

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 September 30, 2023

OR

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

For the transition period from _____ to _____

Commission File 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 October 31, 2023: 2,534,023,084

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Part I - Financial Information

Item 1. Financial Statements

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Sales	\$ 15,962	\$ 14,959	\$ 45,485	\$ 45,453
Costs, Expenses and Other				
Cost of sales	4,264	3,934	12,214	13,530
Selling, general and administrative	2,519	2,520	7,700	7,355
Research and development	3,307	4,399	20,904	9,773
Restructuring costs	126	94	344	288
Other (income) expense, net	126	429	388	1,576
	10,342	11,376	41,550	32,522
Income Before Taxes	5,620	3,583	3,935	12,931
Taxes on Income	870	330	2,332	1,423
Net Income	4,750	3,253	1,603	11,508
Less: Net Income Attributable to Noncontrolling Interests	5	5	12	6
Net Income Attributable to Merck & Co., Inc.	\$ 4,745	\$ 3,248	\$ 1,591	\$ 11,502
Basic Earnings per Common Share Attributable to Merck & Co., Inc. Common Shareholders	\$ 1.87	\$ 1.28	\$ 0.63	\$ 4.55
Earnings per Common Share Assuming Dilution Attributable to Merck & Co., Inc. Common Shareholders	\$ 1.86	\$ 1.28	\$ 0.62	\$ 4.53

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Net Income Attributable to Merck & Co., Inc.	\$ 4,745	\$ 3,248	\$ 1,591	\$ 11,502
Other Comprehensive Loss Net of Taxes:				
Net unrealized gain on derivatives, net of reclassifications	159	338	171	584
Benefit plan net (loss) gain and prior service (cost) credit, net of amortization	—	(186)	(75)	92
Cumulative translation adjustment	(175)	(568)	(244)	(990)
	(16)	(416)	(148)	(314)
Comprehensive Income Attributable to Merck & Co., Inc.	\$ 4,729	\$ 2,832	\$ 1,443	\$ 11,188

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)

	September 30, 2023	December 31, 2022
Assets		
Current Assets		
Cash and cash equivalents	\$ 8,605	\$ 12,694
Short-term investments	168	498
Accounts receivable (net of allowance for doubtful accounts of \$85 in 2023 and \$72 in 2022)	10,394	9,450
Inventories (excludes inventories of \$3,151 in 2023 and \$2,938 in 2022 classified in Other assets - see Note 7)	6,131	5,911
Other current assets	6,656	7,169
Total current assets	31,954	35,722
Investments	1,306	1,015
Property, Plant and Equipment, at cost, net of accumulated depreciation of \$18,446 in 2023 and \$17,985 in 2022	22,526	21,422
Goodwill	21,183	21,204
Other Intangibles, Net	19,199	20,269
Other Assets	10,559	9,528
	\$ 106,727	\$ 109,160
Liabilities and Equity		
Current Liabilities		
Loans payable and current portion of long-term debt	\$ 887	\$ 1,946
Trade accounts payable	3,509	4,264
Accrued and other current liabilities	14,840	14,159
Income taxes payable	1,981	1,986
Dividends payable	1,877	1,884
Total current liabilities	23,094	24,239
Long-Term Debt	33,972	28,745
Deferred Income Taxes	1,018	1,795
Other Noncurrent Liabilities	7,343	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	44,358	44,379
Retained earnings	57,082	61,081
Accumulated other comprehensive loss	(4,916)	(4,768)
	98,312	102,480
Less treasury stock, at cost: 1,041,809,729 shares in 2023 and 1,039,269,638 shares in 2022	57,066	56,489
Total Merck & Co., Inc. stockholders' equity	41,246	45,991
Noncontrolling Interests	54	67
Total equity	41,300	46,058
	\$ 106,727	\$ 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)

