

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 June 30, 2023

OR

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

For the transition period from _____ to _____

Commission File No. 1-6571

Merck & Co., Inc.

(Exact name of registrant as specified in its charter)

New Jersey
(State or other jurisdiction of incorporation)

22-1918501
(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:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
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	<input checked="" type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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 July 31, 2023: 2,537,521,169

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Part I - Financial Information

Item 1. Financial Statements

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Sales	\$ 15,035	\$ 14,593	\$ 29,522	\$ 30,494
Costs, Expenses and Other				
Cost of sales	4,024	4,216	7,951	9,596
Selling, general and administrative	2,702	2,512	5,182	4,834
Research and development	13,321	2,798	17,597	5,374
Restructuring costs	151	142	218	194
Other (income) expense, net	172	438	259	1,148
	20,370	10,106	31,207	21,146
(Loss) Income Before Taxes	(5,335)	4,487	(1,685)	9,348
Income Tax Provision	637	538	1,462	1,092
Net (Loss) Income	(5,972)	3,949	(3,147)	8,256
Less: Net Income Attributable to Noncontrolling Interests	3	5	7	2
Net (Loss) Income Attributable to Merck & Co., Inc.	\$ (5,975)	\$ 3,944	\$ (3,154)	\$ 8,254
Basic (Loss) Earnings per Common Share Attributable to Merck & Co., Inc. Common Shareholders	\$ (2.35)	\$ 1.56	\$ (1.24)	\$ 3.26
(Loss) Earnings per Common Share Assuming Dilution Attributable to Merck & Co., Inc. Common Shareholders	\$ (2.35)	\$ 1.55	\$ (1.24)	\$ 3.25

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Net (Loss) Income Attributable to Merck & Co., Inc.	\$ (5,975)	\$ 3,944	\$ (3,154)	\$ 8,254
Other Comprehensive (Loss) Income Net of Taxes:				
Net unrealized gain on derivatives, net of reclassifications	145	183	12	246
Benefit plan net (loss) gain and prior service (cost) credit, net of amortization	(25)	246	(75)	278
Cumulative translation adjustment	(137)	(387)	(69)	(422)
	(17)	42	(132)	102
Comprehensive (Loss) Income Attributable to Merck & Co., Inc.	\$ (5,992)	\$ 3,986	\$ (3,286)	\$ 8,356

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)

	June 30, 2023	December 31, 2022
Assets		
Current Assets		
Cash and cash equivalents	\$ 5,660	\$ 12,694
Short-term investments	718	498
Accounts receivable (net of allowance for doubtful accounts of \$86 in 2023 and \$72 in 2022)	11,030	9,450
Inventories (excludes inventories of \$3,220 in 2023 and \$2,938 in 2022 classified in Other assets - see Note 7)	5,930	5,911
Other current assets	6,639	7,169
Total current assets	29,977	35,722
Investments	1,214	1,015
Property, Plant and Equipment, at cost, net of accumulated depreciation of \$18,432 in 2023 and \$17,985 in 2022	22,231	21,422
Goodwill	21,195	21,204
Other Intangibles, Net	19,665	20,269
Other Assets	10,187	9,528
	\$ 104,469	\$ 109,160
Liabilities and Equity		
Current Liabilities		
Loans payable and current portion of long-term debt	\$ 2,839	\$ 1,946
Trade accounts payable	3,442	4,264
Accrued and other current liabilities	13,747	14,159
Income taxes payable	1,489	1,986
Dividends payable	1,877	1,884
Total current liabilities	23,394	24,239
Long-Term Debt	34,072	28,745
Deferred Income Taxes	996	1,795
Other Noncurrent Liabilities	7,265	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	44,219	44,379
Retained earnings	54,198	61,081
Accumulated other comprehensive loss	(4,900)	(4,768)
	95,305	102,480
Less treasury stock, at cost: 1,037,678,033 shares in 2023 and 1,039,269,638 shares in 2022	56,612	56,489
Total Merck & Co., Inc. stockholders' equity	38,693	45,991
Noncontrolling Interests	49	67
Total equity	38,742	46,058
	\$ 104,469	\$ 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)

	Six Months Ended June 30,	
	2023	2022
Cash Flows from Operating Activities		
Net (loss) income	\$ (3,147)	\$ 8,256
Adjustments to reconcile net (loss) income to net cash provided by operating activities:		
Amortization	1,020	1,163
Depreciation	874	895
(Income) loss from investments in equity securities, net	(274)	991
Charge for the acquisition of Prometheus Biosciences, Inc.	10,217	—
Charge for the acquisition of Imago BioSciences, Inc.	1,192	—
Deferred income taxes	(632)	(600)
Share-based compensation	314	257
Other	5	799
Net changes in assets and liabilities	(4,526)	(2,698)
Net Cash Provided by Operating Activities	5,043	9,063
Cash Flows from Investing Activities		
Capital expenditures	(1,972)	(2,113)
Purchases of securities and other investments	(587)	(705)
Proceeds from sales of securities and other investments	785	374
Acquisition of Prometheus Biosciences, Inc., net of cash acquired	(10,705)	—
Acquisition of Imago BioSciences, Inc., net of cash acquired	(1,327)	—
Other	4	194
Net Cash Used in Investing Activities	(13,802)	(2,250)
Cash Flows from Financing Activities		
Net change in short-term borrowings	1,937	—
Proceeds from issuance of debt	5,946	—
Payments on debt	(1,751)	(1,250)
Purchases of treasury stock	(487)	—
Dividends paid to stockholders	(3,738)	(3,515)
Proceeds from exercise of stock options	112	109
Other	(315)	(207)
Net Cash Provided by (Used in) Financing Activities	1,704	(4,863)
Effect of Exchange Rate Changes on Cash, Cash Equivalents and Restricted Cash	(6)	(364)
Net (Decrease) Increase in Cash, Cash Equivalents and Restricted Cash	(7,061)	1,586
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 <i>Other current assets</i>)	12,773	8,167
Cash, Cash Equivalents and Restricted Cash at End of Period (includes restricted cash of \$52 and \$78 at June 30, 2023 and 2022, respectively, included in <i>Other current assets</i>)	\$ 5,712	\$ 9,753

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 Standards

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.

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 Company adopted the guidance effective July 1, 2023. There was no impact to the Company's 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 June 2023, Merck acquired 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. Total consideration paid of \$11.0 billion included \$1.2 billion of costs to settle share-based equity awards (including \$700 million to settle unvested equity awards). Prometheus' lead candidate, MK-7240 (formerly PRA023), is a humanized monoclonal antibody directed to tumor necrosis factor-like ligand 1A, a target associated with both intestinal inflammation and fibrosis. MK-7240 is being developed for the treatment of immune-mediated diseases including ulcerative colitis, Crohn's disease, and other autoimmune conditions. The transaction was accounted for as an acquisition of an asset since MK-7240 accounted for substantially all of the fair value of the gross assets acquired (excluding cash and deferred income taxes). Merck recorded net assets of \$877 million, including cash of \$368 million, investments of \$296 million, deferred tax assets of \$218 million and other net liabilities of \$5 million, as well as *Research and development* expenses of \$10.2 billion in the second quarter and first six months of 2023 related to the transaction. There are no future contingent payments associated with the acquisition.

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 six months 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

thrombocytopenia, myelofibrosis, and polycythemia vera, in addition to other indications. The transaction was accounted for as an acquisition of an asset since bomegestat 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 six months of 2023 related to the transaction. There are no future contingent payments associated with the acquisition.

In May 2022, in connection with an existing arrangement, Merck exercised its option to obtain an exclusive license outside of Chinese mainland, Hong Kong, Macau and Taiwan for the development, manufacture and commercialization of Kelun-Biotech's trophoblast antigen 2 (TROP2)-targeting ADC programs, including its lead compound, SKB-264 (MK-2870), which is currently in Phase 2 clinical development. Under the terms of the agreement, Merck and Kelun-Biotech will collaborate on certain early clinical development plans, including evaluating the potential of MK-2870 as a monotherapy and in combination with *Keytruda* for advanced solid tumors. Upon option exercise, Merck made a payment of \$30 million, which was recorded in *Research and development* expenses in the second quarter and first six months of 2022, and agreed to make additional payments of \$30 million upon completion of specified project activities and \$25 million upon technology transfer. Merck also agreed to make quarterly payments in 2022 and 2023 aggregating up to \$111 million to fund Kelun-Biotech's ongoing research and development activities, of which \$81 million has been paid through June 2023. In addition, Kelun-Biotech is eligible to receive future contingent milestone payments (which include all program compounds) aggregating up to \$90 million in developmental milestones, \$290 million in first commercial sale milestones, and \$780 million in sales-based milestones. The agreement also provides for Merck to pay tiered royalties ranging from a mid-single-digit rate to a low-double-digit rate on future net sales.

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 PLC

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 June 30, 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 six months of 2022. Additionally, in the first six months 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 of \$105 million (which had been previously accrued for). In the second quarter of 2023, Lynparza received a regulatory approval triggering a future milestone payment of up to \$245 million from Merck to AstraZeneca. In 2022, Lynparza received regulatory approvals triggering capitalized milestone payments of \$250 million from Merck to AstraZeneca (of which \$175 million was paid in the first six months of 2022). Potential future regulatory milestone payments of \$850 million remain under the agreement.

The intangible asset balance related to Lynparza (which includes capitalized sales-based and regulatory milestone payments) was \$1.7 billion at June 30, 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 June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Alliance revenue - Lynparza	\$ 310	\$ 275	\$ 585	\$ 541
Alliance revenue - Kosalugo	25	24	48	33
Total alliance revenue	\$ 335	\$ 299	\$ 633	\$ 574
Cost of sales ⁽¹⁾	78	62	148	361
Selling, general and administrative	51	46	98	90
Research and development	22	25	43	51
(\$ in millions)			June 30, 2023	December 31, 2022
Receivables from AstraZeneca included in <i>Other current assets</i>			\$ 332	\$ 303
Payables to AstraZeneca included in <i>Accrued and other current liabilities</i> ⁽²⁾			260	123
Payables to AstraZeneca included in <i>Other Noncurrent Liabilities</i> ⁽²⁾			600	600

⁽¹⁾ Represents amortization of capitalized milestone payments. Amount in the first six months of 2022 includes \$250 million of cumulative amortization catch-up expense as noted above.

⁽²⁾ Includes accrued milestone payments.

Eisai Co., Ltd.

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 the first six months of 2023. The Company made this sales-based milestone payment to Eisai in the second quarter of 2023. In the first six months of 2022, Merck made sales-based milestone payments to Eisai (which had been previously accrued for) aggregating \$600 million. 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 six months 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 \$756 million at June 30, 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 June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Alliance revenue - Lenvima	\$ 242	\$ 231	\$ 474	\$ 459
Cost of sales ⁽¹⁾	57	53	183	106
Selling, general and administrative	48	42	99	73
Research and development	17	47	56	104
(\$ in millions)			June 30, 2023	December 31, 2022
Receivables from Eisai included in <i>Other current assets</i>			\$ 242	\$ 214

⁽¹⁾ Represents amortization of capitalized milestone payments. Amount in the first six months of 2023 includes \$72 million of cumulative amortization catch-up expense as noted above.

