and $114 million, respectively, related to upfront and milestone payments received by Merck for out-licensing arrangements.*

Product sales are recorded net of the provision for discounts, including chargebacks, which are customer discounts that occur when a contracted customer purchases through an intermediary wholesale purchaser, and rebates that are owed based upon definitive contractual agreements or legal requirements with private sector and public sector (Medicaid and Medicare Part D) benefit providers, after the final dispensing of the product by a pharmacy to a benefit plan participant. These discounts, in the aggregate, reduced U.S. sales by $3.1 billion and $2.9 billion for the three months ended March 31, 2023 and 2022, respectively.

Consolidated sales by geographic area where derived are as follows:

	Three Months Ended March 31,	
($ in millions)	2023	2022
United States	$ 6,659	$ 7,339
Europe, Middle East and Africa	3,303	4,359
China	1,715	1,143
Asia Pacific (other than China and Japan)	846	930
Japan	758	989
Latin America	661	607
Other	545	534
	$ 14,487	$ 15,901

A reconciliation of segment profits to *Income Before Taxes* is as follows:

	Three Months Ended March 31,	
($ in millions)	2023	2022
Segment profits:		
Pharmaceutical segment	$ 9,140	$ 9,501
Animal Health segment	566	585
Total segment profits	9,706	10,086
Other profits	164	194
Unallocated:		
Interest income	112	7
Interest expense	(242)	(243)
Amortization	(543)	(699)
Depreciation	(398)	(378)
Research and development	(4,147)	(2,446)
Restructuring costs	(67)	(53)
Charge for Zetia antitrust litigation settlements	(573)	—
Other unallocated, net	(362)	(1,607)
	$ 3,650	$ 4,861

Pharmaceutical segment profits are comprised of segment sales less standard costs, as well as selling, general and administrative expenses directly incurred by the segment. Animal Health segment profits are comprised of segment sales, less all cost of sales, as well as selling, general and administrative expenses and research and development costs directly incurred by the segment. For internal management reporting presented to the chief operating decision maker, Merck does not allocate the remaining cost of sales not included in segment profits as described above, research and development expenses incurred in Merck Research Laboratories, the Company's research and development division that focuses on human health-related activities, or general and administrative expenses, nor the cost of financing these activities. Separate divisions maintain responsibility for monitoring and managing these costs, including depreciation related to fixed assets utilized by these divisions and, therefore, they are not included in segment profits. In addition, costs related to restructuring activities, as well as the amortization of intangible assets and purchase accounting adjustments are not allocated to segments.

Other profits are primarily comprised of miscellaneous corporate profits, as well as operating profits related to third-party manufacturing arrangements.

Other unallocated, net, includes expenses from corporate and manufacturing cost centers, goodwill and other intangible asset impairment charges, gains or losses on sales of businesses, expense or income related to changes in the estimated fair value measurement of liabilities for contingent consideration, and other miscellaneous income or expense items.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

Business Developments

Below is a summary of significant business development activity thus far in 2023. See Note 2 to the condensed consolidated financial statements for additional information.

In April 2023, Merck announced an agreement to acquire Prometheus Biosciences, Inc. (Prometheus), a clinical-stage biotechnology company pioneering a precision medicine approach for the discovery, development, and commercialization of novel therapeutic and companion diagnostic products for the treatment of immune-mediated diseases. Prometheus' lead candidate, PRA023, is a humanized monoclonal antibody directed to tumor necrosis factor-like ligand 1A, a target associated with both intestinal inflammation and fibrosis. Prometheus is developing PRA023 for the treatment of immune-mediated diseases including ulcerative colitis, Crohn's disease, and other autoimmune conditions. Under the terms of the acquisition agreement, Merck, through a subsidiary, will acquire all of the outstanding shares of Prometheus for $200 per share in cash for a total equity value of approximately $10.8 billion. The acquisition is subject to Prometheus shareholder approval. The closing of the proposed transaction will be subject to certain conditions, including the expiration of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act and other customary conditions. The transaction is expected to close in the third quarter of 2023. If the proposed transaction closes, the Company anticipates it will be accounted for as an asset acquisition, which would result in a charge of approximately $10.3 billion in *Research and development* expenses or approximately $4.00 per share. Additionally, Merck anticipates earnings per share (EPS) will be negatively affected by approximately $0.25 in the first 12 months following the closing of the transaction resulting from investments to advance the related pipeline assets, as well as the cost of financing.

In February 2023, Merck and Kelun-Biotech (a holding subsidiary of Sichuan Kelun Pharmaceutical Co., Ltd.) closed a license and collaboration agreement expanding their relationship in which Merck gained exclusive rights for the research, development, manufacture and commercialization of up to seven investigational preclinical antibody drug conjugates (ADCs) for the treatment of cancer. Kelun-Biotech retained the right to research, develop, manufacture and commercialize certain licensed and option ADCs for Chinese mainland, Hong Kong and Macau. Merck made an upfront payment of $175 million, which was recorded in *Research and development* expenses in the first quarter of 2023. In addition, Kelun-Biotech is eligible to receive future contingent milestone payments and tiered royalties on future net sales for any commercialized ADC product. Also, in connection with the agreement, Merck invested $100 million in Kelun-Biotech's Series B preferred shares in January 2023.

In January 2023, Merck acquired Imago BioSciences, Inc. (Imago), a clinical stage biopharmaceutical company developing new medicines for the treatment of myeloproliferative neoplasms and other bone marrow diseases, for $1.35 billion (including payments to settle share-based equity awards) and also incurred approximately $60 million of transaction costs. Imago's lead candidate bomedemstat, MK-3543 (formerly IMG-7289), is an investigational orally available lysine-specific demethylase 1 inhibitor currently being evaluated in multiple Phase 2 clinical trials for the treatment of essential thrombocythemia, myelofibrosis, and polycythemia vera, in addition to other indications. The transaction was accounted for as an acquisition of an asset. Merck recorded net assets of $219 million, as well as *Research and development* expenses of $1.2 billion in the first quarter of 2023 related to the transaction. There are no future contingent payments associated with the acquisition.

Pricing

Global efforts toward health care cost containment continue to exert pressure on product pricing and market access worldwide. Changes to the U.S. health care system enacted in prior years as part of health care reform, as well as increased purchasing power of entities that negotiate on behalf of Medicare, Medicaid, and private sector beneficiaries, have contributed to pricing pressure. In several international markets, government-mandated pricing actions have reduced prices of generic and patented drugs. In addition, the Company's sales performance in the first three months of 2023 was negatively affected by other cost-reduction measures taken by governments and other third parties to lower health care costs. In 2022, the U.S. Congress passed the Inflation Reduction Act, which makes significant changes to how drugs are covered and paid for under the Medicare program, including the creation of financial penalties for drugs whose prices rise faster than the rate of inflation, redesign of the Medicare Part D program to require manufacturers to bear more of the liability for certain drug benefits, and government price-setting for certain Medicare Part D drugs (starting in 2026) and Medicare Part B drugs (starting in 2028). In the U.S., the Biden Administration and Congress continue to discuss legislation designed to control health care costs, including the cost of drugs. The Company anticipates all of these actions and additional actions in the future will negatively affect sales and profits.

Supply Chain

As a result of global macroeconomic conditions, the Company is experiencing some minor disruption and volatility in its global supply chain network. These disruptions could increase in the future and cause delays in shipments of raw materials and packaging, as well as related cost inflation.

Operating Results

Sales

($ in millions)	Three Months Ended March 31, 2023	2022	% Change	% Change Excluding Foreign Exchange
United States	$ 6,659	$ 7,339	(9)%	(9)%
International	7,828	8,563	(9)%	(2)%
Total	$ 14,487	$ 15,901	(9)%	(5)%

U.S. plus international may not equal total due to rounding.