	Nine Months Ended September 30,	
	2023	2022
Cash Flows from Operating Activities		
Net income	\$ 1,603	\$ 11,508
Adjustments to reconcile net income to net cash provided by operating activities:		
Amortization	1,582	1,623
Depreciation	1,326	1,394
Intangible asset impairment charges	13	910
(Income) loss from investments in equity securities, net	(240)	1,361
Charge for the acquisition of Prometheus Biosciences, Inc.	10,217	—
Charge for the acquisition of Imago BioSciences, Inc.	1,192	—
Deferred income taxes	(968)	(1,261)
Share-based compensation	478	396
Other	(94)	1,169
Net changes in assets and liabilities	(2,349)	(2,435)
Net Cash Provided by Operating Activities	12,760	14,665
Cash Flows from Investing Activities		
Capital expenditures	(2,874)	(3,239)
Purchases of securities and other investments	(704)	(710)
Proceeds from sales of securities and other investments	1,489	709
Acquisition of Prometheus Biosciences, Inc., net of cash acquired	(10,705)	—
Acquisition of Imago BioSciences, Inc., net of cash acquired	(1,327)	—
Other acquisitions, net of cash acquired	—	(121)
Other	(15)	149
Net Cash Used in Investing Activities	(14,136)	(3,212)
Cash Flows from Financing Activities		
Proceeds from issuance of debt	5,939	—
Payments on debt	(1,752)	(2,250)
Purchases of treasury stock	(953)	—
Dividends paid to stockholders	(5,593)	(5,262)
Proceeds from exercise of stock options	119	119
Other	(325)	(172)
Net Cash Used in Financing Activities	(2,565)	(7,565)
Effect of Exchange Rate Changes on Cash, Cash Equivalents and Restricted Cash	(163)	(776)
Net (Decrease) Increase in Cash, Cash Equivalents and Restricted Cash	(4,104)	3,112
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 \$64 and \$134 at September 30, 2023 and 2022, respectively, included in <i>Other current assets</i>)	\$ 8,669	\$ 11,279

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 Financial Accounting Standards Board (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.

Recently Issued Accounting Standard Not Yet Adopted

In August 2023, the FASB issued amended guidance that requires a newly formed joint venture to recognize and initially measure its assets and liabilities at fair value upon formation. The amended guidance includes exceptions to fair value measurement that are consistent with the accounting for business combinations guidance. The amended guidance is effective prospectively for all joint ventures with a formation date on or after January 1, 2025, however existing joint ventures have the option to apply the guidance retrospectively. Early adoption is permitted for both interim and annual periods. The Company anticipates there will be no impact to its consolidated financial statements upon adoption.

2. Acquisitions, Research Collaborations and Licensing Agreements

The Company continues to pursue acquisitions and the establishment of external alliances such as research collaborations and licensing agreements to complement its internal research capabilities. These arrangements often include upfront payments; expense reimbursements or payments to the third party; milestone, royalty or profit share arrangements contingent upon the occurrence of certain future events linked to the success of the asset in development; and can also include option and continuation payments. 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.

2023 Transactions

In October 2023, Merck and Daiichi Sankyo entered into a global development and commercialization agreement for three of Daiichi Sankyo's deruxtecan (DXd) antibody drug conjugate (ADC) candidates: patritumab deruxtecan (HER3-DXd) (MK-1022), ifinatamab deruxtecan (I-DXd) (MK-2400) and raludotatug deruxtecan (R-DXd) (MK-5909). See Note 3 for additional information related to this collaboration.

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 a charge of \$10.2 billion to *Research and development* expenses in the first nine 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 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 nine months of 2023. In October 2023, Merck notified Kelun-Biotech it was terminating two of the seven candidates under the agreement. Kelun-Biotech remains eligible to receive future contingent payments aggregating up to \$725 million in development-related payments, \$1.95 billion in regulatory milestones, and \$3.9 billion in sales-based milestones if Kelun-Biotech does not retain Chinese mainland, Hong Kong and Macau rights for the option ADCs and all remaining 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 shares in January 2023.