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 six months 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 \$586 million and \$55 million, respectively, at June 30, 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 June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Alliance revenue - Adempas/Verquvo	\$ 68	\$ 98	\$ 167	\$ 170
Net sales of Adempas recorded by Merck	65	63	125	124
Net sales of Verquvo recorded by Merck	9	6	16	9
Total sales	\$ 142	\$ 167	\$ 308	\$ 303
Cost of sales ⁽¹⁾	56	54	113	103
Selling, general and administrative	34	42	67	65
Research and development	25	17	50	34
(\$ in millions)			June 30, 2023	December 31, 2022
Receivables from Bayer included in <i>Other current assets</i>			\$ 144	\$ 143
Payables to Bayer included in <i>Accrued and other current liabilities</i>			82	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:

(\$ in millions)	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Net sales of <i>Lagevrio</i> recorded by Merck	\$ 203	\$ 1,177	\$ 595	\$ 4,424
Cost of sales ⁽¹⁾⁽²⁾	193	615	414	2,341
Selling, general and administrative ⁽²⁾	24	34	51	69
Research and development ⁽²⁾	10	30	26	56
(\$ in millions)			June 30, 2023	December 31, 2022
Receivables from Ridgeback included in <i>Other current assets</i> ⁽³⁾			\$ 51	\$ —
Payables to Ridgeback included in <i>Accrued and other current liabilities</i> ⁽⁴⁾			30	348

⁽¹⁾ Includes royalty expense, amortization of capitalized milestone payments and inventory reserves.

⁽²⁾ Expenses include an allocation for overhead charges.

⁽³⁾ Includes partner advances.

⁽⁴⁾ Includes accrued royalties. Amount at December 31, 2022 also includes an accrued milestone payment.

Bristol-Myers Squibb Company

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 Company (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. Alliance revenue related to this collaboration (recorded within *Sales*) consists of royalties and, for the first six months of 2022, also includes the receipt of a regulatory approval milestone payment of \$20 million. Merck recorded alliance revenue related to this collaboration of \$47 million and \$90 million in the second quarter and first six months of 2023, respectively, compared with \$33 million and \$86 million in the second quarter and first six months of 2022, respectively.

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. A majority of the services provided under the TSA terminated within 25 months following the spin-off; a majority of the remaining services will terminate within 35 months following the spin-off. 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 operations for the above MSAs include sales of \$96 million and \$95 million and related cost of sales of \$101 million and \$103 million for the second quarter of 2023 and 2022, respectively, and sales of \$191 million and \$194 million and related cost of sales of \$208 million and \$208 million for the first six months of 2023 and 2022, respectively. Amounts included in the condensed consolidated statement of operations for the TSAs were immaterial for the three and six months ended June 30, 2023 and June 30, 2022.

The amounts due from Organon under all of the above agreements were \$539 million and \$511 million at June 30, 2023 and December 31, 2022, respectively, and are reflected in *Other current assets*. The amounts due to Organon under these agreements were \$351 million and \$345 million at June 30, 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 \$3.9 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 \$236 million and \$258 million in the second quarter of 2023 and 2022, respectively, and \$333 million and \$384 million for the first six months of 2023 and 2022, respectively, related to restructuring program activities. Since inception of the Restructuring Program through June 30, 2023, Merck has recorded total pretax accumulated costs of approximately \$3.7 billion. For the full year of 2023, the Company expects to record charges of approximately \$550 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:

(\$ in millions)	Three Months Ended June 30, 2023				Six Months Ended June 30, 2023			
	Separation Costs	Accelerated Depreciation	Other	Total	Separation Costs	Accelerated Depreciation	Other	Total
Cost of sales	\$ —	\$ 22	\$ 10	\$ 32	\$ —	\$ 43	\$ 18	\$ 61
Selling, general and administrative	—	—	52	52	—	—	53	53
Research and development	—	—	1	1	—	—	1	1
Restructuring costs	110	—	41	151	151	—	67	218
	\$ 110	\$ 22	\$ 104	\$ 236	\$ 151	\$ 43	\$ 139	\$ 333

(\$ in millions)	Three Months Ended June 30, 2022				Six Months Ended June 30, 2022			
	Separation Costs	Accelerated Depreciation	Other	Total	Separation Costs	Accelerated Depreciation	Other	Total
Cost of sales	\$ —	\$ 17	\$ 50	\$ 67	\$ —	\$ 35	\$ 78	\$ 113
Selling, general and administrative	—	8	19	27	—	12	36	48
Research and development	—	22	—	22	—	29	—	29
Restructuring costs	106	—	36	142	132	—	62	194
	\$ 106	\$ 47	\$ 105	\$ 258	\$ 132	\$ 76	\$ 176	\$ 384

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 11) and share-based compensation.

The following table summarizes the charges and spending relating to restructuring program activities for the six months ended June 30, 2023:

(\$ in millions)	Separation Costs	Accelerated Depreciation	Other	Total
Restructuring reserves January 1, 2023	\$ 479	\$ —	\$ 34	\$ 513
Expenses	151	43	139	333
(Payments) receipts, net	(84)	—	(74)	(158)
Non-cash activity	—	(43)	(68)	(111)
Restructuring reserves June 30, 2023 ⁽¹⁾	\$ 546	\$ —	\$ 31	\$ 577

⁽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 Condensed Consolidated Statement of Operations are shown below:

(\$ in millions)	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 June 30,		Six Months Ended June 30,		Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022	2023	2022	2023	2022
Net Investment Hedging Relationships								
Foreign exchange contracts	\$ —	\$ (31)	\$ 1	\$ (46)	\$ —	\$ (1)	\$ 1	\$ (2)
Euro-denominated notes	21	(128)	73	(181)	—	—	—	—

⁽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. The Company is not currently a party to any interest rate swaps.

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:

		June 30, 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						
Foreign exchange contracts	Other current assets	\$ 200	\$ —	\$ 5,976	\$ 220	\$ —	\$ 4,824
Foreign exchange contracts	Other Assets	43	—	1,750	27	—	1,609
Foreign exchange contracts	Accrued and other current liabilities	—	62	2,245	—	101	2,691
Foreign exchange contracts	Other Noncurrent Liabilities	—	1	328	—	1	91
		\$ 243	\$ 63	\$ 10,299	\$ 247	\$ 102	\$ 9,215
Derivatives Not Designated as Hedging Instruments	Balance Sheet Caption						
Foreign exchange contracts	Other current assets	\$ 222	\$ —	\$ 8,838	\$ 186	\$ —	\$ 8,540
Foreign exchange contracts	Accrued and other current liabilities	—	181	10,112	—	307	10,926
		\$ 222	\$ 181	\$ 18,950	\$ 186	\$ 307	\$ 19,466
		\$ 465	\$ 244	\$ 29,249	\$ 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:

(\$ in millions)	June 30, 2023		December 31, 2022	
	Asset	Liability	Asset	Liability
Gross amounts recognized in the condensed consolidated balance sheet	\$ 465	\$ 244	\$ 433	\$ 409
Gross amounts subject to offset in master netting arrangements not offset in the condensed consolidated balance sheet	(180)	(180)	(220)	(220)
Cash collateral received/posted	(102)	—	(66)	(19)
Net amounts	\$ 183	\$ 64	\$ 147	\$ 170

Notes to Condensed Consolidated Financial Statements (unaudited) (continued)

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:

(\$ in millions)	Three Months Ended June 30,						Six Months Ended June 30,					
	2023	2022	2023	2022	2023	2022	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)		Sales		Other (income) expense, net ⁽¹⁾		Other comprehensive income (loss)	
	\$ 15,035	\$ 14,593	\$ 172	\$ 438	\$ (17)	\$ 42	\$ 29,522	\$ 30,494	\$ 259	\$ 1,148	\$ (132)	\$ 102
(Gain) loss on fair value hedging relationships:												
Interest rate swap contracts												
Hedged items	—	—	—	(4)	—	—	—	—	—	(14)	—	—
Derivatives designated as hedging instruments	—	—	—	1	—	—	—	—	—	4	—	—
Impact of cash flow hedging relationships:												
Foreign exchange contracts												
Amount of gain recognized in OCI on derivatives	—	—	—	—	194	403	—	—	—	—	128	551
Increase in Sales as a result of AOCL reclassifications	24	172	—	—	(24)	(172)	125	239	—	—	(125)	(239)
Interest rate contracts												
Amount of gain recognized in Other (income) expense, net on derivatives	—	—	—	—	—	—	—	—	(1)	(1)	—	—
Amount of gain (loss) recognized in OCI on derivatives	—	—	—	—	13	—	—	—	—	—	13	(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:

(\$ in millions)	Derivatives Not Designated as Hedging Instruments	Income Statement Caption	Amount of Derivative Pretax (Gain) Loss Recognized in Income			
			Three Months Ended June 30,		Six Months Ended June 30,	
			2023	2022	2023	2022
	Foreign exchange contracts ⁽¹⁾	Other (income) expense, net	\$ (41)	\$ (64)	\$ (28)	\$ (36)
	Foreign exchange contracts ⁽²⁾	Sales	(5)	(36)	(3)	(38)

⁽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 June 30, 2023, the Company estimates \$83 million of pretax net unrealized gains 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:

(\$ in millions)	June 30, 2023				December 31, 2022			
	Amortized Cost	Gross Unrealized		Fair Value	Amortized Cost	Gross Unrealized		Fair Value
		Gains	Losses			Gains	Losses	
Commercial paper	\$ 561	\$ —	\$ —	\$ 561	\$ 498	\$ —	\$ —	\$ 498
U.S. government and agency securities	256	—	—	256	68	—	—	68
Corporate notes and bonds	4	—	—	4	3	—	—	3
Total debt securities	\$ 821	\$ —	\$ —	\$ 821	\$ 569	\$ —	\$ —	\$ 569
Publicly traded equity securities ⁽¹⁾				1,520				1,284
Total debt and publicly traded equity securities				\$ 2,341				\$ 1,853

⁽¹⁾ Unrealized net losses (gains) of \$71 million and \$(267) million were recorded in Other (income) expense, net in the second quarter and first six months of 2023, respectively, on equity securities still held at June 30, 2023. Unrealized net (gains) losses of \$(25) million and \$194 million were recorded in Other (income) expense, net in the second quarter and first six months of 2022, respectively, on equity securities still held at June 30, 2022.

At June 30, 2023 and June 30, 2022, the Company also had \$949 million and \$671 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 six months of 2023, the Company recorded unrealized gains of \$3 million and unrealized losses of \$23 million related to certain of these equity investments still held at June 30, 2023. During the first six months of 2022, the Company recorded unrealized gains of \$20 million and unrealized losses of \$1 million related to certain of these investments still held at June 30, 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 June 30, 2023 were \$287 million and \$42 million, respectively.