Worldwide sales declined 9% to $14.5 billion in the first quarter of 2023 primarily due to lower sales in the virology franchise, largely attributable to *Lagevrio* (molnupiravir), which had sales of $392 million in the first quarter of 2023 compared with $3.2 billion in the first quarter of 2022. Also contributing to the revenue decline in the first quarter of 2023 were lower sales in the diabetes franchise due to *Januvia* (sitagliptin) and *Janumet* (sitagliptin and metformin HCl), as well as lower sales of *Pneumovax* 23 (pneumococcal vaccine polyvalent). The sales decline in the first quarter of 2023 was partially offset by higher sales in the oncology franchise, largely driven by strong growth of *Keytruda* (pembrolizumab), higher sales in the vaccines franchise, primarily attributable to growth of *Gardasil* 9 (Human Papillomavirus 9-valent Vaccine, Recombinant) and the ongoing launch of *Vaxneuvance* (Pneumococcal 15-valent Conjugate Vaccine) for pediatric use, as well as higher sales of hospital acute care products, including *Bridion* (sugammadex) Injection.

See Note 15 to the condensed consolidated financial statements for details on sales of the Company's products. A discussion of performance for select products in the franchises follows.

Pharmaceutical Segment

Oncology

($ in millions)	Three Months Ended March 31, 2023	2022	% Change	% Change Excluding Foreign Exchange
Keytruda	$ 5,795	$ 4,809	20 %	24 %
Alliance Revenue - Lynparza [(1)]	275	266	3 %	8 %
Alliance Revenue - Lenvima [(1)]	232	227	2 %	5 %
Alliance Revenue - Reblozyl [(2)]	43	52	(19)%	(19)%
Welireg	42	18	*	*

** > 100%*

(1) Alliance revenue represents Merck's share of profits, which are product sales net of cost of sales and commercialization costs (see Note 3 to the condensed consolidated financial statements).

(2) Alliance revenue represents royalties and, for 2022, also includes a payment received related to the achievement of a regulatory approval milestone (see Note 3 to the consolidated financial statements).

Keytruda is an anti-PD-1 (programmed death receptor-1) therapy that has been approved as monotherapy for the treatment of certain patients with cervical cancer, classical Hodgkin lymphoma, cutaneous squamous cell carcinoma, esophageal or gastroesophageal junction (GEJ) carcinoma, head and neck squamous cell carcinoma (HNSCC), hepatocellular carcinoma (HCC), non-small-cell lung cancer (NSCLC), melanoma, Merkel cell carcinoma, microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) cancer (solid tumors) including MSI-H/dMMR colorectal cancer, MSI-H/dMMR advanced endometrial carcinoma, primary mediastinal large B-cell lymphoma (PMBCL), tumor mutational burden-high (TMB-H) cancer (solid tumors), and urothelial carcinoma including non-muscle invasive bladder cancer. Additionally, *Keytruda* is approved as monotherapy for the adjuvant treatment of certain patients with renal cell carcinoma (RCC) at intermediate-high or high risk of recurrence and for certain patients with completely resected stage IIB, IIC or III melanoma, and for adjuvant treatment following resection and platinum-based chemotherapy for adult patients with stage 1B (T2a ≥4 cm), II, or IIIA NSCLC. *Keytruda* is also approved for certain patients with high-risk early-stage triple-negative breast cancer (TNBC) in combination with chemotherapy as neoadjuvant treatment, and then continued as a single agent as adjuvant treatment after surgery. In addition, *Keytruda* is approved for the treatment of certain patients in combination with chemotherapy for metastatic squamous and nonsquamous NSCLC, in combination with chemotherapy with or without bevacizumab for advanced cervical cancer, in combination with chemotherapy for esophageal cancer, in combination with trastuzumab, fluoropyrimidine- and platinum-containing chemotherapy for human epidermal growth factor 2 (HER2)-positive gastric or GEJ adenocarcinoma, in combination with chemotherapy for HNSCC, in combination with chemotherapy for locally recurrent unresectable or metastatic TNBC, in combination with axitinib for advanced RCC, in combination with Lenvima for certain patients with advanced endometrial carcinoma or advanced RCC, and in combination with enfortumab vedotin for certain patients with locally advanced or metastatic urothelial carcinoma who are not eligible for cisplatin-containing chemotherapy. The *Keytruda* clinical development program includes studies across a broad range of cancer types. See "Research and Development Update" below.

Global sales of *Keytruda* grew 20% in the first quarter of 2023. Sales growth was primarily driven by higher demand as the Company continues to launch *Keytruda* with multiple new indications globally. Sales growth in the U.S. reflects increased

uptake across earlier-stage indications including in high-risk early stage TNBC, as well as certain types of RCC and melanoma, and higher demand across the multiple approved metastatic indications, in particular for the treatment of certain types of RCC, NSCLC, TNBC, and HNSCC cancers. *Keytruda* sales growth in international markets reflects higher demand for the HNSCC and RCC metastatic indications, as well as uptake in earlier-stage indications, particularly in Europe and Latin America.

Keytruda received the following regulatory approvals thus far in 2023.

Date	Approval
January 2023	FDA approval as a single agent for adjuvant treatment following surgical resection and platinum-based chemotherapy for adult patients with stage IB (T2a ≥4 cm), II, or IIIA NSCLC, based on the KEYNOTE-091 trial.
March 2023	FDA full approval for the treatment of adult and pediatric patients with unresectable or metastatic MSI-H or dMMR solid tumors that have progressed following prior treatment and who have no satisfactory alternative treatment options. The conversion from an accelerated to a full (regular) approval is based on results from the Phase 2 KEYNOTE-158, KEYNOTE-164 and KEYNOTE-051 trials.
April 2023	FDA accelerated approval in combination with enfortumab vedotin-ejfv for the treatment of adult patients with locally advanced or metastatic urothelial carcinoma who are not eligible for cisplatin-containing chemotherapy, based on data from the KEYNOTE-869 trial dose escalation cohort, Cohort A and Cohort K, which was conducted in collaboration with Seagen and Astellas.

Lynparza (olaparib) is an oral poly (ADP-ribose) polymerase (PARP) inhibitor being developed as part of a collaboration with AstraZeneca PLC (AstraZeneca) (see Note 3 to the condensed consolidated financial statements). Lynparza is approved for the treatment of certain types of advanced or recurrent ovarian, early or metastatic breast, metastatic pancreatic and metastatic castration-resistant prostate cancers. Alliance revenue related to Lynparza increased 3% in the first quarter of 2023 largely driven by higher demand, particularly in Europe in certain patients with ovarian cancer.

Lenvima is an oral receptor tyrosine kinase inhibitor being developed as part of a collaboration with Eisai Co., Ltd. (Eisai) (see Note 3 to the condensed consolidated financial statements). Lenvima is approved for the treatment of certain types of thyroid cancer, RCC, HCC, in combination with everolimus for certain patients with advanced RCC, and in combination with *Keytruda* for certain patients with advanced endometrial carcinoma or advanced RCC. Alliance revenue related to Lenvima grew 2% in the first quarter of 2023 reflecting uptake in the advanced RCC indication in Europe, partially offset by lower volumes in China.

Reblozyl (luspatercept-aamt) is a first-in-class erythroid maturation recombinant fusion protein that is being commercialized through a global collaboration with Bristol Myers Squibb (see Note 3 to the condensed consolidated financial statements). Reblozyl is approved for the treatment of anemia in certain rare blood disorders. Merck recorded alliance revenue related to this collaboration of $43 million in the first quarter of 2023 (consisting of royalties) compared with $52 million in the first quarter of 2022 (consisting of royalties of $32 million and the receipt of a regulatory approval milestone payment of $20 million).

Sales of *Welireg* (belzutifan), for the treatment of adult patients with certain von Hippel-Lindau disease-associated tumors, were $42 million in the first quarter of 2023 compared with $18 million in the first quarter of 2022 due to continued uptake in the U.S. following launch in 2021.

Vaccines

($ in millions)	Three Months Ended March 31, 2023	Three Months Ended March 31, 2022	% Change	% Change Excluding Foreign Exchange
Gardasil/Gardasil 9	$ 1,972	$ 1,460	35 %	43 %
ProQuad	190	162	17 %	18 %
M-M-R II	102	103	(1)%	— %
Varivax	236	204	15 %	17 %
RotaTeq	297	216	38 %	42 %
Vaxneuvance	106	5	*	*
Pneumovax 23	96	173	(44)%	(40)%

** > 100%*

Combined worldwide sales of *Gardasil* (Human Papillomavirus Quadrivalent [Types 6, 11, 16 and 18] Vaccine, Recombinant) and *Gardasil* 9, vaccines to help prevent certain cancers and other diseases caused by certain types of human papillomavirus (HPV), grew 35% in the first quarter of 2023 driven primarily by strong demand outside of the U.S., particularly in China, which also benefited from the timing of shipments and increased supply. Sales of *Gardasil* 9 in the U.S. were essentially flat in the first quarter of 2023 as lower sales due to public sector buying patterns were offset by higher pricing.