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

2022 Transactions

In October 2022, Merck and Royalty Pharma plc (Royalty Pharma) entered into a funding arrangement under which Royalty Pharma paid Merck \$50 million to co-fund Merck's development costs for a Phase 2b trial of MK-8189, an investigational oral phosphodiesterase 10A (PDE10A) inhibitor, which is being evaluated for the treatment of schizophrenia. As Royalty Pharma is sharing the risk of technical and regulatory success with Merck, the development funding was recognized by Merck as an obligation to perform contractual services. Accordingly, the payment received is being recognized by Merck as a reduction to *Research and development* expenses ratably over the estimated Phase 2b research period. Under the agreement, Royalty Pharma has no rights to MK-8189 and has no decision-making authority over the program. If Merck elects to advance MK-8189 into a Phase 3 study, Royalty Pharma has the option to provide additional funding of 50% of the development costs up to \$375 million. Royalty Pharma is eligible to receive royalties on future sales. If Royalty Pharma elects to provide the additional funding noted above, Royalty Pharma becomes eligible to receive future regulatory milestone payments contingent upon certain marketing approvals, as well as a higher royalty rate. Merck will record the milestone payments as an expense within *Other (income) expense, net* upon receipt of the related approvals.

In September 2022, Merck exercised its option to jointly develop and commercialize V940 (mRNA-4157), an investigational individualized neoantigen therapy, pursuant to the terms of an existing collaboration and license agreement with Moderna, Inc. (Moderna), which resulted in a \$250 million charge to *Research and development* expenses in the third quarter and first nine months of 2022. Merck and Moderna will collaborate on development and commercialization and will share costs and any profits equally under this worldwide collaboration. V940 (mRNA-4157) is currently being evaluated in combination with *Keytruda* (pembrolizumab), Merck's anti-PD-1 therapy, as an adjuvant treatment in patients with resected high-risk (Stage IIB-IV) melanoma in a Phase 3 clinical trial being conducted by Moderna.

In August 2022, Merck and Orna Therapeutics (Orna), a biotechnology company pioneering a new investigational class of engineered circular RNA (oRNA) therapies, entered into a collaboration agreement to discover, develop, and commercialize multiple programs, including vaccines and therapeutics in the areas of infectious disease and oncology. Under the terms of the agreement, Merck made an upfront payment to Orna of \$150 million, which was recorded in *Research and development* expenses in the third quarter and first nine months of 2022. In addition, Orna is eligible to receive future contingent payments aggregating up to \$440 million in development-related payments, \$675 million in regulatory milestones, and \$2.4 billion in sales-based milestones associated with the progress of the multiple vaccine and therapeutic programs, as well as royalties ranging from a high-single-digit rate to a low-double-digit rate on any approved products derived from the collaboration. Merck also invested \$100 million in Orna's Series B preferred shares in fourth quarter of 2022.

In July 2022, Merck and Orion Corporation (Orion) announced a global co-development and co-commercialization agreement for Orion's investigational candidate ODM-208 (MK-5684) and other drugs targeting cytochrome P450 11A1 (CYP11A1), an enzyme important in steroid production. MK-5684 is an oral, non-steroidal inhibitor of CYP11A1 currently being evaluated in a Phase 2 clinical trial for the treatment of patients with metastatic castration-resistant prostate cancer. Merck made an upfront payment to Orion of \$290 million, which was recorded in *Research and development* expenses in the third quarter and first nine months of 2022. Orion is responsible for the manufacture of clinical and commercial supply of MK-5684. In addition, the contract provides both parties with an option to convert the initial co-development and co-commercialization agreement into a global exclusive license to Merck. If the option is exercised, Merck would assume full responsibility for all past development and commercialization expenses associated with the program since inception of the agreement, as well as all future development and commercialization expenses. In addition, Orion would be eligible to receive milestone payments associated with progress in the development and commercialization of MK-5684, as well as tiered double-digit royalties on sales if the product is approved.