At June 30, 2023 and June 30, 2022, the Company also had \$622 million and \$805 million, 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 \$105 million and \$302 million for the second quarter of 2023 and 2022, respectively, and were \$(27) million and \$811 million for the first six months 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:

(\$ in millions)	Fair Value Measurements Using				Fair Value Measurements Using											
	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3	Total								
	June 30, 2023				December 31, 2022											
Assets																
Investments																
Commercial paper	\$	—	\$	561	\$	—	\$	498	\$	—	\$	498				
U.S. government and agency securities		—		187		—		187		—		—				
Publicly traded equity securities		1,184		—		—		1,184		1,015		—		1,015		
		1,184		748		—		1,932		1,015		498		—	1,513	
Other assets ⁽¹⁾																
U.S. government and agency securities		69		—		—		69		68		—		—	68	
Corporate notes and bonds		4		—		—		4		3		—		—	3	
Publicly traded equity securities		336		—		—		336		269		—		—	269	
		409		—		—		409		340		—		—	340	
Derivative assets ⁽²⁾																
Forward exchange contracts		—		316		—		316		—		218		—	218	
Purchased currency options		—		149		—		149		—		215		—	215	
		—		465		—		465		—		433		—	433	
Total assets	\$	1,593	\$	1,213	\$	—	\$	2,806	\$	1,355	\$	931	\$	—	\$	2,286
Liabilities																
Other liabilities																
Contingent consideration	\$	—	\$	—	\$	349	\$	349	\$	—	\$	—	\$	456	\$	456
Derivative liabilities ⁽²⁾																
Forward exchange contracts		—		235		—		235		—		402		—		402
Written currency options		—		9		—		9		—		7		—		7
		—		244		—		244		—		409		—		409
Total liabilities	\$	—	\$	244	\$	349	\$	593	\$	—	\$	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 June 30, 2023 and December 31, 2022, *Cash and cash equivalents* included \$4.9 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⁾	10	(114)
Payments	(117)	(119)
Other	—	(2)
Fair value June 30 ⁽²⁾	\$ 349	\$ 542

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

⁽²⁾ At June 30, 2023, \$262 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 June 30, 2023 includes \$130 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 June 30, 2023, was \$34.0 billion compared with a carrying value of \$36.9 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 \$2.9 billion and \$2.5 billion of accounts receivable as of June 30, 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 June 30, 2023 and December 31, 2022, the Company had collected \$44 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 July 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 \$102 million and \$66 million at June 30, 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)	June 30, 2023		December 31, 2022	
Finished goods	\$	1,841	\$	1,841
Raw materials and work in process		7,453		7,063
Supplies		269		238
Total		9,563		9,142
Decrease to LIFO cost		(413)		(293)
	\$	9,150	\$	8,849
Recognized as:				
Inventories	\$	5,930	\$	5,911
Other Assets		3,220		2,938

Amounts recognized as *Other Assets* are comprised almost entirely of raw materials and work in process inventories. At June 30, 2023 and December 31, 2022, these amounts included \$2.6 billion and \$2.4 billion, respectively, of inventories not expected to be sold within one year. In addition, these amounts included \$663 million and \$516 million at June 30, 2023 and December 31, 2022, respectively, of inventories produced in preparation for product launches.

8. Long-Term Debt

In May 2023, the Company issued \$6.0 billion principal amount of senior unsecured notes consisting of \$500 million of 4.05% notes due 2028, \$750 million of 4.30% notes due 2030, \$1.5 billion of 4.50% notes due 2033, \$750 million of 4.90% notes due 2044, \$1.5 billion of 5.00% notes due 2053, and \$1.0 billion of 5.15% notes due 2063.

The Company used a portion of the \$5.9 billion net proceeds from this offering to fund a portion of the cash consideration paid for the acquisition of Prometheus and related fees and expenses, and used the remaining net proceeds for general corporate purposes including to repay commercial paper borrowings and other indebtedness with upcoming maturities.

9. 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 June 30, 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.

Governmental Proceedings

Inflation Reduction Act

On June 6, 2023, Merck filed a complaint in the U.S. District Court for the District of Columbia against the U.S. government regarding the Inflation Reduction Act's "Drug Price Negotiation Program" for Medicare (the Program). This litigation seeks relief from the Program by challenging its constitutionality as violative of the First and Fifth Amendments to the U.S. Constitution.

Other 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) were 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 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.

As previously disclosed, 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 agreed to 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. On June 6, 2023, the court granted preliminary approval of the indirect purchaser class settlement and scheduled a fairness hearing for September 21, 2023.

Qui Tam Litigation

As previously disclosed, in June 2012, the U.S. District Court for the Eastern District of Pennsylvania unsealed a complaint that had been filed against the Company under the federal False Claims Act by two former employees alleging, among other things, that the Company defrauded the U.S. government by falsifying data in connection with a clinical study conducted on the mumps component of the Company's *M-M-R* II vaccine. The complaint alleges the fraud took place between 1999 and 2001. The U.S. government had the right to participate in and take over the prosecution of this lawsuit but notified the court that it declined to exercise that right. The two former employees are pursuing the lawsuit without the involvement of the U.S. government. In addition, as previously disclosed, two putative class action lawsuits on behalf of direct purchasers of the *M-M-R* II vaccine, which charge that the Company misrepresented the efficacy of the *M-M-R* II vaccine in violation of federal antitrust laws and various state consumer protection laws, are pending in the Eastern District of Pennsylvania. In September 2014, the court denied Merck's motion to dismiss the False Claims Act suit and granted in part and denied in part its motion to dismiss the then-pending antitrust suit. As a result, both the False Claims Act suit and the antitrust suits proceeded into discovery, which is complete, and the parties filed and briefed cross-motions for summary judgment. On July 27, 2023, in the False Claims Act case, the court denied relators' motion for summary judgment, granted two of the Company's motions for summary judgment, and denied the Company's remaining motions for summary judgment as moot. The court entered judgment in favor of the Company and dismissed relators' amended complaint in full with prejudice. Relators can appeal that decision. In the antitrust case, the court granted the Company's motion for summary judgment as to plaintiffs' state law claims and denied the motion as to plaintiffs' antitrust claim. Plaintiffs' antitrust claim will proceed in litigation.

Patent Litigation

From time to time, generic manufacturers of pharmaceutical products file abbreviated New Drug Applications (NDAs) with the U.S. Food and Drug Administration (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 were consolidated. 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 stipulated to infringement of the asserted claims and withdrew all remaining claims and defenses other than a defense seeking to shorten the patent term extension (PTE) 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 PTE calculation defense and held closing arguments on February 3, 2023.

While the New Jersey action was pending, the Company 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 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.

On June 13, 2023, the U.S. District Court for the District of New Jersey ruled in Merck's favor. The court held that Merck's calculation of PTE for the sugammadex patent covering the compound is not invalid and that the U.S. Patent & Trademark Office correctly granted a full 5-year extension. This ruling affirms and validates Merck's U.S. patent protection for *Bridion* through at least January 2026. On June 29, 2023, the U.S. District Court for the District of New Jersey issued a final judgment prohibiting the FDA from approving any of the pending or tentatively approved generic applications until January 27, 2026, except for any subsequent agreements between Defendants and Merck or further order by the court.

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. The Company also filed a patent infringement lawsuit against Mylan in the U.S. District Court for the Northern District of West Virginia.

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 U.S. 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 Viatris has agreed to voluntarily dismiss the appeal following entry of an amended final judgment by the district court.

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 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 2027 salt/polymorph 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 could be available prior to 2026.

Supplementary Protection Certificates (SPCs) for *Janumet* expired in April 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 in the third quarter with a decision in the fourth quarter of 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 U.S. 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.

Other Matters

As previously disclosed, the Company was involved in an arbitration with Johnson & Johnson with respect to two agreements pursuant to which Merck was supporting the manufacture and supply of Johnson & Johnson's SARS-CoV-2/COVID-19 vaccine and vaccine drug product. The arbitration has been settled with no material impact to the Company's financial statements.

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 June 30, 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.

10. Equity

(\$ and shares in millions except per share amounts)	Three Months Ended June 30,								
	Common Stock		Other Paid-In Capital	Retained Earnings	Accumulated Other Comprehensive Loss	Treasury Stock		Non-controlling Interests	Total
	Shares	Par Value				Shares	Cost		
Balance at April 1, 2022	3,577	\$ 1,788	\$ 44,275	\$ 56,252	\$ (4,369)	1,049	\$ (57,063)	\$ 70	\$ 40,953
Net income attributable to Merck & Co., Inc.	—	—	—	3,944	—	—	—	—	3,944
Other comprehensive income, net of taxes	—	—	—	—	42	—	—	—	42
Cash dividends declared on common stock (\$0.69 per share)	—	—	—	(1,759)	—	—	—	—	(1,759)
Share-based compensation plans and other	—	—	(160)	—	—	(5)	293	—	133
Net income attributable to noncontrolling interests	—	—	—	—	—	—	—	5	5
Balance at June 30, 2022	3,577	\$ 1,788	\$ 44,115	\$ 58,437	\$ (4,327)	1,044	\$ (56,770)	\$ 75	\$ 43,318
Balance at April 1, 2023	3,577	\$ 1,788	\$ 44,467	\$ 62,039	\$ (4,883)	1,040	\$ (56,577)	\$ 71	\$ 46,905
Net loss attributable to Merck & Co., Inc.	—	—	—	(5,975)	—	—	—	—	(5,975)
Other comprehensive loss, net of taxes	—	—	—	—	(17)	—	—	—	(17)
Cash dividends declared on common stock (\$0.73 per share)	—	—	—	(1,866)	—	—	—	—	(1,866)
Treasury stock shares purchased	—	—	—	—	—	3	(338)	—	(338)
Share-based compensation plans and other	—	—	(248)	—	—	(5)	303	—	55
Net income attributable to noncontrolling interests	—	—	—	—	—	—	—	3	3
Distributions attributable to noncontrolling interests	—	—	—	—	—	—	—	(25)	(25)
Balance at June 30, 2023	3,577	\$ 1,788	\$ 44,219	\$ 54,198	\$ (4,900)	1,038	\$ (56,612)	\$ 49	\$ 38,742