Global sales of *ProQuad* (Measles, Mumps, Rubella and Varicella Virus Vaccine Live), a pediatric combination vaccine to help protect against measles, mumps, rubella and varicella, increased 17% in the first quarter of 2023 primarily reflecting higher demand and pricing in the U.S. and higher demand in Europe.

Worldwide sales of *M-M-R* II (Measles, Mumps and Rubella Virus Vaccine Live), a vaccine to help protect against measles, mumps and rubella, declined 1% in the first quarter of 2023 primarily due to lower tenders in Latin America, largely offset by higher pricing and demand in the U.S.

Global sales of *Varivax* (Varicella Virus Vaccine Live), a vaccine to help prevent chickenpox (varicella), grew 15% in the first quarter of 2023 primarily attributable to higher demand and pricing in the U.S.

Global sales of *RotaTeq* (Rotavirus Vaccine, Live Oral, Pentavalent), a vaccine to help protect against rotavirus gastroenteritis in infants and children, grew 38% in the first quarter of 2023 primarily due to inventory stocking in China.

Worldwide sales of *Vaxneuvance*, a vaccine to help prevent invasive pneumococcal disease, increased to $106 million in the first quarter of 2023 primarily due to continued uptake in the pediatric indication in the U.S. following launch in 2022.

Worldwide sales of *Pneumovax* 23, a vaccine to help prevent pneumococcal disease, declined 44% in the first quarter of 2023 primarily reflecting lower demand in the U.S. as the market continues to shift toward newer adult pneumococcal conjugate vaccines following changes in the recommendations of the U.S. Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices in 2021. The Company expects the decline in U.S. sales of *Pneumovax* 23 to continue.

Hospital Acute Care

($ in millions)	Three Months Ended March 31, 2023	Three Months Ended March 31, 2022	% Change	% Change Excluding Foreign Exchange
Bridion	$ 487	$ 395	23 %	27 %
Prevymis	129	94	38 %	44 %

Worldwide sales of *Bridion*, for the reversal of two types of neuromuscular blocking agents used during surgery, grew 23% in the first quarter of 2023 primarily due to higher demand, particularly in the U.S., reflecting *Bridion*'s growing share among neuromuscular blockade reversal agents. The patent that provides market exclusivity for *Bridion* in the European Union (EU) will expire in July 2023; the Company anticipates sales of *Bridion* in these markets will decline thereafter.

Worldwide sales of *Prevymis* (letermovir), a medicine for prophylaxis (prevention) of cytomegalovirus (CMV) infection and disease in adult CMV-seropositive recipients of an allogenic hematopoietic stem cell transplant, grew 38% in the first quarter of 2023 due to higher demand in the U.S. and Europe, as well as uptake from the 2022 launch in China. In February 2023, the FDA granted priority review for a supplemental New Drug Application (NDA) for *Prevymis* for prophylaxis of CMV disease in adult kidney transplant recipients at high risk (D+/R-); the Prescription Drug User Fee Act (PDUFA), or target action, date is June 5, 2023.

Cardiovascular

($ in millions)	Three Months Ended March 31, 2023	Three Months Ended March 31, 2022	% Change	% Change Excluding Foreign Exchange
Alliance Revenue - Adempas/Verquvo [(1)]	$ 99	$ 72	38 %	38 %
Adempas	59	61	(3)%	5 %

[(1)] *Alliance revenue represents Merck's share of profits from sales in Bayer's marketing territories, which are product sales net of cost of sales and commercialization costs (see Note 3 to the condensed consolidated financial statements).*

Adempas (riociguat) and Verquvo (vericiguat) are part of a worldwide collaboration with Bayer AG (Bayer) to market and develop soluble guanylate cyclase (sGC) modulators (see Note 3 to the condensed consolidated financial statements). Adempas is approved for the treatment of certain types of pulmonary arterial hypertension and chronic pulmonary hypertension. Verquvo is approved to reduce the risk of cardiovascular death and heart failure hospitalization following a hospitalization for heart failure or need for outpatient intravenous diuretics in adults with symptomatic chronic heart failure and reduced ejection fraction. Verquvo was approved in the U.S., the EU and Japan in 2021 and has since been approved in several other markets. Alliance revenue from the collaboration grew 38% in the first quarter of 2023 primarily due to higher profit sharing reflecting increased demand in Bayer's marketing territories. Revenue also includes sales of Adempas and Verquvo in Merck's marketing territories. Sales of Adempas in Merck's marketing territories were nearly flat in the first quarter of 2023 compared with the prior year.

Virology

($ in millions)	Three Months Ended March 31, 2023	Three Months Ended March 31, 2022	% Change	% Change Excluding Foreign Exchange
Lagevrio	$ 392	$ 3,247	(88)%	(87)%
Isentress/Isentress HD	123	158	(23)%	(20)%

Lagevrio is an investigational oral antiviral COVID-19 medicine being developed in a collaboration with Ridgeback (see Note 3 to the condensed consolidated financial statements). Following initial authorizations in certain markets in the fourth quarter of 2021, *Lagevrio* has since received multiple additional authorizations worldwide. Sales of *Lagevrio* declined 88% in the first quarter of 2023 largely attributable to sales in the U.S. and UK markets in the first quarter of 2022 that did not recur in the first quarter of 2023. The *Lagevrio* sales decline was also attributable to lower sales in Japan and Australia. The Company expects full-year 2023 *Lagevrio* sales to be approximately $1.0 billion. In April 2023, Japan's Ministry of Health, Labor and Welfare granted full approval for *Lagevrio*. *Lagevrio* was previously granted Special Approval for Emergency in Japan in December 2021.

Global combined sales of *Isentress/Isentress HD* (raltegravir), an HIV integrase inhibitor for use in combination with other antiretroviral agents for the treatment of HIV-1 infection, declined 23% in the first quarter of 2023 primarily due to lower global demand, reflecting in part competitive pressure particularly in Europe and the U.S. The Company expects competitive pressure for *Isentress/Isentress HD* to continue. The patent that provides market exclusivity for *Isentress/Isentress HD* in the EU will expire in July 2023; the Company anticipates sales declines of *Isentress/Isentress HD* in these markets will accelerate thereafter.

Diabetes

($ in millions)	Three Months Ended March 31, 2023	Three Months Ended March 31, 2022	% Change	% Change Excluding Foreign Exchange
Januvia/Janumet	$ 880	$ 1,233	(29)%	(25)%

Worldwide combined sales of *Januvia* and *Janumet*, medicines that help lower blood sugar levels in adults with type 2 diabetes, declined 29% in the first quarter of 2023 primarily reflecting the loss of exclusivity in several markets in Europe and the Asia Pacific region, as well as in Canada, coupled with lower demand and pricing in the U.S. due to competitive pressures.

While the key U.S. patent for *Januvia* and *Janumet* claiming the sitagliptin compound expired in January 2023, as a result of favorable court rulings and settlement agreements related to a later expiring patent directed to the specific sitagliptin salt form of the products (see Note 8 to the condensed consolidated financial statements), the Company expects that *Januvia* and *Janumet* will not lose market exclusivity in the U.S. until May 2026 and *Janumet XR* will not lose market exclusivity in the U.S. until July 2026, although another non-automatically substitutable form of sitagliptin is likely to be available prior to 2026. As a result of competitive pressures, the Company anticipates pricing and volume declines for *Januvia* and *Janumet* in the U.S. for the remainder of 2023 and thereafter.

The Company lost market exclusivity for *Januvia* in all of the EU and for *Janumet* in some European countries in September 2022. Exclusivity for *Janumet* was lost in other European countries in April 2023. While the Company lost market exclusivity for *Januvia* in China in 2022 with the launch of a generic equivalent product, the impact on sales in 2023 is expected to be modest. Although several generic equivalents of *Janumet* have been approved in China, none have launched, and the Company expects it is unlikely that any will launch prior to December 2023.