Also in July 2022, Merck and Kelun-Biotech closed a license and collaboration agreement in which Merck gained exclusive worldwide rights for the development, manufacture and commercialization of an investigational ADC (MK-1200) for the treatment of solid tumors. Under the terms of the agreement, Merck and Kelun-Biotech will collaborate on the early clinical

development of the investigational ADC. Merck made an upfront payment of \$35 million, which was recorded in *Research and development* expenses in the third quarter and first nine months of 2022. Kelun-Biotech is also eligible to receive future contingent milestone payments aggregating up to \$82 million in developmental milestones, \$334 million in regulatory milestones, and \$485 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.

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 first nine months of 2022. Additionally, Merck agreed to make an additional payment of \$25 million upon technology transfer, which occurred in the third quarter of 2023 and will be paid in the fourth quarter of 2023. 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 \$95 million has been paid through September 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 September 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 nine months of 2022. Additionally, in the first nine 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 (all of which were paid in the first nine 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 \$1.6 billion at September 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 September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Alliance revenue - Lynparza	\$ 299	\$ 284	\$ 884	\$ 825
Alliance revenue - Koselugo	26	10	74	43
Total alliance revenue	\$ 325	\$ 294	\$ 958	\$ 868
Cost of sales ⁽¹⁾	82	64	230	425
Selling, general and administrative	44	45	143	135
Research and development	23	28	65	79
(\$ in millions)			September 30, 2023	December 31, 2022
Receivables from AstraZeneca included in <i>Other current assets</i>			\$ 337	\$ 303
Payables to AstraZeneca included in <i>Accrued and other current liabilities</i> ⁽²⁾			257	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 nine 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. Similarly, in the third quarter of 2023 an additional \$125 million sales-based milestone payment to Eisai was deemed to be probable of payment. Accordingly, Merck recorded \$250 million of liabilities for these payments and corresponding increases to the intangible asset related to Lenvima. Merck also recognized \$81 million and \$154 million of cumulative amortization catch-up expense related to the recognition of these milestones in the third quarter and first nine months of 2023, respectively. The sales-based milestone payment that was accrued in the first quarter of 2023 was paid to Eisai in the second quarter of 2023. In the first nine 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 \$2.3 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 (all of which were paid in the first nine 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 \$743 million at September 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 September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Alliance revenue - Lenvima	\$ 260	\$ 202	\$ 734	\$ 660
Cost of sales ⁽¹⁾	137	53	320	159
Selling, general and administrative	46	42	145	115
Research and development	5	24	61	128
(\$ in millions)			September 30, 2023	December 31, 2022
Receivables from Eisai included in <i>Other current assets</i>			\$ 260	\$ 214
Payables to Eisai included in <i>Accrued and other current liabilities</i> ⁽²⁾			125	—

⁽¹⁾ Represents amortization of capitalized milestone payments. Amounts in the third quarter and first nine months of 2023 include \$81 million and \$154 million, respectively, of cumulative amortization catch-up expense as noted above.

⁽²⁾ Represents an accrued milestone payment.

Bayer AG

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

In addition, the agreement provided for contingent payments from Merck to Bayer related to the successful achievement of sales-based milestones. In the first nine 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 \$533 million and \$51 million, respectively, at September 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 September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Alliance revenue - Adempas/Verquvo	\$ 92	\$ 88	\$ 259	\$ 258
Net sales of Adempas recorded by Merck	65	57	189	181
Net sales of Verquvo recorded by Merck	8	6	24	15
Total sales	\$ 165	\$ 151	\$ 472	\$ 454
Cost of sales ⁽¹⁾	53	55	165	158
Selling, general and administrative	33	42	100	107
Research and development	26	18	76	52
(\$ in millions)			September 30, 2023	December 31, 2022
Receivables from Bayer included in <i>Other current assets</i>			\$ 157	\$ 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 September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Net sales of <i>Lagevrio</i> recorded by Merck	\$ 640	\$ 436	\$ 1,236	\$ 4,859
Cost of sales ⁽¹⁾⁽²⁾	348	244	762	2,586
Selling, general and administrative ⁽²⁾	21	48	72	117
Research and development ⁽²⁾	8	18	33	74
(\$ in millions)			September 30, 2023	December 31, 2022
Payables to Ridgeback included in <i>Accrued and other current liabilities</i> ⁽³⁾			\$ 242	\$ 348

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

⁽²⁾ Expenses include an allocation for overhead charges.