(\$ and shares in millions except per share amounts)	Six Months Ended June 30,								
	Common Stock		Other Paid-In Capital	Retained Earnings	Accumulated Other Comprehensive Loss	Treasury Stock		Non-controlling Interests	Total
	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.	—	—	—	8,254	—	—	—	—	8,254
Other comprehensive income, net of taxes	—	—	—	—	102	—	—	—	102
Cash dividends declared on common stock (\$1.38 per share)	—	—	—	(3,513)	—	—	—	—	(3,513)
Share-based compensation plans and other	—	—	(123)	—	—	(5)	339	—	216
Net income attributable to noncontrolling interests	—	—	—	—	—	—	—	2	2
Balance at June 30, 2022	3,577	\$ 1,788	\$ 44,115	\$ 58,437	\$ (4,327)	1,044	\$ (56,770)	\$ 75	\$ 43,318
Balance at January 1, 2023	3,577	\$ 1,788	\$ 44,379	\$ 61,081	\$ (4,768)	1,039	\$ (56,489)	\$ 67	\$ 46,058
Net loss attributable to Merck & Co., Inc.	—	—	—	(3,154)	—	—	—	—	(3,154)
Other comprehensive loss, net of taxes	—	—	—	—	(132)	—	—	—	(132)
Cash dividends declared on common stock (\$1.46 per share)	—	—	—	(3,729)	—	—	—	—	(3,729)
Treasury stock shares purchased	—	—	—	—	—	4	(487)	—	(487)
Share-based compensation plans and other	—	—	(160)	—	—	(5)	364	—	204
Net income attributable to noncontrolling interests	—	—	—	—	—	—	—	7	7
Distributions attributable to noncontrolling interests	—	—	—	—	—	—	—	(25)	(25)
Balance at June 30, 2023	3,577	\$ 1,788	\$ 44,219	\$ 54,198	\$ (4,900)	1,038	\$ (56,612)	\$ 49	\$ 38,742

11. 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:

(\$ in millions)	Three Months Ended June 30,				Six Months Ended June 30,			
	2023		2022		2023		2022	
	U.S.	International	U.S.	International	U.S.	International	U.S.	International
Service cost	\$ 76	\$ 50	\$ 99	\$ 72	\$ 152	\$ 99	\$ 198	\$ 147
Interest cost	133	75	103	37	266	149	206	75
Expected return on plan assets	(185)	(130)	(197)	(98)	(372)	(257)	(393)	(199)
Amortization of unrecognized prior service cost (credit)	—	16	(8)	(3)	(1)	12	(16)	(7)
Net (gain) loss amortization	—	(1)	56	25	—	(2)	112	50
Termination benefits	1	—	1	—	1	—	1	—
Curtailments	2	—	4	—	5	—	8	—
Settlements	5	—	101	—	26	—	101	—
	\$ 32	\$ 10	\$ 159	\$ 33	\$ 77	\$ 1	\$ 217	\$ 66

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:

(\$ in millions)	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Service cost	\$ 8	\$ 12	\$ 17	\$ 25
Interest cost	16	11	31	23
Expected return on plan assets	(16)	(21)	(32)	(43)
Amortization of unrecognized prior service credit	(12)	(14)	(25)	(29)
Net gain amortization	(11)	(11)	(21)	(21)
	\$ (15)	\$ (23)	\$ (30)	\$ (45)

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 partial settlement charges in the second quarter and first six months of both 2023 and 2022. These partial settlements triggered remeasurements of some of the Company's U.S. pension plans. Remeasurements during the first six months of 2023 resulted in an increase of \$47 million to net pension liabilities and 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 12), with the exception of certain amounts for termination benefits, curtailments and settlements, which are recorded in *Restructuring costs* if the event giving rise to the termination benefits, curtailment or settlement related to restructuring actions.

12. Other (Income) Expense, Net

Other (income) expense, net, consisted of:

(\$ in millions)	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Interest income	\$ (109)	\$ (15)	\$ (221)	\$ (22)
Interest expense	277	240	519	483
Exchange losses	62	86	122	124
Loss (income) from investments in equity securities, net ⁽¹⁾	175	284	(274)	991
Net periodic defined benefit plan (credit) cost other than service cost	(111)	(27)	(226)	(148)
Other, net	(122)	(130)	339	(280)
	\$ 172	\$ 438	\$ 259	\$ 1,148

⁽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 six months of 2023 includes a \$572.5 million charge related to settlements with certain plaintiffs in the Zetia antitrust litigation (see Note 9).

Interest paid for both the six months ended June 30, 2023 and 2022 was \$449 million.

13. Income Taxes

The income tax provision of \$637 million and \$1.5 billion for the second quarter and first six months of 2023, respectively, on pretax losses of \$5.3 billion and \$1.7 billion, respectively, resulted in effective income tax rates of (11.9)% and (86.8)%, respectively. The second quarter 2023 effective tax rate includes the impact of a charge for the acquisition of Prometheus for which no tax benefit was recognized, which unfavorably affected the tax rate by 25.1 percentage points, as well as the favorable impact of net unrealized losses from investments in equity securities, which were taxed at the U.S. tax rate. The effective income tax rate for the first six months of 2023 includes a 101.9 percentage point combined unfavorable impact of charges for the acquisitions of Prometheus and Imago for which no tax benefits were recognized, as well as higher foreign taxes, the impact of the R&D capitalization provision of the Tax Cuts and Jobs Act of 2017 (TCJA) 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 rates of 12.0% for the second quarter of 2022 and 11.7% for the first six months of 2022 reflect the favorable impact of net unrealized losses from investments in equity securities, which were taxed at the U.S. tax rate.

The Internal Revenue Service (IRS) is currently conducting examinations of the Company's tax returns for the years 2017 and 2018, including the one-time transition tax enacted under the TCJA. If the IRS disagrees with the Company's transition tax position, it may result in a significant tax liability.

14. Earnings Per Share

The calculations of (loss) earnings per share are as follows:

(\$ and shares in millions except per share amounts)	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Net (Loss) Income Attributable to Merck & Co., Inc.	\$ (5,975)	\$ 3,944	\$ (3,154)	\$ 8,254
Average common shares outstanding	2,539	2,531	2,539	2,529
Common shares issuable ⁽¹⁾	—	9	—	9
Average common shares outstanding assuming dilution	2,539	2,540	2,539	2,538
Basic (Loss) Earnings per Common Share Attributable to Merck & Co., Inc. Common Shareholders	\$ (2.35)	\$ 1.56	\$ (1.24)	\$ 3.26
(Loss) Earnings per Common Share Assuming Dilution Attributable to Merck & Co., Inc. Common Shareholders	\$ (2.35)	\$ 1.55	\$ (1.24)	\$ 3.25

⁽¹⁾ Issuable primarily under share-based compensation plans.

The Company recorded a net loss for the three and six months ended June 30, 2023; therefore, no potential dilutive common shares were used in the computations of loss per common share assuming dilution because the effects would have been antidilutive. For the three and six months ended June 30, 2022, 2 million and 6 million, respectively, of common shares issuable under share-based compensation plans were excluded from the computations of earnings per common share assuming dilution because the effect would have been antidilutive.

15. Other Comprehensive Income (Loss)

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

(\$ in millions)	Three Months Ended June 30,			
	Derivatives	Employee Benefit Plans	Foreign Currency Translation Adjustment	Accumulated Other Comprehensive Loss
Balance April 1, 2022, net of taxes	\$ 207	\$ (2,711)	\$ (1,865)	\$ (4,369)
Other comprehensive income (loss) before reclassification adjustments, pretax	403	168	(365)	206
Tax	(85)	(35)	(22)	(142)
Other comprehensive income (loss) before reclassification adjustments, net of taxes	318	133	(387)	64
Reclassification adjustments, pretax	(171) ⁽¹⁾	144 ⁽²⁾	—	(27)
Tax	36	(31)	—	5
Reclassification adjustments, net of taxes	(135)	113	—	(22)
Other comprehensive income (loss), net of taxes	183	246	(387)	42
Balance June 30, 2022, net of taxes	\$ 390	\$ (2,465)	\$ (2,252)	\$ (4,327)
Balance April 1, 2023, net of taxes	\$ (60)	\$ (2,458)	\$ (2,365)	\$ (4,883)
Other comprehensive income (loss) before reclassification adjustments, pretax	194	(6)	(115)	73
Tax	(41)	1	(22)	(62)
Other comprehensive income (loss) before reclassification adjustments, net of taxes	153	(5)	(137)	11
Reclassification adjustments, pretax	(11) ⁽¹⁾	(23) ⁽²⁾	—	(34)
Tax	3	3	—	6
Reclassification adjustments, net of taxes	(8)	(20)	—	(28)
Other comprehensive income (loss), net of taxes	145	(25)	(137)	(17)
Balance June 30, 2023, net of taxes	\$ 85	\$ (2,483)	\$ (2,502)	\$ (4,900)

(\$ in millions)	Six Months Ended June 30,			
	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	551	169	(383)	337
Tax	(116)	(37)	(39)	(192)
Other comprehensive income (loss) before reclassification adjustments, net of taxes	435	132	(422)	145
Reclassification adjustments, pretax	(239) ⁽¹⁾	189 ⁽²⁾	—	(50)
Tax	50	(43)	—	7
Reclassification adjustments, net of taxes	(189)	146	—	(43)
Other comprehensive income (loss), net of taxes	246	278	(422)	102
Balance June 30, 2022, net of taxes	\$ 390	\$ (2,465)	\$ (2,252)	\$ (4,327)
Balance January 1, 2023, net of taxes	\$ 73	\$ (2,408)	\$ (2,433)	\$ (4,768)
Other comprehensive income (loss) before reclassification adjustments, pretax	128	(53)	(36)	39
Tax	(27)	3	(42)	(66)
Other comprehensive income (loss) before reclassification adjustments, net of taxes	101	(50)	(78)	(27)
Reclassification adjustments, pretax	(113) ⁽¹⁾	(30) ⁽²⁾	9	(134)
Tax	24	5	—	29
Reclassification adjustments, net of taxes	(89)	(25)	9	(105)
Other comprehensive income (loss), net of taxes	12	(75)	(69)	(132)
Balance June 30, 2023, net of taxes	\$ 85	\$ (2,483)	\$ (2,502)	\$ (4,900)

⁽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 11)

16. 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:

(\$ in millions)	Three Months Ended June 30,						Six Months Ended June 30,					
	2023			2022			2023			2022		
	U.S.	Int'l	Total	U.S.	Int'l	Total	U.S.	Int'l	Total	U.S.	Int'l	Total
Pharmaceutical:												
Oncology												
Keytruda	\$ 3,863	\$ 2,408	\$ 6,271	\$ 3,197	\$ 2,055	\$ 5,252	\$ 7,348	\$ 4,718	\$ 12,065	\$ 5,976	\$ 4,085	\$ 10,061
Alliance revenue-Lynparza ⁽¹⁾	144	166	310	143	132	275	286	299	585	283	257	541
Alliance revenue-Lenvima ⁽¹⁾	163	79	242	128	103	231	316	158	474	284	175	459
Welireg	49	2	50	27	—	27	90	3	92	45	—	45
Alliance revenue-Reblozyl ⁽²⁾	36	11	47	28	5	33	66	24	90	55	30	86
Vaccines												
Gardasil/Gardasil 9	464	1,994	2,458	428	1,245	1,674	880	3,550	4,430	846	2,287	3,133
ProQuad/M-M-R II/Varivax	447	135	582	434	143	578	868	242	1,109	805	243	1,047
RotaTeq	93	37	131	98	75	173	273	155	428	273	116	389
Vaxneuvance	147	20	168	11	—	12	241	33	274	16	1	16
Pneumovax 23	23	69	92	94	59	153	63	125	188	212	114	325
Vaqta	29	13	42	16	19	35	59	23	82	45	25	71
Hospital Acute Care												
Bridion	299	203	502	237	190	426	576	413	989	432	389	821
Prevymis	61	82	143	47	56	103	116	157	273	87	110	197
Difcid	68	8	76	63	3	66	130	11	141	113	6	119
Primaxin	(2)	56	53	—	64	64	2	132	133	1	122	122
Noxafil	11	45	55	16	45	60	25	91	116	25	92	118
Zerbaxa	30	24	54	22	24	46	57	47	104	40	36	76
Cardiovascular												
Alliance revenue-Adempas/Verquuvo ⁽³⁾	70	(2)	68	88	10	98	153	14	167	159	11	170
Adempas	—	65	65	—	63	63	—	125	125	—	124	124
Virology												
Lagevrio	2	201	203	—	1,177	1,177	—	595	595	1,523	2,901	4,424
Isentress/Isentress HD	56	80	136	67	80	147	108	151	259	128	177	305
Neuroscience												
Belsomra	21	42	63	19	50	69	37	82	119	39	98	137
Immunology												
Simponi	—	180	180	—	181	181	—	359	359	—	366	366
Remicade	—	48	48	—	53	53	—	99	99	—	114	114
Diabetes												
Januvia	243	267	511	301	455	756	514	548	1,062	626	909	1,535
Janumet	82	272	354	105	371	476	138	544	683	168	762	931
Other pharmaceutical ⁽⁴⁾	171	382	553	157	372	528	342	793	1,138	317	814	1,131
Total Pharmaceutical segment sales	6,570	6,887	13,457	5,726	7,030	12,756	12,688	13,491	26,179	12,498	14,364	26,863
Animal Health:												
Livestock	165	643	807	164	662	826	338	1,318	1,656	335	1,322	1,658
Companion Animal	310	339	649	313	328	641	618	673	1,291	616	676	1,291
Total Animal Health segment sales	475	982	1,456	477	990	1,467	956	1,991	2,947	951	1,998	2,949
Total segment sales	7,045	7,869	14,913	6,203	8,020	14,223	13,644	15,482	29,126	13,449	16,362	29,812
Other ⁽⁵⁾	(27)	149	122	35	335	370	32	364	396	128	555	682
	\$ 7,018	\$ 8,018	\$ 15,035	\$ 6,238	\$ 8,355	\$ 14,593	\$ 13,676	\$ 15,846	\$ 29,522	\$ 13,577	\$ 16,917	\$ 30,494

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 the first six months of 2022, also includes the receipt of a regulatory approval milestone payment (see Note 3).

⁽³⁾ Alliance revenue for Adempas/Verquuvo 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 \$128 million and \$277 million for the six months ended June 30, 2023 and 2022, respectively, as well as revenue from third-party manufacturing arrangements (including sales to Organon). Other for the six months ended June 30, 2023 and 2022 also includes \$54 million and \$146 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 \$3.2 billion and \$3.0 billion for the three months ended June 30, 2023 and 2022, respectively, and \$6.3 billion and \$5.9 billion for the six months ended June 30, 2023 and 2022, respectively.

Consolidated sales by geographic area where derived are as follows:

(\$ in millions)	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
United States	\$ 7,018	\$ 6,238	\$ 13,676	\$ 13,577
Europe, Middle East and Africa	3,348	3,582	6,651	7,942
China	1,913	1,372	3,628	2,515
Asia Pacific (other than China and Japan)	848	1,008	1,694	1,938
Japan	675	1,114	1,434	2,103
Latin America	742	642	1,403	1,249
Other	491	637	1,036	1,170
	\$ 15,035	\$ 14,593	\$ 29,522	\$ 30,494

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

(\$ in millions)	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Segment profits:				
Pharmaceutical segment	\$ 9,854	\$ 9,173	\$ 18,993	\$ 18,673
Animal Health segment	467	571	1,032	1,156
Total segment profits	10,321	9,744	20,025	19,829
Other profits	19	260	184	454
Unallocated:				
Interest income	109	15	221	22
Interest expense	(277)	(240)	(519)	(483)
Amortization	(477)	(463)	(1,020)	(1,163)
Depreciation	(376)	(431)	(775)	(809)
Research and development	(13,194)	(2,652)	(17,341)	(5,097)
Restructuring costs	(151)	(142)	(218)	(194)
Charge for Zetia antitrust litigation settlements	—	—	(573)	—
Other unallocated, net	(1,309)	(1,604)	(1,669)	(3,211)
	\$ (5,335)	\$ 4,487	\$ (1,685)	\$ 9,348

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, 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 June 2023, Merck acquired 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. Total consideration paid of \$11.0 billion included \$1.2 billion of costs to settle share-based equity awards (including \$700 million to settle unvested equity awards). Prometheus' lead candidate, MK-7240 (formerly PRA023), is a humanized monoclonal antibody directed to tumor necrosis factor-like ligand 1A, a target associated with both intestinal inflammation and fibrosis. MK-7240 is being developed for the treatment of immune-mediated diseases including ulcerative colitis, Crohn's disease, and other autoimmune conditions. The transaction was accounted for as an acquisition of an asset. Merck recorded net assets of \$877 million, including cash of \$368 million, investments of \$296 million, deferred tax assets of \$218 million and other net liabilities of \$5 million, as well as *Research and development* expenses of \$10.2 billion in the second quarter and first six months of 2023 related to the transaction or \$4.02 per share. There are no future contingent payments associated with the acquisition.

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 six months 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 six months 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 six 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 (IRA), 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). The Company has sued the U.S. government regarding the IRA's "Drug Price Negotiation Program" for Medicare (see Note 9 to the condensed consolidated financial statements). Furthermore, 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.

Operating Results

Sales

(\$ in millions)	Three Months Ended June 30,		% Change	% Change Excluding Foreign Exchange	Six Months Ended June 30,		% Change	% Change Excluding Foreign Exchange
	2023	2022			2023	2022		
United States	\$ 7,018	\$ 6,238	12 %	12 %	\$ 13,676	\$ 13,577	1 %	1 %
International	8,018	8,355	(4)%	2 %	15,846	16,917	(6)%	— %
Total	\$ 15,035	\$ 14,593	3 %	7 %	\$ 29,522	\$ 30,494	(3)%	— %

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

Worldwide sales grew 3% to \$15.0 billion in the second quarter of 2023 primarily due to higher sales in the oncology franchise, largely driven by strong growth of *Keytruda* (pembrolizumab), and 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. Also contributing to revenue growth in the second quarter were higher sales of hospital acute care products, including *Bridion* (sugammadex) Injection and *Prevymis* (letermovir). Sales growth in the second quarter of 2023 was partially offset by lower sales in the virology franchise largely due to *Lagevrio* (molnupiravir) which had sales of \$203 million in the second quarter of 2023 compared with \$1.2 billion in the second quarter of 2022. Lower sales in the diabetes franchise attributable to *Januvia* (sitagliptin) and *Janumet* (sitagliptin and metformin HCl), as well as lower sales of *Pneumovax* 23 (pneumococcal vaccine polyvalent) also partially offset revenue growth in the second quarter of 2023.

Worldwide sales declined 3% to \$29.5 billion in the first six months of 2023 primarily due to lower sales in the virology franchise, largely attributable to *Lagevrio*, which had sales of \$595 million in the first six months of 2023 compared with \$4.4 billion in the first six months of 2022. Also contributing to the revenue decline in the first six months of 2023 were lower sales in the diabetes franchise due to *Januvia* and *Janumet*, as well as lower sales of *Pneumovax* 23. The sales decline in the first six months of 2023 was largely offset by higher sales in the oncology franchise, primarily driven by strong growth of *Keytruda*, higher sales in the vaccines franchise, primarily attributable to growth of *Gardasil* 9 and the ongoing launch of *Vaxneuvance* for pediatric use, as well as higher sales of hospital acute care products, including *Bridion* and *Prevymis*.

See Note 16 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 June 30,		% Change	% Change Excluding Foreign Exchange	Six Months Ended June 30,		% Change	% Change Excluding Foreign Exchange
	2023	2022			2023	2022		
<i>Keytruda</i>	\$ 6,271	\$ 5,252	19 %	21 %	\$ 12,065	\$ 10,061	20 %	23 %
Alliance Revenue - Lynparza ⁽¹⁾	310	275	13 %	15 %	585	541	8 %	12 %
Alliance Revenue - Lenvima ⁽¹⁾	242	231	5 %	6 %	474	459	3 %	5 %
<i>Welireg</i>	50	27	89 %	89 %	92	45	*	*
Alliance Revenue - Reblozyl ⁽²⁾	47	33	41 %	41 %	90	86	4 %	4 %

* > 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 the first six months 2022, also includes a payment received related to the achievement of a regulatory approval milestone (see Note 3 to the condensed 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), melanoma, Merkel cell carcinoma, microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) solid tumors (including MSI-H/dMMR colorectal cancer and endometrial carcinoma), non-small-cell lung cancer (NSCLC), primary mediastinal large B-cell lymphoma (PMBCL), tumor mutational burden-high (TMB-H) 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 melanoma, and for certain patients with renal cell carcinoma (RCC) post-surgery. *Keytruda* is approved for adjuvant treatment following resection and platinum-based chemotherapy for certain patients with NSCLC. *Keytruda* is also approved for 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 in combination with chemotherapy for the treatment of certain patients with advanced NSCLC, in combination with chemotherapy with or without bevacizumab for advanced cervical cancer, in combination with chemotherapy for advanced esophageal cancer, in combination with trastuzumab and chemotherapy for certain patients with advanced gastric or GEJ adenocarcinoma, in combination with chemotherapy for HNSCC, in combination with chemotherapy for advanced TNBC, in combination with axitinib for advanced RCC, in combination with Lenvima for patients with advanced RCC or certain types of

advanced endometrial carcinoma, and in combination with enfortumab vedotin for certain cisplatin-ineligible patients with locally advanced or metastatic urothelial carcinoma. 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 19% and 20% in the second quarter and first six months of 2023, respectively. Sales growth in both periods 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, Latin America and Japan.

Keytruda received the following regulatory approvals thus far in 2023.

Date	Approval
January 2023	U.S. Food and Drug Administration (FDA) approval as a single agent for adjuvant treatment following surgical resection and platinum-based chemotherapy for adult patients with stage IB (T2a \geq 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 the 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 the KEYNOTE-869 trial dose escalation cohort, Cohort A and Cohort K, which was conducted in collaboration with Seagen and Astellas.
June 2023	Japan's Ministry of Health, Labor and Welfare (MHLW) approval for the treatment of patients with relapsed or refractory PMBCL, based on the KEYNOTE-170 and the KEYNOTE-A33 studies.