Combined sales of *Januvia* and *Janumet* in Europe, China and the U.S. represented 11%, 13% and 37%, respectively, of total combined *Januvia* and *Janumet* sales for the first quarter of 2023.

In response to a request from a regulatory authority, Merck evaluated its sitagliptin-containing products for the presence of nitrosamines. Nitrosamines are organic compounds found at trace levels in water and food. Nitrosamines can also result from chemical reactions and can form in drugs either due to the drug's manufacturing process, chemical structure, or the conditions in which the drugs are stored or packaged. The Company detected a nitrosamine identified as Nitroso-STG-19 (NTTP) in some batches of its sitagliptin-containing medicines. The Company has engaged with major health authorities around the world and has implemented additional quality controls to ensure its portfolio of sitagliptin-containing products meet health authorities' interim acceptable NTTP limits for continuing distribution of product to the market. The Company is making progress in its efforts to reduce the level of nitrosamines in its sitagliptin-containing medicines. However, difficulties in reducing those levels, or achieving timely regulatory approvals for required changes, could result in product shortages.

Animal Health Segment

($ in millions)	Three Months Ended March 31, 2023	Three Months Ended March 31, 2022	% Change	% Change Excluding Foreign Exchange
Livestock	$ 849	$ 832	2 %	8 %
Companion Animal	642	650	(1)%	2 %

Sales of livestock products grew 2% in the first quarter of 2023 primarily reflecting strong demand in the ruminant and poultry product portfolio, which includes technology solution products, as well as higher pricing. Sales of companion animal products declined 1% in the first quarter of 2023. Excluding the unfavorable effect of foreign exchange, companion animal sales performance primarily reflects higher pricing. Sales of the *Bravecto* (fluralaner) parasiticide line of products were $314 million in both the first quarter of 2023 and the first quarter of 2022.

Costs, Expenses and Other

($ in millions)	Three Months Ended March 31, 2023	2022	% Change
Cost of sales	$ 3,926	$ 5,380	(27)%
Selling, general and administrative	2,479	2,323	7 %
Research and development	4,276	2,576	66 %
Restructuring costs	67	53	26 %
Other (income) expense, net	89	708	(87)%
	$ 10,837	$ 11,040	(2)%

Cost of Sales

Cost of sales decreased 27% in the first quarter of 2023. Cost of sales includes $221 million and $1.7 billion in the first quarter of 2023 and 2022, respectively, related to sales of *Lagevrio*, which is being developed in a collaboration with Ridgeback (see Note 3 to the condensed consolidated financial statements). Cost of sales also includes the amortization of intangible assets recorded in connection with acquisitions, collaborations, and licensing arrangements, which totaled $532 million and $683 million in the first quarter of 2023 and 2022, respectively. Amortization expense in the first quarter of 2023 and 2022 includes $72 million and $250 million, respectively, of cumulative catch-up amortization related to Merck's collaborations with Eisai and AstraZeneca, respectively, (see Note 3 to the condensed consolidated financial statements). Also included in cost of sales are expenses associated with restructuring activities, which amounted to $29 million and $46 million in the first quarter of 2023 and 2022, respectively, including accelerated depreciation and asset write-offs related to the planned sale or closure of manufacturing facilities. Separation costs associated with manufacturing-related headcount reductions have been incurred and are reflected in *Restructuring costs* as discussed below.

Gross margin was 72.9% in the first quarter of 2023 compared with 66.2% in the first quarter of 2022. The gross margin improvement primarily reflects the favorable impacts of lower *Lagevrio* sales (which have a low gross margin), product mix and lower amortization of intangible assets (noted above).

Selling, General and Administrative

Selling, general and administrative (SG&A) expenses increased 7% in the first quarter of 2023 primarily due to higher administrative costs and increased promotional spending, partially offset by the favorable effect of foreign exchange.

Research and Development

Research and development (R&D) expenses increased 66% to $4.3 billion in the first quarter of 2023 primarily due to a $1.2 billion charge for the acquisition of Imago, as well as higher upfront charges related to collaborations and licensing arrangements. Also contributing to the increase in R&D expenses were higher compensation and benefit costs, reflecting in part increased headcount to support clinical development activity, higher investments in discovery research and early drug development, as well as increased clinical development spending. The increase in R&D expenses was partially offset by the favorable effect of foreign exchange.

R&D expenses are comprised of the costs directly incurred by Merck Research Laboratories (MRL), the Company's research and development division that focuses on human health-related activities, which were $2.1 billion and $1.8 billion for the first quarter of 2023 and 2022, respectively. Also included in R&D expenses are Animal Health research costs, licensing costs and costs incurred by other divisions in support of R&D activities, including depreciation, production and general and administrative, which in the aggregate were approximately $2.2 billion and $750 million for the first quarter of 2023 and 2022, respectively. The increase in these expenses in the first quarter of 2023 was largely attributable to a $1.2 billion charge for the acquisition of Imago (as noted above) and a $175 million charge for a license and collaboration agreement with Kelun-Biotech. See Note 2 for additional information related to business development activity.

Restructuring Costs

In 2019, Merck approved a global restructuring program (Restructuring Program) as part of a worldwide initiative focused on optimizing the Company's manufacturing and supply network, as well as reducing its global real estate footprint. The actions contemplated under the Restructuring Program are expected to be substantially completed by the end of 2023, with the cumulative pretax costs to be incurred by the Company to implement the program estimated to be approximately $3.7 billion. Merck expects to record charges of approximately $400 million for the full year of 2023 related to the Restructuring Program. The Company anticipates the actions under the Restructuring Program will result in cumulative annual net cost savings of approximately $900 million by the end of 2023.

Restructuring costs, primarily representing separation and other related costs associated with these restructuring activities, were $67 million and $53 million for the first quarter of 2023 and 2022, respectively. Separation costs incurred were associated with actual headcount reductions, as well as estimated expenses under existing severance programs for involuntary headcount reductions that were probable and could be reasonably estimated. Also included in restructuring costs are asset abandonment, facility shut-down and other related costs, as well as employee-related costs such as curtailment, settlement and

termination charges associated with pension and other postretirement benefit plans and share-based compensation plan costs. For segment reporting, restructuring costs are unallocated expenses.

Additional costs associated with the Company's restructuring activities are included in *Cost of sales*, *Selling, general and administrative* expenses and *Research and development* costs. The Company recorded aggregate pretax costs of $97 million and $127 million in the first quarter of 2023 and 2022, respectively, related to restructuring program activities (see Note 5 to the condensed consolidated financial statements).

Other (Income) Expense, Net

Other (income) expense, net, was $89 million of expense in the first quarter of 2023 compared with $708 million of expense in the first quarter of 2022. The change was primarily due to net unrealized gains from investments in equity securities recorded in the first quarter of 2023 compared with net unrealized losses recorded in the first quarter of 2022, as well as higher interest income in the first quarter of 2023. The favorability was partially offset by a $572.5 million charge in the first quarter of 2023 related to settlements with certain plaintiffs in the Zetia antitrust litigation (see Note 8 to the consolidated financial statements).

For details on the components of Other (income) expense, net, see Note 11 to the condensed consolidated financial statements.

Segment Profits

($ in millions)	Three Months Ended March 31, 2023	Three Months Ended March 31, 2022
Pharmaceutical segment profits	$ 9,140	$ 9,501
Animal Health segment profits	566	585
Other	(6,056)	(5,225)
Income Before Taxes	$ 3,650	$ 4,861

Pharmaceutical segment profits are comprised of segment sales less standard costs, as well as SG&A expenses directly incurred by the segment. Animal Health segment profits are comprised of segment sales, less all cost of sales, as well as SG&A and R&D expenses directly incurred by the segment. For internal management reporting presented to the chief operating decision maker, Merck does not allocate the remaining cost of sales not included in segment profits as described above, R&D expenses incurred by MRL, or general and administrative expenses, nor the cost of financing these activities. Separate divisions maintain responsibility for monitoring and managing these costs, including depreciation related to fixed assets utilized by these divisions and, therefore, they are not included in segment profits. Also excluded from the determination of segment profits are costs related to restructuring activities and acquisition- and divestiture-related costs, including the amortization of intangible assets and amortization of purchase accounting adjustments, intangible asset impairment charges, and expense or income related to changes in the estimated fair value measurement of liabilities for contingent consideration. Additionally, segment profits do not reflect other expenses from corporate and manufacturing cost centers and other miscellaneous income or expense. These unallocated items are reflected in "Other" in the above table. Also included in "Other" are miscellaneous corporate profits (losses), as well as operating profits (losses) related to third-party manufacturing arrangements.