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

Bristol-Myers Squibb Company

Reblozyl (lusatercept-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 nine 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 \$52 million and \$142 million in the third quarter and first nine months of 2023, respectively, compared with \$39 million and \$124 million in the third quarter and first nine months of 2022, respectively.

Daiichi Sankyo

In October 2023, Merck and Daiichi Sankyo entered into a global development and commercialization agreement for three of Daiichi Sankyo's DXd ADC candidates: patritumab deruxtecan (HER3-DXd) (MK-1022), ifinatamab deruxtecan (I-DXd) (MK-2400) and raludotatug deruxtecan (R-DXd) (MK-5909). All three potentially first-in-class DXd ADCs are in various stages of clinical development for the treatment of multiple solid tumors both as monotherapy and/or in combination with other treatments. The companies will jointly develop and potentially commercialize these ADC candidates worldwide, except in Japan where Daiichi Sankyo will maintain exclusive rights. Daiichi Sankyo will be solely responsible for manufacturing and supply.

Under the terms of the agreement, Merck made payments to Daiichi Sankyo totaling \$4.0 billion. These payments included \$1.0 billion (\$500 million each for patritumab deruxtecan and ifinatamab deruxtecan) which may be refundable on a pro-rated basis in the event of early termination of development with respect to either program. In addition, the agreement provides for a continuation payment of \$750 million related to patritumab deruxtecan due from Merck in October 2024 and a continuation payment of \$750 million related to raludotatug deruxtecan due from Merck in October 2025. Merck may opt out of the collaboration for patritumab deruxtecan and/or raludotatug deruxtecan by electing not to pay the applicable continuation payment. If Merck opts out of patritumab deruxtecan and/or raludotatug deruxtecan, the non-refundable upfront payments already paid will be retained by Daiichi Sankyo and rights related to such DXd ADCs will be returned to Daiichi Sankyo. The agreement also provides for contingent payments from Merck to Daiichi Sankyo of up to an additional \$5.5 billion for each DXd ADC upon the successful achievement of certain sales-based milestones.

Following regulatory approval, Daiichi Sankyo will generally record sales worldwide (Daiichi Sankyo will be the principal on sales transactions) and the companies will equally share expenses as well as profits worldwide except for Japan where Daiichi Sankyo retains exclusive rights and Merck will receive a sales-based royalty. Merck will record its share of product sales, net of cost of sales and commercialization costs, as alliance revenue. For raludotatug deruxtecan, Merck will be responsible for 75% of the first \$2.0 billion of research and development expenses; the companies will share equally all other

expenses as well as profits worldwide. Merck will include its share of development costs associated with the collaboration as part of *Research and development* expenses.

In conjunction with this transaction, Merck will record an aggregate pretax charge of \$5.5 billion to *Research and development* expenses in the fourth quarter of 2023 for the \$4.0 billion upfront payments and the \$1.5 billion in continuation payments.

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 income for the above MSAs include sales of \$100 million and \$100 million and related cost of sales of \$106 million and \$104 million for the third quarter of 2023 and 2022, respectively, and sales of \$290 million and \$293 million and related cost of sales of \$314 million and \$312 million for the first nine months of 2023 and 2022, respectively. Amounts included in the condensed consolidated statement of income for the TSAs were immaterial for the three and nine months ended September 30, 2023 and September 30, 2022.