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 13% and 8% in the second quarter and first six months of 2023, respectively, primarily driven by higher demand in certain international markets, particularly in Europe for certain patients with ovarian, early breast and prostate cancers, and in Japan in certain patients with ovarian and early breast cancers. In May 2023, the FDA approved Lynparza in combination with abiraterone and prednisone or prednisolone for the treatment of certain adult patients with deleterious or suspected deleterious *BRCA*-mutated (*BRCAm*) metastatic castration-resistant prostate cancer (mCRPC), based on the PROpel trial.

Lenvima (lenvatinib) 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 5% and 3% in the second quarter and first six months of 2023, respectively, largely reflecting uptake in the advanced RCC and endometrial indications in the U.S., partially offset by lower demand in China.

Sales of *Welireg* (belzutifan), for the treatment of adult patients with certain von Hippel-Lindau disease-associated tumors, were \$50 million and \$27 million in the second quarter of 2023 and 2022, respectively, and were \$92 million and \$45 million in the first six months of 2023 and 2022, respectively. The sales increase in both periods is due to continued uptake in the U.S. following launch in 2021.

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 Company (see Note 3 to the condensed consolidated financial statements). Reblozyl is approved for the treatment of anemia in certain rare blood disorders. Alliance revenue related to this collaboration consists of royalties and, for the first six months of 2022, also includes the receipt of a regulatory approval milestone payment of \$20 million. Alliance revenue increased 41% and 4% in the second quarter and first six months of 2023, respectively, due to strong underlying sales performance. The increase in alliance revenue in the first six months of 2023 was partially offset by the receipt of the regulatory approval milestone in 2022 as noted above.

Vaccines

(\$ in millions)	Three Months Ended June 30,		% Change	% Change Excluding Foreign Exchange	Six Months Ended June 30,		% Change	% Change Excluding Foreign Exchange
	2023	2022			2023	2022		
<i>Gardasil/Gardasil 9</i>	\$ 2,458	\$ 1,674	47 %	53 %	\$ 4,430	\$ 3,133	41 %	48 %
<i>ProQuad</i>	222	214	4 %	4 %	412	376	10 %	10 %
<i>M-M-R II</i>	104	103	2 %	2 %	207	206	— %	1 %
<i>Varivax</i>	255	261	(2)%	(2)%	491	465	5 %	6 %
<i>RotaTeq</i>	131	173	(25)%	(24)%	428	389	10 %	13 %
<i>Vaxneuvance</i>	168	12	*	*	274	16	*	*
<i>Pneumovax 23</i>	92	153	(40)%	(38)%	188	325	(42)%	(39)%

* > 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 47% and 41% in the second quarter and first six months of 2023, respectively, driven primarily by higher global demand, particularly in China due in part to continued uptake of the expanded indication of *Gardasil 9* for girls and women 9 to 45 years of age. The Company anticipates the growth rate of combined *Gardasil/Gardasil 9* sales will moderate in the second half of 2023 due in part to the timing of shipments in China.

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 4% and 10% in the second quarter and first six months of 2023, respectively, primarily reflecting higher pricing in the U.S. and the timing of shipments in certain ex-U.S. markets.

Worldwide sales of *M-M-R II* (Measles, Mumps and Rubella Virus Vaccine Live), a vaccine to help protect against measles, mumps and rubella, were nearly flat in both the second quarter and first six months of 2023 compared with the corresponding prior year periods.

Global sales of *Varivax* (Varicella Virus Vaccine Live), a vaccine to help prevent chickenpox (varicella), declined 2% in the second quarter of 2023 primarily attributable to lower sales in Latin America reflecting both lower demand and the timing of shipments, partially offset by higher pricing in the U.S. Global sales of *Varivax* grew 5% in the first six months of 2023 largely due to higher pricing and demand in the U.S., partially offset by lower sales in Latin America reflecting both lower demand and the timing of shipments.

Global sales of *RotaTeq* (Rotavirus Vaccine, Live Oral, Pentavalent), a vaccine to help protect against rotavirus gastroenteritis in infants and children, declined 25% in the second quarter of 2023 and increased 10% in first six months of 2023 primarily due to first quarter 2023 inventory stocking in China that was partially bought out in the second quarter of 2023.

Worldwide sales of *Vaxneuvance*, a vaccine to help prevent invasive pneumococcal disease, increased to \$168 million and \$274 million in the second quarter and first six months of 2023, respectively, 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 40% and 42% in the second quarter and first six months of 2023, respectively, 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 June 30,		% Change	% Change Excluding Foreign Exchange	Six Months Ended June 30,		% Change	% Change Excluding Foreign Exchange
	2023	2022			2023	2022		
<i>Bridion</i>	\$ 502	\$ 426	18 %	19 %	\$ 989	\$ 821	21 %	23 %
<i>Prevymis</i>	143	103	39 %	42 %	273	197	39 %	43 %

Worldwide sales of *Bridion*, for the reversal of two types of neuromuscular blocking agents used during surgery, grew 18% and 21% in the second quarter and first six months of 2023, respectively, primarily due to higher demand, particularly in the U.S., reflecting *Bridion's* growing market share among neuromuscular blockade reversal agents. The patent that provided market exclusivity for *Bridion* in the European Union (EU) expired in July 2023; the Company anticipates sales of *Bridion* in these markets will decline in future periods.

Worldwide sales of *Prevymis*, a medicine for prophylaxis (prevention) of cytomegalovirus (CMV) infection and disease in adult CMV-seropositive recipients of an allogeneic hematopoietic stem cell transplant, grew 39% in both the second quarter and first six months of 2023 largely due to higher demand in the U.S. and Europe, as well as continued uptake from the 2022 launch

in China. In June 2023, the FDA approved a new indication for *Prevymis* for prophylaxis of CMV disease in adult kidney transplant recipients at high risk (Donor CMV-seropositive/Recipient CMV-seronegative [D+/R-]) following a priority review.

Cardiovascular

(\$ in millions)	Three Months Ended June 30,		% Change	% Change Excluding Foreign Exchange	Six Months Ended June 30,		% Change	% Change Excluding Foreign Exchange
	2023	2022			2023	2022		
Alliance Revenue - Adempas/ Verquvo ⁽¹⁾	\$ 68	\$ 98	(31)%	(31)%	\$ 167	\$ 170	(2)%	(2)%
Adempas	65	63	3 %	5 %	125	124	— %	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 declined 31% and 2% in the second quarter and first six months of 2023, respectively, primarily due to lower profit sharing, which reflects decreased 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 both the second quarter and first six months of 2023 compared with the same prior year periods.

Virology

(\$ in millions)	Three Months Ended June 30,		% Change	% Change Excluding Foreign Exchange	Six Months Ended June 30,		% Change	% Change Excluding Foreign Exchange
	2023	2022			2023	2022		
Lagevrio	\$ 203	\$ 1,177	(83)%	(82)%	\$ 595	\$ 4,424	(87)%	(85)%
Isentress/Isentress HD	136	147	(7)%	(4)%	259	305	(15)%	(12)%

Lagevrio is an investigational oral antiviral COVID-19 medicine being developed in a collaboration with Ridgeback Biotherapeutics LP (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 83% and 87% in the second quarter and first six months of 2023, respectively, primarily due to lower demand in Japan and the Asia Pacific region. Additionally, the Company had sales of *Lagevrio* in the UK in the second quarter and first six months of 2022 and in the U.S. in the first six months of 2022 that did not recur in the corresponding periods of 2023, which also contributed to the sales declines. The Company expects full-year 2023 *Lagevrio* sales to be approximately \$1.0 billion. In April 2023, Japan's MHLW 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 7% and 15% in the second quarter and first six months of 2023, respectively, primarily due to competitive pressure in Europe and the U.S. The Company expects competitive pressure for *Isentress/Isentress HD* to continue. The patent that provided market exclusivity for *Isentress/Isentress HD* in the EU expired in July 2023; the Company anticipates sales declines of *Isentress/Isentress HD* in these markets will accelerate in future periods.

Diabetes

(\$ in millions)	Three Months Ended June 30,		% Change	% Change Excluding Foreign Exchange	Six Months Ended June 30,		% Change	% Change Excluding Foreign Exchange
	2023	2022			2023	2022		
Januvia/Janumet	\$ 864	\$ 1,233	(30)%	(28)%	\$ 1,744	\$ 2,466	(29)%	(26)%

Worldwide combined sales of *Januvia* and *Janumet*, medicines that help lower blood sugar levels in adults with type 2 diabetes, declined 30% and 29% in the second quarter and first six months of 2023, respectively, primarily reflecting the ongoing impact of the loss of exclusivity in most 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 9 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 could 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 and an additional generic equivalent product was launched in the second quarter of 2023, the impact on sales for full-year 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%, 14% and 37%, respectively, of total combined *Januvia* and *Janumet* sales for the first six months of 2023.

In response to a request from a regulatory authority in 2022, 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 has made significant progress in reducing the level of nitrosamines in its sitagliptin-containing medicines and does not anticipate product shortages at this time, subject to regulatory approvals for submitted changes.

Animal Health Segment

(\$ in millions)	Three Months Ended June 30,		% Change	% Change Excluding Foreign Exchange	Six Months Ended June 30,		% Change	% Change Excluding Foreign Exchange
	2023	2022			2023	2022		
Livestock	\$ 807	\$ 826	(2)%	2 %	\$ 1,656	\$ 1,658	— %	5 %
Companion Animal	649	641	1 %	2 %	1,291	1,291	— %	2 %

Sales of livestock products declined 2% in the second quarter of 2023 and were essentially flat in the first six months of 2023 compared with the corresponding period of 2022. Excluding the unfavorable effect of foreign exchange, livestock sales performance in both periods primarily reflects higher pricing, as well as higher demand for poultry and swine products, partially offset by lower demand for ruminant products, due in part to reduced herd sizes. Sales of companion animal products grew 1% in the second quarter of 2023 and were flat in the first six months of 2023 compared with the corresponding periods of 2022. Excluding the unfavorable effect of foreign exchange, companion animal sales performance in both periods primarily reflects higher pricing, including for the *Bravecto* (fluralaner) parasiticide line of products, partially offset by supply challenges for certain companion animal vaccines. Sales of *Bravecto* products were \$326 million and \$640 million for the second quarter and first six months of 2023, respectively, representing growth of 5% and 3%, respectively, compared with the corresponding prior year periods, or 7% and 5%, respectively, excluding the unfavorable effect of foreign exchange.