Pharmaceutical segment profits declined 4% in the first quarter of 2023 reflecting lower sales, largely attributable to *Lagevrio*, as well as higher administrative and promotional costs, and the unfavorable effect of foreign exchange. Animal Health segment profits declined 3% in the first quarter of 2023 reflecting higher administrative and promotional costs, as well as increased research and development expenses.

Taxes on Income

The effective income tax rates were 22.6% and 11.4% for the first quarter of 2023 and 2022, respectively. The effective income tax rate for the first quarter of 2023 reflects the unfavorable discrete impact of a charge for the acquisition of Imago for which no tax benefit was recognized, as well as higher foreign taxes, the impact of the R&D capitalization provision of the Tax Cuts and Jobs Act of 2017 on the Company's U.S. global intangible low-taxed income inclusion, and net unrealized gains from investments in equity securities, which were taxed at the U.S. tax rate, partially offset by higher foreign tax credits. The effective income tax rate in the first quarter of 2022 includes the favorable impact of net unrealized losses from investments in equity securities, which were taxed at the U.S. tax rate.

Non-GAAP Income and Non-GAAP EPS

Non-GAAP income and non-GAAP EPS are alternative views of the Company's performance that Merck is providing because management believes this information enhances investors' understanding of the Company's results since management uses non-GAAP measures to assess performance. Non-GAAP income and non-GAAP EPS exclude certain items because of the nature of these items and the impact that they have on the analysis of underlying business performance and trends. The excluded items (which should not be considered non-recurring) consist of acquisition- and divestiture-related costs, restructuring costs, income and losses from investments in equity securities, and certain other items. These excluded items are significant components in understanding and assessing financial performance.

Non-GAAP income and non-GAAP EPS are important internal measures for the Company. Senior management receives a monthly analysis of operating results that includes a non-GAAP EPS metric. Management uses non-GAAP measures internally for planning and forecasting purposes and to measure the performance of the Company along with other metrics. In addition, senior management's annual compensation is derived in part using a non-GAAP pretax income metric. Since non-GAAP income and non-GAAP EPS are not measures determined in accordance with GAAP, they have no standardized meaning prescribed by GAAP and, therefore, may not be comparable to the calculation of similar measures of other companies. The information on non-GAAP income and non-GAAP EPS should be considered in addition to, but not as a substitute for or superior to, net income and EPS prepared in accordance with generally accepted accounting principles in the U.S. (GAAP).

A reconciliation between GAAP financial measures and non-GAAP financial measures is as follows:

	Three Months Ended March 31,	
($ in millions except per share amounts)	2023	2022
Income before taxes as reported under GAAP	$ 3,650	$ 4,861
Increase (decrease) for excluded items:		
Acquisition- and divestiture-related costs	590	637
Restructuring costs	97	127
(Income) loss from investments in equity securities, net	(429)	684
Other items:		
Charge for Zetia antitrust litigation settlements	573	—
Non-GAAP income before taxes	4,481	6,309
Taxes on income as reported under GAAP	825	554
Estimated tax benefit on excluded items [(1)]	88	329
Non-GAAP taxes on income	913	883
Non-GAAP net income	3,568	5,426
Less: Net income (loss) attributable to noncontrolling interests as reported under GAAP	4	(3)
Non-GAAP net income attributable to Merck & Co., Inc.	$ 3,564	$ 5,429
EPS assuming dilution as reported under GAAP	$ 1.11	$ 1.70
EPS difference	0.29	0.44
Non-GAAP EPS assuming dilution	$ 1.40	$ 2.14

[(1)] *The estimated tax impact on the excluded items is determined by applying the statutory rate of the originating territory of the non-GAAP adjustments.*

Acquisition- and Divestiture-Related Costs

Non-GAAP income and non-GAAP EPS exclude the impact of certain amounts recorded in connection with acquisitions and divestitures of businesses. These amounts include the amortization of intangible assets and amortization of purchase accounting adjustments to inventories, as well as intangible asset impairment charges, and expense or income related to changes in the estimated fair value measurement of liabilities for contingent consideration. Also excluded are integration, transaction, and certain other costs associated with acquisitions and divestitures of businesses. Non-GAAP income and non-GAAP EPS also exclude amortization of intangible assets related to collaborations and licensing arrangements.

Restructuring Costs

Non-GAAP income and non-GAAP EPS exclude costs related to restructuring actions (see Note 5 to the condensed consolidated financial statements). These amounts include employee separation costs and accelerated depreciation associated with facilities to be closed or divested. Accelerated depreciation costs represent the difference between the depreciation expense to be recognized over the revised useful life of the asset, based upon the anticipated date the site will be closed or divested or the equipment disposed of, and depreciation expense as determined utilizing the useful life prior to the restructuring actions. Restructuring costs also include asset abandonment, facility shut-down and other related costs, as well as employee-related costs such as curtailment, settlement and termination charges associated with pension and other postretirement benefit plans and share-based compensation costs.

Income and Losses from Investments in Equity Securities

Non-GAAP income and non-GAAP EPS exclude realized and unrealized gains and losses from investments in equity securities either owned directly or through ownership interests in investment funds.

Certain Other Items

Non-GAAP income and non-GAAP EPS exclude certain other items. These items are adjusted for after evaluating them on an individual basis, considering their quantitative and qualitative aspects. Typically, these consist of items that are unusual in nature, significant to the results of a particular period or not indicative of future operating results. Excluded from non-GAAP income and non-GAAP EPS in 2023 is a charge related to settlements with certain plaintiffs in the Zetia antitrust litigation (see Note 8 to the condensed consolidated financial statements).

Research and Development Update

The Company currently has several candidates under regulatory review in the U.S. and internationally.

MK-4482, *Lagevrio*, is an investigational oral antiviral medicine for the treatment of mild to moderate COVID-19 in adults who are at risk for progressing to severe disease. Merck is developing *Lagevrio* in collaboration with Ridgeback. The FDA granted Emergency Use Authorization for *Lagevrio* in December 2021; last issued in February 2023, to authorize *Lagevrio* for the treatment of adults with a current diagnosis of mild to moderate COVID-19, and who are at high risk for progression to severe COVID-19, including hospitalization or death, and for whom alternative COVID-19 treatment options approved or authorized by the FDA are not accessible or clinically appropriate. The authorization is based on the Phase 3 MOVe-OUT trial. *Lagevrio* is not approved for any use in the U.S. and is authorized only for the duration of the declaration that circumstances exist justifying the authorization of its emergency use under the Food, Drug and Cosmetic Act, unless the authorization is terminated or revoked sooner. In November 2021, the European Medicines Agency (EMA) issued a positive scientific opinion for *Lagevrio*, which is intended to support national decision-making on the possible use of *Lagevrio* prior to marketing authorization. In October 2021, the EMA initiated a rolling review for *Lagevrio* for the treatment of COVID-19 in adults. In February 2023, Merck and Ridgeback announced that the Committee for Medicinal Products for Human Use (CHMP) of the EMA has recommended the refusal of the marketing authorization application (MAA) for *Lagevrio*. Merck and Ridgeback have appealed the decision and requested a re-examination of the MAA. Applications to other regulatory bodies are underway.