The amounts due from Organon under all of the above agreements were \$526 million and \$511 million at September 30, 2023 and December 31, 2022, respectively, and are reflected in *Other current assets*. The amounts due to Organon under these agreements were \$385 million and \$345 million at September 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 \$4.0 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 \$199 million and \$175 million in the third quarter of 2023 and 2022, respectively, and \$532 million and \$559 million for the first nine months of 2023 and 2022, respectively, related to restructuring program activities. Since inception of the Restructuring Program through September 30, 2023, Merck has recorded total pretax accumulated costs of approximately \$3.9 billion. For the full year of 2023, the Company expects to record charges of approximately \$650 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 September 30, 2023				Nine Months Ended September 30, 2023			
	Separation Costs	Accelerated Depreciation	Other	Total	Separation Costs	Accelerated Depreciation	Other	Total
Cost of sales	\$ —	\$ 31	\$ 2	\$ 33	\$ —	\$ 74	\$ 20	\$ 94
Selling, general and administrative	—	5	35	40	—	5	88	93
Research and development	—	—	—	—	—	—	1	1
Restructuring costs	95	—	31	126	246	—	98	344
	\$ 95	\$ 36	\$ 68	\$ 199	\$ 246	\$ 79	\$ 207	\$ 532

(\$ in millions)	Three Months Ended September 30, 2022				Nine Months Ended September 30, 2022			
	Separation Costs	Accelerated Depreciation	Other	Total	Separation Costs	Accelerated Depreciation	Other	Total
Cost of sales	\$ —	\$ 16	\$ 38	\$ 54	\$ —	\$ 51	\$ 116	\$ 167
Selling, general and administrative	—	5	21	26	—	17	57	74
Research and development	—	—	1	1	—	29	1	30
Restructuring costs	65	—	29	94	197	—	91	288
	\$ 65	\$ 21	\$ 89	\$ 175	\$ 197	\$ 97	\$ 265	\$ 559

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 12) and share-based compensation.

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

(\$ in millions)	Separation Costs	Accelerated Depreciation	Other	Total
Restructuring reserves January 1, 2023	\$ 479	\$ —	\$ 34	\$ 513
Expenses	246	79	207	532
(Payments) receipts, net	(191)	—	(103)	(294)
Non-cash activity	—	(79)	(105)	(184)
Restructuring reserves September 30, 2023 ⁽¹⁾	\$ 534	\$ —	\$ 33	\$ 567

⁽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:

	Amount of Pretax (Gain) Loss Recognized in Other Comprehensive Income ⁽¹⁾				Amount of Pretax (Gain) Loss Recognized in <i>Other (income) expense, net</i> for Amounts Excluded from Effectiveness Testing			
	Three Months Ended September 30,		Nine Months Ended September 30,		Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022	2023	2022	2023	2022
(\$ in millions)								
Net Investment Hedging Relationships								
Foreign exchange contracts	\$ (1)	\$ (1)	\$ —	\$ (47)	\$ —	\$ —	\$ 1	\$ (2)
Euro-denominated notes	(100)	(250)	(26)	(431)	—	—	—	—

⁽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.

At September 30, 2023, the Company was a party to three pay-floating, receive-fixed interest rate swap contracts designated as fair value hedges of a portion of fixed-rate notes as detailed in the table below.

(\$ in millions)	September 30, 2023		
	Par Value of Debt	Number of Interest Rate Swaps Held	Total Swap Notional Amount
4.50% notes due 2033	\$ 1,500	3	\$ 750

The interest rate swap contracts are designated hedges of the fair value changes in the notes attributable to changes in the benchmark Secured Overnight Financing Rate (SOFR) swap rate. The fair value change in the notes attributable to changes in the SOFR swap rate are recorded in interest expense along with the offsetting fair value changes in the swap contracts. In October 2023, the Company entered into an additional interest rate swap with a notional amount of \$250 million also related to its 4.50% notes due 2033. The cash flows from these contracts are reported as operating activities in the Condensed Consolidated Statement of Cash Flows.