Costs, Expenses and Other

(\$ in millions)	Three Months Ended June 30,		% Change	Six Months Ended June 30,		% Change
	2023	2022		2023	2022	
Cost of sales	\$ 4,024	\$ 4,216	(5)%	\$ 7,951	\$ 9,596	(17)%
Selling, general and administrative	2,702	2,512	8 %	5,182	4,834	7 %
Research and development	13,321	2,798	*	17,597	5,374	*
Restructuring costs	151	142	6 %	218	194	12 %
Other (income) expense, net	172	438	(61)%	259	1,148	(77)%
	\$ 20,370	\$ 10,106	*	\$ 31,207	\$ 21,146	48 %

* > 100%

Cost of Sales

Cost of sales decreased 5% and 17% in the second quarter and first six months of 2023, respectively. Cost of sales includes \$193 million and \$615 million in the second quarter of 2023 and 2022, respectively, and \$414 million and \$2.3 billion in the first six months 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 \$468 million and \$447 million in the second quarter of 2023 and 2022, respectively, and \$1.0 billion and \$1.1 billion in the first six months of 2023 and 2022, respectively. Amortization expense in the first six months 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 \$32 million and \$67 million in the second quarter of 2023 and 2022, respectively, and \$61 million and \$113 million in the first six months 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 73.2% in the second quarter of 2023 compared with 71.1% in the second quarter of 2022. Gross margin was 73.1% in the first six months of 2023 compared with 68.5% in the first six months of 2022. The gross margin improvement in both periods primarily reflects the favorable impacts of lower *Lagevrio* sales (which have a low gross margin) and product mix, partially offset by the unfavorable impact of foreign exchange and increased restructuring costs. Higher amortization of intangible assets also partially offset the gross margin improvement in the first six months of 2023.

Selling, General and Administrative

Selling, general and administrative (SG&A) expenses increased 8% in the second quarter of 2023 and rose 7% in the first six months of 2023 primarily due to higher administrative costs, including higher compensation and benefit costs, as well as increased promotional spending and higher selling costs, partially offset by the favorable effect of foreign exchange and lower acquisition-related costs.

Research and Development

Research and development (R&D) expenses were \$13.3 billion in the second quarter of 2023 compared with \$2.8 billion in the second quarter of 2022 and were \$17.6 billion in the first six months of 2023 compared with \$5.4 billion in the first six months of 2022. The increase in both periods was primarily due to a \$10.2 billion charge for the acquisition of Prometheus. Also contributing to the increase in R&D expenses in both periods were higher compensation and benefit costs, reflecting in part increased headcount, higher investments in discovery research and early drug development, as well as increased clinical development spending. The increase in R&D expenses in the first six months of 2023 was also attributable to a \$1.2 billion charge for the acquisition of Imago and higher upfront charges related to collaborations and licensing arrangements. The increase in R&D expenses in both periods 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 \$2.3 billion and \$1.9 billion for the second quarter of 2023 and 2022, respectively, and \$4.3 billion and \$3.7 billion for the first six months of 2023 and 2022, respectively. Also included in R&D expenses are Animal Health research costs, licensing costs, charges for transactions accounted for as asset acquisitions, 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 \$11.1 billion and \$880 million for the second quarter of 2023 and 2022, respectively, and \$13.3 billion and \$1.6 billion for the first six months of 2023 and 2022, respectively. The increase in these expenses in the second quarter and first six months of 2023 was largely attributable to the \$10.2 billion charge for the acquisition of Prometheus (as noted above). The increase in these expenses for the first six months of 2023 was also due in part 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 to the condensed consolidated financial statements 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 \$3.9 billion. Merck expects to record charges of approximately \$550 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 \$151 million and \$142 million for the second quarter of 2023 and 2022, respectively, and \$218 million and \$194 million for the first six months 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 \$236 million and \$258 million in the second quarter of 2023 and 2022, respectively, and \$333 million and \$384 million for the first six months 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 \$172 million of expense in the second quarter of 2023 compared with \$438 million of expense in the second quarter of 2022 primarily due to lower losses from investments in equity securities and lower pension settlement costs. Other (income) expense, net, was \$259 million of expense for the first six months of 2023 compared with \$1.1 billion of expense for the first six months of 2022 primarily due to net unrealized gains from investments in equity securities recorded in 2023 compared with net unrealized losses recorded in 2022, and lower pension settlement costs, partially offset by a \$572.5 million charge in 2023 related to settlements with certain plaintiffs in the Zetia antitrust litigation (see Note 9 to the condensed consolidated financial statements).

For details on the components of Other (income) expense, net, see Note 12 to the condensed consolidated financial statements.

Segment Profits

(\$ in millions)	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Pharmaceutical segment profits	\$ 9,854	\$ 9,173	\$ 18,993	\$ 18,673
Animal Health segment profits	467	571	1,032	1,156
Other	(15,656)	(5,257)	(21,710)	(10,481)
(Loss) Income Before Taxes	\$ (5,335)	\$ 4,487	\$ (1,685)	\$ 9,348

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 grew 7% and 2% in the second quarter and first six months of 2023, respectively, reflecting higher sales, partially offset by higher administrative and promotional costs, as well as the unfavorable effect of foreign exchange. Animal Health segment profits declined 18% and 11% in the second quarter and first six months of 2023, respectively, reflecting higher administrative and promotional costs, increased research and development expenses, as well as the unfavorable effect of foreign exchange.

Income Taxes

The income tax provision of \$637 million and \$1.5 billion for the second quarter and first six months of 2023, respectively, on pretax losses of \$5.3 billion and \$1.7 billion, respectively, resulted in effective income tax rates of (11.9)% and (86.8)%, respectively. The second quarter 2023 effective tax rate includes the impact of a charge for the acquisition of Prometheus for which no tax benefit was recognized, which unfavorably affected the tax rate by 25.1 percentage points, as well as the favorable impact of net unrealized losses from investments in equity securities, which were taxed at the U.S. tax rate. The effective income tax rate for the first six months of 2023 includes a 101.9 percentage point combined unfavorable impact of charges for the acquisitions of Prometheus and Imago for which no tax benefits were 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 rates of 12.0% for the second quarter of 2022 and 11.7% for the first six months of 2022 reflect the favorable impact of net unrealized losses from investments in equity securities, which were taxed at the U.S. tax rate.

Non-GAAP (Loss) Income and Non-GAAP EPS

Non-GAAP (loss) income and non-GAAP (loss) earnings per share (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 (loss) 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 (loss) 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 (loss) 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 (loss) 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:

(\$ in millions except per share amounts)	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
(Loss) income before taxes as reported under GAAP	\$ (5,335)	\$ 4,487	\$ (1,685)	\$ 9,348
Increase (decrease) for excluded items:				
Acquisition- and divestiture-related costs	498	530	1,088	1,168
Restructuring costs	236	258	333	384
Loss (income) from investments in equity securities, net	194	234	(235)	918
Other items:				
Charge for Zetia antitrust litigation settlements	—	—	573	—
Non-GAAP (loss) income before taxes	(4,407)	5,509	74	11,818
Income tax provision as reported under GAAP	637	538	1,462	1,092
Estimated tax benefit on excluded items ⁽¹⁾	173	223	261	552
Non-GAAP income tax provision	810	761	1,723	1,644
Non-GAAP net (loss) income	(5,217)	4,748	(1,649)	10,174
Less: Net income attributable to noncontrolling interests as reported under GAAP	3	5	7	2
Non-GAAP net (loss) income attributable to Merck & Co., Inc.	\$ (5,220)	\$ 4,743	\$ (1,656)	\$ 10,172
EPS assuming dilution as reported under GAAP ⁽²⁾	\$ (2.35)	\$ 1.55	\$ (1.24)	\$ 3.25
EPS difference	0.29	0.32	0.59	0.76
Non-GAAP EPS assuming dilution ⁽²⁾	\$ (2.06)	\$ 1.87	\$ (0.65)	\$ 4.01

⁽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.

⁽²⁾ The Company recorded a net loss on both a GAAP and non-GAAP basis for the three and six months ended June 30, 2023; therefore, no potential dilutive common shares were used in the computations of loss per common share assuming dilution because the effects would have been antidilutive.

Acquisition- and Divestiture-Related Costs

Non-GAAP (loss) 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. Non-GAAP (loss) income and non-GAAP EPS also exclude amortization of intangible assets related to collaborations and licensing arrangements.

Restructuring Costs

Non-GAAP (loss) 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 (loss) 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 (loss) 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 (loss) income and non-GAAP EPS in 2023 is a charge related to settlements with certain plaintiffs in the Zetia antitrust litigation (see Note 9 to the condensed consolidated financial statements).

Research and Development Update

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

MK-7264, gefapixant, is an investigational, non-narcotic, orally selective P2X3 receptor antagonist, for the treatment of adults with refractory or unexplained chronic cough under review by the FDA and the European Medicines Agency (EMA). The marketing applications for gefapixant are based on results from the COUGH-1 and COUGH-2 clinical trials. In July 2023, the FDA accepted Merck's resubmission of the New Drug Application (NDA) for gefapixant and assigned a Prescription Drug User Fee Act (PDUFA), or target action, date of December 27, 2023. Merck submitted additional analyses to the FDA in June 2023 in response to the Complete Response Letter (CRL) that was received in January 2022 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. In July 2023, the Committee for Medicinal Products for Human Use (CHMP) of the EMA recommended the approval of gefapixant. The CHMP's recommendation will now be reviewed by the European Commission (EC) for marketing authorization in the EU and a final decision is expected later in 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.

Keytruda is also 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.

Additionally, *Keytruda* is under review by the FDA in combination with standard of care chemotherapy (gemcitabine and cisplatin) for the treatment of patients with locally advanced unresectable or metastatic biliary tract cancer. The submission is based on data from the KEYNOTE-966 trial. The FDA set a PDUFA date of February 7, 2024. KEYNOTE-966 is also under review in the EU and Japan.

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. The FDA set a PDUFA date of December 16, 2023. KEYNOTE-859 is also under review in the EU and Japan.

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 also under review in the EU in combination with trastuzumab, fluoropyrimidine- and platinum-containing chemotherapy, for the first-line treatment of locally advanced unresectable or metastatic human epidermal growth factor 2 (HER2)-positive gastric or GEJ adenocarcinoma in adults whose tumors express PD-L1. In July 2023, the CHMP adopted a positive opinion recommending approval of *Keytruda* for this indication based on interim results from the Phase 3 KEYNOTE-811 trial. The CHMP's recommendation will now be reviewed by the EC for marketing authorization in the EU, and a final decision is expected in the third quarter of 2023. This indication was approved by the FDA under accelerated approval based on objective response rate data from KEYNOTE-811, and continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials. Merck is working with the FDA to update this indication to patients whose tumors are PD-L1 positive.

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). Lynparza is under review in Japan for the treatment of certain patients with mCRPC based on the PROpel trial.

In July 2023, Merck submitted a Biologics License Application to the FDA for sotatercept (MK-7962), Merck's novel investigational activin signaling inhibitor for the treatment of adults with pulmonary arterial hypertension (World Health Organization Group 1).

Also in July 2023, Merck and Moderna, Inc. announced the initiation of the pivotal Phase 3 randomized V940-001 clinical trial evaluating V940 (mRNA-4157), an investigational individualized neoantigen therapy, in combination with *Keytruda*, as an adjuvant treatment in patients with resected high-risk (Stage IIB-IV) melanoma. The FDA and EMA granted Breakthrough Therapy Designation and the Priority Medicines (PRIME) scheme, respectively, for V940 (mRNA-4157) in combination with *Keytruda* for the adjuvant treatment of patients with high-risk melanoma based on data from the Phase 2b KEYNOTE-942/mRNA-4157-P201 study.