MK-7264, gefapixant, is an investigational, orally administered, selective P2X3 receptor antagonist, for the treatment of refractory chronic cough or unexplained chronic cough in adults under review by the FDA and the EMA. The marketing applications for gefapixant are based on results from the COUGH-1 and COUGH-2 clinical trials. In January 2022, the FDA issued a Complete Response Letter (CRL) regarding Merck's NDA for gefapixant. In the CRL, the FDA requested additional information related to the cough counting system that was used to assess efficacy. The CRL was not related to the safety of gefapixant. The Company is performing additional analyses and anticipates submitting this information to the FDA in the second quarter of 2023 in response to the CRL. The review period in the EU was extended pending the receipt of additional information, which Merck submitted to the EMA in the first quarter of 2023.

MK-3475, *Keytruda*, is an anti-PD-1 therapy approved for the treatment of many cancers that is in clinical development for expanded indications. These approvals were the result of a broad clinical development program that currently encompasses more than 30 cancer types including: biliary, estrogen receptor positive breast cancer, cervical, colorectal, cutaneous squamous cell, endometrial, esophageal, gastric, glioblastoma, head and neck, hepatocellular, Hodgkin lymphoma, non-Hodgkin lymphoma, non-small-cell lung, small-cell lung, melanoma, mesothelioma, ovarian, prostate, renal, triple-negative breast, and urothelial, many of which are currently in Phase 3 clinical development. Further trials are being planned for other cancers.

Keytruda is under review by the FDA for the treatment of patients with previously treated advanced HCC. This submission is based on data from the Phase 3 KEYNOTE-394 trial along with supportive data from the KEYNOTE-240 and KEYNOTE-224 trials. *Keytruda* is approved for this indication in the U.S. under the FDA's accelerated approval process. This submission is to convert the accelerated approval to full (regular) approval.

Additionally, *Keytruda* is under review by the FDA for the treatment of adult and pediatric patients with recurrent locally advanced or metastatic Merkel cell carcinoma. This submission is based on data from the Phase 3 KEYNOTE-913 trial. *Keytruda* is approved for this indication in the U.S. under the FDA's accelerated approval process. This submission is to convert the accelerated approval to full (regular) approval.

Keytruda is also under review by the FDA in combination with fluoropyrimidine- and platinum-containing chemotherapy, for the first-line treatment of patients with locally advanced unresectable or metastatic gastric or GEJ adenocarcinoma. The submission is based on data from the KEYNOTE-859 trial, in which *Keytruda* plus chemotherapy demonstrated a statistically significant improvement in overall survival versus chemotherapy alone, regardless of PD-L1 expression, in patients who were HER2 negative. The FDA set a PDUFA date of December 16, 2023. KEYNOTE-859 is also under review in the EU.

In addition, *Keytruda* is under review by the FDA as a perioperative treatment regimen for patients with resectable stage II, IIIA or IIIB NSCLC based on the KEYNOTE-671 study. A perioperative treatment regimen includes treatment before surgery (neoadjuvant) and continued after surgery (adjuvant). The FDA set a PDUFA date of October 16, 2023. KEYNOTE-671 is also under review in the EU.

Keytruda is under review in the EU for the adjuvant treatment of patients with stage IB (≥4 cm), II or IIIA NSCLC following complete surgical resection. The submission is based on data from the pivotal Phase 3 KEYNOTE-091 trial, also known as EORTC-1416-LCG/ETOP-8-15 – PEARLS.

Keytruda is under review in Japan for the treatment of patients with relapsed or refractory PMBCL. This submission is based on data from the Phase 2 KEYNOTE-170 study and the Phase 1 KEYNOTE-A33 study.

In February 2023, Merck announced it was discontinuing the Phase 3 KEYNOTE-641 trial evaluating *Keytruda* in combination with enzalutamide and androgen deprivation therapy (ADT) for the treatment of patients with metastatic castration-resistant prostate cancer (mCRPC) based on the recommendation of an independent Data Monitoring Committee. At an interim analysis, *Keytruda* in combination with enzalutamide and ADT did not demonstrate an improvement in radiographic progression-

free survival or overall survival, the trial's dual primary endpoints, compared to placebo plus enzalutamide and ADT, and crossed a pre-specified futility boundary for overall survival.

In March 2023, Merck provided an update on the open-label arm of the non-registrational Phase 2 KeyVibe-002 trial. KeyVibe-002 is evaluating MK-7684A, a coformulation of vibostolimab, an anti-TIGIT therapy, and *Keytruda*, with or without docetaxel for the treatment of patients with metastatic NSCLC with progressive disease after treatment with immunotherapy and platinum-doublet chemotherapy. KeyVibe-002, a partially blinded study, was designed with two primary objectives: 1) to evaluate the efficacy of MK-7684A alone compared with docetaxel, a standard of care; and 2) in a blinded assessment, evaluate the efficacy of adding MK-7684A to docetaxel compared with docetaxel alone. Results from the open-label arm of the study evaluating MK-7684A alone showed that the coformulation did not reach statistical significance for the primary endpoint of progression-free survival and was numerically less effective compared with docetaxel. The blinded arms of the study will continue to further evaluate MK-7684A with docetaxel versus docetaxel alone. Results will be presented at an upcoming medical meeting once further data from the blinded study arms are available.

MK-7339, Lynparza, is an oral PARP inhibitor currently approved for the treatment of several cancers being co-developed for additional cancer types as part of a collaboration with AstraZeneca (see Note 3 to the condensed consolidated financial statements).

In April 2023, the FDA convened its Oncologic Drugs Advisory Committee (ODAC) to discuss the supplemental NDA for use of Lynparza in combination with abiraterone and prednisone or prednisolone (abi/pred) for the treatment of adult patients with mCRPC, based on the results of the Phase 3 PROpel trial. By a vote of 11 to 1 with one abstention, the OADC supported FDA approval of Lynparza plus abi/pred for the first-line treatment of adult patients with *BRCA*-mutated (*BRCA*m) mCRPC. The committee voted that the FDA should restrict use of Lynparza plus abi/pred to these *BRCA*m mCRPC patients, recommending against approval beyond this patient population. The ODAC provides the FDA with independent, expert advice and recommendations on marketed and investigational medicines for use in the treatment of cancer. The FDA is not bound by the committee's guidance but takes its advice into consideration. AstraZeneca and Merck will continue to work with the FDA as the agency completes its review of the application. Lynparza is also under review in Japan for the treatment of certain patients with mCRPC based on the PROpel trial.

MK-7902, Lenvima, is an oral receptor tyrosine kinase inhibitor currently approved for the treatment of several cancers being developed as part of a collaboration with Eisai. Merck and Eisai are studying the *Keytruda* plus Lenvima combination through the LEAP (LEnvatinib And Pembrolizumab) clinical program.

In April 2023, Merck and Eisai announced the discontinuation of the Phase 3 LEAP-003 trial evaluating *Keytruda* plus Lenvima for the first-line treatment of adults with unresectable or metastatic melanoma based on the recommendation of an independent Data Monitoring Committee, which reviewed data from a planned interim analysis and determined *Keytruda* plus Lenvima did not demonstrate an improvement in overall survival, one of the study's dual primary endpoints, versus *Keytruda* alone. Merck and Eisai also provided an update on the Phase 3 LEAP-017 trial evaluating *Keytruda* plus Lenvima for the treatment of patients with unresectable and metastatic colorectal cancer that is mismatch repair proficient or not MSI-H who experienced disease progression on, or became intolerant to, prior therapy. The trial did not meet statistical significance for its primary endpoint of overall survival in the final pre-specified analysis.

The charts below reflect the Company's research pipeline as of May 3, 2023. Candidates shown in Phase 3 include the date such candidate entered into Phase 3 development. Candidates shown in Phase 2 include the most advanced compound with a specific mechanism or, if listed compounds have the same mechanism, they are each currently intended for commercialization in a given therapeutic area. Small molecules and biologics are given MK-number designations and vaccine candidates are given V-number designations. Except as otherwise noted, candidates in Phase 1, additional indications in the same therapeutic area (other than with respect to cancer) and additional claims, line extensions or formulations for in-line products are not shown.