KEYNOTE-A86, a study evaluating pembrolizumab subcutaneous versus pembrolizumab intravenous administered with platinum doublet chemotherapy in patients with metastatic squamous or nonsquamous NSCLC, met its dual primary endpoints and Merck anticipates disclosing details in the future.

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, which was last reissued in February 2023. *Lagevrio* is authorized 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 EMA issued a positive scientific opinion for *Lagevrio*, which was 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 CHMP of the EMA recommended the refusal of the marketing authorization application (MAA) for *Lagevrio*. Merck and Ridgeback appealed the decision and requested a re-examination of the MAA. In June 2023, Merck and Ridgeback announced that they have withdrawn the EU application for marketing authorization of *Lagevrio* based on the CHMP's view that the data submitted are not sufficient to satisfy EU regulatory requirements for marketing authorization of *Lagevrio*. Applications to other regulatory bodies are underway.

The Company is in the process of discontinuing development of ladiratuzumab vedotin, an ADC targeting LIV-1, which was being developed in collaboration with Seagen Inc.

The charts below reflect the Company's research pipeline as of August 2, 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 <i>Keytruda</i> Advanced Solid Tumors Prostate MK-3543 (bomedemstat) Myeloproliferative Disorders MK-4280 (favezelimab) ⁽²⁾ Non-Small-Cell Lung MK-4280A (favezelimab+pembrolizumab) Bladder Esophageal Melanoma Renal Cell Small-Cell Lung MK-4830 ⁽²⁾ Colorectal Esophageal Melanoma Non-Small-Cell Lung Ovarian Renal Cell Small-Cell Lung	Cancer MK-5684 ⁽¹⁾ Prostate MK-5890 (boserolimab) ⁽²⁾ Non-Small-Cell Lung Small-Cell Lung MK-6482 <i>Welireg</i> ⁽³⁾ Biliary Colorectal Endometrial Esophageal Hepatocellular Pancreatic Rare cancers Von Hippel-Lindau Disease-Associated Tumors (EU) MK-7119 <i>Tukysa</i> ⁽¹⁾ Advanced Solid Tumors Biliary Bladder Cervical Endometrial Gastric Non-Small-Cell Lung MK-7339 <i>Lynparza</i> ⁽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 <i>Lenvima</i> ⁽¹⁾⁽²⁾ Biliary Pancreatic Prostate Small-Cell Lung Dengue Fever Virus Vaccine V181 HIV-1 Infection MK-8591B (islatravir+MK-8507) ⁽⁴⁾ MK-8591D (islatravir+tenacapavir) ⁽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 Ulcerative Colitis MK-7240

Phase 3 (Phase 3 entry date)	Under Review	
Antiviral COVID-19 MK-4482 <i>Lagevrio</i> (U.S.) (May 2021) ⁽¹⁾⁽⁷⁾ Cancer MK-1026 (nemtabrutinib) Hematological Malignancies (March 2023) MK-1308A (quavonlimab+pembrolizumab) Renal Cell (April 2021) MK-3475 <i>Keytruda</i> Cutaneous Squamous Cell (August 2019) (EU) Hepatocellular (May 2016) (EU) Mesothelioma (May 2018) Ovarian (December 2018) Small-Cell Lung (May 2017) MK-3475A (pembrolizumab+hyaluronidase subcutaneous) Non-Small-Cell Lung (February 2023) MK-4280A (favezelimab+pembrolizumab) Colorectal (November 2021) Hematological Malignancies (October 2022) MK-6482 <i>Welireg</i> ⁽³⁾ Renal Cell (February 2020) MK-7119 <i>Tukysa</i> ⁽¹⁾ Breast (October 2019) Colorectal (August 2022) MK-7339 <i>Lynparza</i> ⁽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 <i>Lenvima</i> ⁽¹⁾⁽²⁾ Esophageal (July 2021) Gastric (December 2020) Head and Neck (February 2020) Non-Small-Cell Lung (March 2019) V940 ⁽¹⁾⁽²⁾ Melanoma (July 2023) 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 Cough MK-7264 (gefapixant) (U.S.) ⁽⁶⁾ (EU)	Certain Supplemental Filings Cancer MK-3475 <i>Keytruda</i> • Second-Line Hepatocellular Carcinoma (KEYNOTE-394) (U.S.) • Locally Advanced or Metastatic Merkel Cell Carcinoma (KEYNOTE-913) (U.S.) • First-Line Advanced or Unresectable Biliary Tract Cancer (KEYNOTE-966) (U.S.) (EU) (JPN) • First-Line HER2 Negative Locally Advanced Unresectable or Metastatic Gastric Cancer (KEYNOTE-859) (U.S.) (EU) (JPN) • Resectable Stage II, IIIA or IIIB NSCLC (KEYNOTE-671) (U.S.) (EU) • Adjuvant Non-Small-Cell Lung Cancer (KEYNOTE-091) (EU) • Metastatic HER2+ Gastric Cancer (KEYNOTE-811) (EU) MK-7339 <i>Lynparza</i> ⁽¹⁾ • First-Line Metastatic Prostate Cancer (PROpel) (JPN)
Footnotes: ⁽¹⁾ Being developed in a collaboration. ⁽²⁾ Being developed in combination with <i>Keytruda</i> . ⁽³⁾ Being developed as monotherapy and/or in combination with <i>Keytruda</i> . ⁽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⁾ In July 2023, the FDA accepted Merck's resubmission of the NDA for gefapixant following the Company's response to the CRL received in January 2022.		

Analysis of Liquidity and Capital Resources

(\$ in millions)	June 30, 2023		December 31, 2022	
Cash and investments	\$	7,592	\$	14,207
Working capital		6,583		11,483
Total debt to total liabilities and equity		35.3 %		28.1 %

Cash provided by operating activities was \$5.0 billion in the first six months of 2023 compared with \$9.1 billion in the first six 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 \$240 million and \$1.7 billion in the first six 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 generally 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 \$13.8 billion in the first six months of 2023 compared with \$2.3 billion in the first six months of 2022. The higher use of cash in investing activities was primarily due to the acquisitions of Prometheus and Imago, partially offset by higher proceeds from sales of securities and other investments, lower purchases of securities and other investments, and lower capital expenditures.

Cash provided by financing activities was \$1.7 billion in the first six months of 2023 compared with a use of cash in financing activities of \$4.9 billion in the first six months of 2022. The change was primarily due to proceeds from the issuance of debt (see below) and an increase in short-term borrowings, partially offset by higher payments on long-term debt (see below), treasury stock purchases and higher dividends paid to shareholders.

The Company has accounts receivable factoring agreements with financial institutions in certain countries to sell accounts receivable. The Company factored \$2.9 billion and \$2.5 billion of accounts receivable at June 30, 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.

In May 2023, the Company issued \$6.0 billion principal amount of senior unsecured notes consisting of \$500 million of 4.05% notes due 2028, \$750 million of 4.30% notes due 2030, \$1.5 billion of 4.50% notes due 2033, \$750 million of 4.90% notes due 2044, \$1.5 billion of 5.00% notes due 2053, and \$1.0 billion of 5.15% notes due 2063. The Company used a portion of the \$5.9 billion net proceeds from this offering to fund a portion of the cash consideration paid for the acquisition of Prometheus and related fees and expenses, and used the remaining net proceeds for general corporate purposes including to repay commercial paper borrowings and other indebtedness with upcoming maturities.

In May 2023, the Company's \$1.75 billion, 2.80% notes matured in accordance with their terms and were repaid. In February 2022, the Company's \$1.25 billion, 2.35% notes matured in accordance with their terms and were repaid.

Dividends paid to stockholders were \$3.7 billion and \$3.5 billion for the first six months of 2023 and 2022, respectively. In May 2023, the Board of Directors declared a quarterly dividend of \$0.73 per share on the Company's outstanding common stock for the second quarter that was paid in July 2023. In July 2023, the Board of Directors declared a quarterly dividend of \$0.73 per share on the Company's outstanding common stock for the third quarter that will be paid in October 2023.

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 has made and anticipates continuing to make modest share repurchases under this program in 2023. During the first six months of 2023, the Company purchased \$487 million (4 million shares) of its common stock for its treasury under this program. As of June 30, 2023, the Company's remaining share repurchase authorization was \$4.6 billion.

The Company has a \$6.0 billion credit facility that matures in May 2028. 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 June 30, 2023, the Company's disclosure controls and procedures are effective. For the second quarter of 2023, there were no changes in internal control over financial reporting that materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

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 9 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 June 30, 2023 were as follows:

ISSUER PURCHASES OF EQUITY SECURITIES

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	(\$ in millions)	
				Approximate Dollar Value of Shares That May Yet Be Purchased Under the Plans or Programs ⁽¹⁾	
April 1 - April 30	376,898	\$110.51	376,898		\$4,856
May 1 - May 31	907,404	\$114.76	907,404		\$4,752
June 1 - June 30	1,734,532	\$110.72	1,734,532		\$4,560
Total	3,018,834	\$111.91	3,018,834		

⁽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 5. Other Information

Insider Trading Arrangements

During the three months ended June 30, 2023, none of the Company’s directors or executive officers adopted or terminated any Rule 10b5-1 trading arrangements or non-Rule 10b5-1 trading arrangements.

Frequency of Future Non-Binding Shareholder Advisory Votes on Executive Compensation

As previously reported in a Current Report on Form 8-K filed on May 26, 2023, at the Company’s 2023 Annual Meeting of Shareholders held on May 23, 2023, the Company’s shareholders approved, on a non-binding advisory basis, the holding of a non-binding shareholder advisory vote on executive compensation annually. Based on this voting result, among other factors, the Company will include a non-binding shareholder advisory vote on executive compensation in its proxy materials annually until the next required shareholder vote on the frequency of such non-binding advisory votes on executive compensation.

Item 6. Exhibits

<u>Number</u>	<u>Description</u>
3.1	— <u>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)</u>
3.2	— <u>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)</u>
31.1	— <u>Rule 13a – 14(a)/15d – 14(a) Certification of Chief Executive Officer</u>
31.2	— <u>Rule 13a – 14(a)/15d – 14(a) Certification of Chief Financial Officer</u>
32.1	— <u>Section 1350 Certification of Chief Executive Officer</u>
32.2	— <u>Section 1350 Certification of Chief Financial Officer</u>
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: August 7, 2023

/s/ Jennifer Zachary

JENNIFER ZACHARY

Executive Vice President and General Counsel

Date: August 7, 2023

/s/ Rita A. Karachun

RITA A. KARACHUN

Senior Vice President Finance - Global Controller

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: August 7, 2023

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

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: August 7, 2023

By: /s/ Caroline Litchfield
CAROLINE LITCHFIELD
Executive Vice President, Chief Financial Officer

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 June 30, 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: August 7, 2023

/s/ Robert M. Davis

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

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 June 30, 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: August 7, 2023

/s/ Caroline Litchfield

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