Phase 2		
Cancer MK-0482[2] Non-Small-Cell Lung MK-1308 (quavonlimab)[2] Non-Small-Cell Lung MK-1308A (quavonlimab+pembrolizumab) Colorectal Hepatocellular Melanoma Small-Cell Lung MK-2140 (zilovertamab vedotin) Bladder Breast Gastric Hematological Malignancies Non-Small-Cell Lung Ovarian Pancreatic MK-2870[1][3] Neoplasm Malignant MK-3475 *Keytruda* Advanced Solid Tumors Prostate MK-3543 (bomedemstat) Myeloproliferative Disorders MK-4280 (favezelimab)[2] Non-Small-Cell Lung MK-4280A (favezelimab+pembrolizumab) Baldder Esophageal Melanoma Renal Cell Small-Cell Lung MK-4830[2] Colorectal Esophageal Melanoma Non-Small-Cell Lung Ovarian Renal Cell Small-Cell Lung MK-5684[1] Prostate MK-5890 (boserolimab)[2] Non-Small-Cell Lung Small-Cell Lung	**Cancer** MK-6440 (ladiratuzumab vedotin)[1][3] Breast Esophageal Gastric Head and Neck Melanoma Non-Small-Cell Lung Prostate Small-Cell Lung MK-6482 *Welireg*[3] Biliary Colorectal Endometrial Esophageal Hepatocellular Pancreatic Rare cancers Von Hippel-Lindau Disease-Associated Tumors (EU) MK-7119 Tukysa[1] Advanced Solid Tumors Biliary Bladder Cervical Endometrial Gastric Non-Small-Cell Lung MK-7339 Lynparza[1][3] Advanced Solid Tumors MK-7684A (vibostolimab+pembrolizumab) Biliary Bladder Breast Cervical Colorectal Endometrial Esophageal Gastric Head and Neck Hematological Malignancies Hepatocellular Ovarian Prostate	**Cancer** MK-7902 Lenvima[1][2] Biliary Melanoma Pancreatic Prostate Small-Cell Lung V940[1][2] Melanoma **Dengue Fever Virus Vaccine** V181 **HIV-1 Infection** MK-8591B (islatravir+MK-8507)[4] MK-8591D (islatravir+lenacapavir)[1][5] **Hypercholesterolemia** MK-0616 **Nonalcoholic Steatohepatitis (NASH)** MK-6024 (efinopegdutide) **Pulmonary Arterial Hypertension** MK-5475 **Pulmonary Hypertension Due To Left Heart Disease** MK-7962 (sotatercept) **Schizophrenia** MK-8189[6] **Thrombosis** MK-2060 **Treatment Resistant Depression** MK-1942

Phase 3 (Phase 3 entry date)	Under Review	
Antiviral COVID-19 MK-4482 *Lagevrio* (U.S.) (May 2021)[(1)(7)] **Cancer** MK-1026 (nemtabrutinib) Hematological Malignancies (March 2023) MK-1308A (quavonlimab+pembrolizumab) Renal Cell (April 2021) MK-3475 *Keytruda* Biliary (September 2019) Cutaneous Squamous Cell (August 2019) (EU) Hepatocellular (May 2016) (EU) Mesothelioma (May 2018) Ovarian (December 2018) Small-Cell Lung (May 2017) MK-3475 (pembrolizumab subcutaneous) Non-Small-Cell Lung (August 2021) MK-3475A (pembrolizumab+hyaluronidase subcutaneous) Non-Small-Cell Lung (February 2023) MK-4280A (favezelimab+pembrolizumab) Colorectal (November 2021) Hematological Malignancies (October 2022) MK-6482 *Welireg*[(3)] Renal Cell (February 2020) MK-7119 Tukysa[(1)] Breast (October 2019) Colorectal (August 2022) MK-7339 Lynparza[(1)(2)] Non-Small-Cell Lung (June 2019) Small-Cell Lung (December 2020) MK-7684A (vibostolimab+pembrolizumab) Melanoma (January 2023) Non-Small-Cell Lung (April 2021) Small-Cell Lung (March 2022) MK-7902 Lenvima[(1)(2)] Esophageal (July 2021) Gastric (December 2020) Head and Neck (February 2020) Non-Small-Cell Lung (March 2019) **HIV-1 Infection** MK-8591A (doravirine+islatravir) (February 2020)[(5)] **Pneumococcal Vaccine Adult** V116 (July 2022) **Pulmonary Arterial Hypertension** MK-7962 (sotatercept) (January 2021) **Respiratory Syncytial Virus** MK-1654 (clesrovimab) (November 2021)	**New Molecular Entities** **Antiviral COVID-19** MK-4482 *Lagevrio* (EU)[(1)(8)] **Cough** MK-7264 (gefapixant) (U.S.)[(9)] (EU)	**Certain Supplemental Filings** **Cancer** MK-3475 *Keytruda* • Second-Line Hepatocellular Carcinoma (KEYNOTE-394) (U.S.) • Locally Advanced or Metastatic Merkel Cell Carcinoma (KEYNOTE-913) (U.S.) • First-Line HER2 Negative Locally Advanced Unresectable or Metastatic Gastric Cancer (KEYNOTE-859) (U.S.) (EU) • Resectable Stage II, IIIA or IIIB NSCLC (KEYNOTE-671) (U.S.) (EU) • Adjuvant Non-Small-Cell Lung Cancer (KEYNOTE-091) (EU) • Relapsed or Refractory Primary Mediastinal B-Cell Lymphoma (KEYNOTE-170/KEYNOTE-A33) (JPN) MK-7339 Lynparza[(1)] • First-Line Metastatic Prostate Cancer (PROpel) (U.S.) (JPN)
	Footnotes: [(1)] Being developed in a collaboration. [(2)] Being developed in combination with *Keytruda*. [(3)] Being developed as monotherapy and/or in combination with *Keytruda*. [(4)] On FDA clinical hold. [(5)] On FDA partial clinical hold for higher doses than those used in current clinical trials. [(6)] Phase 2b development costs are being co-funded. [(7)] Available in the U.S. under Emergency Use Authorization. [(8)] Requested re-examination of EU MAA following CHMP recommendation for the refusal of the marketing authorization. [(9)] In response to the CRL received from the FDA for this application in January 2022, Merck is performing additional analyses and anticipates submitting this information to the FDA in the second quarter of 2023.	

Analysis of Liquidity and Capital Resources

($ in millions)	March 31, 2023	December 31, 2022
Cash and investments	$ 11,677	$ 14,207
Working capital	10,271	11,483
Total debt to total liabilities and equity	28.5 %	28.1 %

Cash provided by operating activities was $1.3 billion in the first three months of 2023 compared with $4.8 billion in the first three months of 2022 primarily reflecting the impact of lower *Lagevrio* sales. Cash provided by operating activities was reduced by milestone payments related to certain collaborations of $115 million and $1.2 billion in the first three months of 2023 and 2022, respectively. Cash provided by operating activities continues to be the Company's primary source of funds to finance operating needs, with excess cash serving as the primary source of funds to finance business development transactions, capital expenditures, dividends paid to shareholders and treasury stock purchases.

Cash used in investing activities was $2.4 billion in the first three months of 2023 compared with $1.2 billion in the first three months of 2022. The higher use of cash in investing activities was primarily due to the acquisition of Imago and higher purchases of securities and other investments, partially offset by higher proceeds from sales of securities and other investments.

Cash used in financing activities was $2.1 billion in the first three months of 2023 compared with $3.1 billion in the first three months of 2022. The decrease in cash used in financing activities was primarily due to lower payments on long-term debt, partially offset by treasury stock purchases and higher dividends paid to shareholders.

Capital expenditures totaled $1.0 billion in the first three months of 2023 compared with $984 million in the first three months of 2022.

The Company has accounts receivable factoring agreements with financial institutions in certain countries to sell accounts receivable. The Company factored $2.4 billion and $2.5 billion of accounts receivable at March 31, 2023 and December 31, 2022, respectively, under these factoring arrangements, which reduced outstanding accounts receivable. The cash received from the financial institutions is reported within operating activities in the Condensed Consolidated Statement of Cash Flows. In certain of these factoring arrangements, for ease of administration, the Company will collect customer payments related to the factored receivables, which it then remits to the financial institutions. The net cash flows relating to these collections are reported as financing activities in the Condensed Consolidated Statement of Cash Flows.

Dividends paid to stockholders were $1.9 billion and $1.7 billion for the first three months of 2023 and 2022, respectively. In January 2023, the Board of Directors declared a quarterly dividend of $0.73 per share on the Company's outstanding common stock for the first quarter that was paid in April 2023.

As discussed above, in April 2023, Merck announced an agreement to acquire Prometheus for $200 per share in cash for a total equity value of approximately $10.8 billion. The acquisition is subject to Prometheus shareholder approval. The closing of the proposed transaction will be subject to certain conditions, including the expiration of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act and other customary conditions. The transaction is expected to close in the third quarter of 2023.

In February 2022, the Company's $1.25 billion, 2.35% notes matured in accordance with their terms and were repaid. In September 2022, the Company's $1.0 billion, 2.40% notes matured in accordance with their terms and were repaid.

In 2018, Merck's Board of Directors authorized purchases of up to $10 billion of Merck's common stock for its treasury. The treasury stock purchase authorization has no time limit and will be made over time in open-market transactions, block transactions on or off an exchange, or in privately negotiated transactions. The Company anticipates making modest share repurchases under this program in 2023. During the first three months of 2023, the Company purchased $149 million (1 million shares) of its common stock for its treasury under this program. As of March 31, 2023, the Company's remaining share repurchase authorization was $4.9 billion.

The Company has a $6.0 billion credit facility that matures in June 2026. The facility provides backup liquidity for the Company's commercial paper borrowing facility and is to be used for general corporate purposes. The Company has not drawn funding from this facility.

Critical Accounting Estimates

The Company's significant accounting policies, which include management's best estimates and judgments, are included in Note 2 to the consolidated financial statements for the year ended December 31, 2022 included in Merck's Form 10-K filed on February 24, 2023. See Note 1 to the condensed consolidated financial statements for information on the adoption of new accounting standards during 2023. A discussion of accounting estimates considered critical because of the potential for a significant impact on the financial statements due to the inherent uncertainty in such estimates are disclosed in the Critical Accounting Estimates section of Management's Discussion and Analysis of Financial Condition and Results of Operations included in Merck's Form 10-K. There have been no significant changes in the Company's critical accounting estimates since December 31, 2022.

Recently Issued Accounting Standards

For a discussion of recently issued accounting standards, see Note 1 to the condensed consolidated financial statements.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

There have been no material changes in market risk exposures that affect the disclosures presented in "Item 7A. Quantitative and Qualitative Disclosures about Market Risk" in the Company's 2022 Form 10-K filed on February 24, 2023.

Item 4. Controls and Procedures

Management of the Company, with the participation of its Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of the Company's disclosure controls and procedures over financial reporting. Based on their evaluation, the Company's Chief Executive Officer and Chief Financial Officer have concluded that as of March 31, 2023, the Company's disclosure controls and procedures are effective. During the quarter, the Company upgraded its financial consolidation system to the latest software version and moved it to an externally hosted cloud-based environment. The Company completed testing of this system prior to its launch, continues to monitor impacted financial and business processes and believes that an effective control environment has been maintained post-implementation.

CAUTIONARY FACTORS THAT MAY AFFECT FUTURE RESULTS

This report and other written reports and oral statements made from time to time by the Company may contain so-called "forward-looking statements," all of which are based on management's current expectations and are subject to risks and uncertainties which may cause results to differ materially from those set forth in the statements. One can identify these forward-looking statements by their use of words such as "anticipates," "expects," "plans," "will," "estimates," "forecasts," "projects" and

other words of similar meaning, or negative variations of any of the foregoing. One can also identify them by the fact that they do not relate strictly to historical or current facts. These statements are likely to address the Company's growth strategy, financial results, product approvals, product potential, development programs, environmental or other sustainability initiatives, and may include statements related to the expected impact of the COVID-19 pandemic. One must carefully consider any such statement and should understand that many factors could cause actual results to differ materially from the Company's forward-looking statements. These factors include inaccurate assumptions and a broad variety of other risks and uncertainties, including some that are known and some that are not. No forward-looking statement can be guaranteed and actual future results may vary materially.

The Company does not assume the obligation to update any forward-looking statement. One should carefully evaluate such statements in light of factors, including risk factors, described in the Company's filings with the Securities and Exchange Commission, especially on Forms 10-K, 10-Q and 8-K. In Item 1A. "Risk Factors" of the Company's Annual Report on Form 10-K for the year ended December 31, 2022, filed on February 24, 2023, the Company discusses in more detail various important risk factors that could cause actual results to differ from expected or historic results. The Company notes these factors for investors as permitted by the Private Securities Litigation Reform Act of 1995. One should understand that it is not possible to predict or identify all such factors. Consequently, the reader should not consider any such list to be a complete statement of all potential risks or uncertainties.

PART II - Other Information

Item 1. Legal Proceedings

The information called for by this Item is incorporated herein by reference to Note 8 included in Part I, Item 1, Financial Statements (unaudited) — Notes to Condensed Consolidated Financial Statements.

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

Issuer purchases of equity securities for the three months ended March 31, 2023 were as follows:

ISSUER PURCHASES OF EQUITY SECURITIES

				($ in millions)
Period	Total Number of Shares Purchased [1]	Average Price Paid Per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Approximate Dollar Value of Shares That May Yet Be Purchased Under the Plans or Programs [1]
January 1 - January 31	—	—	—	$5,047
February 1 - February 28	328,800	$108.43	328,800	$5,012
March 1 - March 31	1,066,937	$106.55	1,066,937	$4,898
Total	1,395,737	$107.00	1,395,737	

[1] *Shares purchased during the period were made as part of a plan approved by the Board of Directors in October 2018 to purchase up to $10 billion of Merck's common stock for its treasury.*

Item 6. Exhibits

Number		Description
3.1	—	Restated Certificate of Incorporation of Merck & Co., Inc. (November 3, 2009) – Incorporated by reference to Merck & Co., Inc.'s Current Report on Form 8-K filed on November 4, 2009 (No. 1-6571)
3.2	—	By-Laws of Merck & Co., Inc. (effective March 22, 2022) – Incorporated by reference to Merck & Co., Inc.'s Current Report on Form 8-K filed on March 25, 2022 (No. 1-6571)
31.1	—	Rule 13a – 14(a)/15d – 14(a) Certification of Chief Executive Officer
31.2	—	Rule 13a – 14(a)/15d – 14(a) Certification of Chief Financial Officer
32.1	—	Section 1350 Certification of Chief Executive Officer
32.2	—	Section 1350 Certification of Chief Financial Officer
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 Linkbase Document.
101.DEF	—	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	—	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	—	XBRL Taxonomy Extension Presentation Linkbase Document.
104	—	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

Signatures

Pursuant to the requirements 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.

MERCK & CO., INC.

Date: May 5, 2023

/s/ Jennifer Zachary
JENNIFER ZACHARY
Executive Vice President and General Counsel

Date: May 5, 2023

/s/ Rita A. Karachun
RITA A. KARACHUN
Senior Vice President Finance - Global Controller

Exhibit 31.1

CERTIFICATION

I, Robert M. Davis, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Merck & Co., Inc.;

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

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

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

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

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

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

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

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

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

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

Date: May 5, 2023

By: /s/ Robert M. Davis
ROBERT M. DAVIS
Chairman, Chief Executive Officer and President

Exhibit 31.2

CERTIFICATION

I, Caroline Litchfield, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Merck & Co., Inc.;

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

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

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

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

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

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

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

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

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

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

Date: May 5, 2023

By: /s/ Caroline Litchfield

CAROLINE LITCHFIELD
Executive Vice President, Chief Financial Officer

Exhibit 32.1

Section 1350
Certification of Chief Executive Officer

Pursuant to 18 U.S.C. Section 1350, the undersigned officer of Merck & Co., Inc. (the "Company"), hereby certifies that the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2023 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 5, 2023

/s/ Robert M. Davis

Name: ROBERT M. DAVIS
Title: Chairman, Chief Executive Officer and President

Exhibit 32.2

Section 1350
Certification of Chief Financial Officer

Pursuant to 18 U.S.C. Section 1350, the undersigned officer of Merck & Co., Inc. (the "Company"), hereby certifies that the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2023 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: May 5, 2023

/s/ Caroline Litchfield

Name: CAROLINE LITCHFIELD
Title: Executive Vice President, Chief Financial Officer