The table below presents the location of amounts recorded on the Condensed Consolidated Balance Sheet related to cumulative basis adjustments for fair value hedges:

(\$ in millions)	Carrying Amount of Hedged Liabilities		Cumulative Amount of Fair Value Hedging Adjustment Increase (Decrease) Included in the Carrying Amount	
	September 30, 2023	December 31, 2022	September 30, 2023	December 31, 2022
Balance Sheet Line Item in which Hedged Item is Included				
Long-Term Debt	\$ 743	\$ —	\$ (7)	\$ —

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:

(\$ in millions)		September 30, 2023			December 31, 2022		
		Fair Value of Derivative		U.S. Dollar Notional	Fair Value of Derivative		U.S. Dollar Notional
		Asset	Liability		Asset	Liability	
Derivatives Designated as Hedging Instruments	Balance Sheet Caption						
Interest rate swap contracts	Other Noncurrent Liabilities	\$ —	\$ 8	\$ 750	\$ —	\$ —	\$ —
Foreign exchange contracts	Other current assets	321	—	8,059	220	—	4,824
Foreign exchange contracts	Other Assets	51	—	1,746	27	—	1,609
Foreign exchange contracts	Accrued and other current liabilities	—	4	680	—	101	2,691
Foreign exchange contracts	Other Noncurrent Liabilities	—	1	178	—	1	91
		\$ 372	\$ 13	\$ 11,413	\$ 247	\$ 102	\$ 9,215
Derivatives Not Designated as Hedging Instruments	Balance Sheet Caption						
Foreign exchange contracts	Other current assets	\$ 229	\$ —	\$ 8,485	\$ 186	\$ —	\$ 8,540
Foreign exchange contracts	Accrued and other current liabilities	—	163	9,910	—	307	10,926
		\$ 229	\$ 163	\$ 18,395	\$ 186	\$ 307	\$ 19,466
		\$ 601	\$ 176	\$ 29,808	\$ 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)	September 30, 2023		December 31, 2022	
	Asset	Liability	Asset	Liability
Gross amounts recognized in the condensed consolidated balance sheet	\$ 601	\$ 176	\$ 433	\$ 409
Gross amounts subject to offset in master netting arrangements not offset in the condensed consolidated balance sheet	(138)	(138)	(220)	(220)
Cash collateral received/posted	(143)	—	(66)	(19)
Net amounts	\$ 320	\$ 38	\$ 147	\$ 170

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

(\$ in millions)	Three Months Ended September 30,						Nine Months Ended September 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)	
	\$ 15,962	\$ 14,959	\$ 126	\$ 429	\$ (16)	\$ (416)	\$ 45,485	\$ 45,453	\$ 388	\$ 1,576	\$ (148)	\$ (314)
(Gain) loss on fair value hedging relationships:												
Interest rate swap contracts												
Hedged items	—	—	(7)	1	—	—	—	—	(7)	(13)	—	—
Derivatives designated as hedging instruments	—	—	8	—	—	—	—	—	8	4	—	—
Impact of cash flow hedging relationships:												
Foreign exchange contracts												
Amount of gain recognized in OCI on derivatives	—	—	—	—	247	682	—	—	—	—	375	1,233
Increase in Sales as a result of AOCL reclassifications	45	253	—	—	(45)	(253)	170	491	—	—	(170)	(491)
Interest rate contracts												
Amount of gain recognized in Other (income) expense, net on derivatives	—	—	—	(1)	—	—	—	—	(1)	(2)	—	—
Amount of (loss) gain recognized in OCI on derivatives	—	—	—	—	—	(1)	—	—	—	—	13	(2)

⁽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 September 30,		Nine Months Ended September 30,	
			2023	2022	2023	2022
	Foreign exchange contracts ⁽¹⁾	Other (income) expense, net	\$ 60	\$ (41)	\$ 32	\$ (77)
	Foreign exchange contracts ⁽²⁾	Sales	—	(4)	(3)	(42)

⁽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 September 30, 2023, the Company estimates \$269 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)	September 30, 2023				December 31, 2022			
	Amortized Cost	Gross Unrealized		Fair Value	Amortized Cost	Gross Unrealized		Fair Value
		Gains	Losses			Gains	Losses	
Commercial paper	\$ 168	\$ —	\$ —	\$ 168	\$ 498	\$ —	\$ —	\$ 498
U.S. government and agency securities	67	—	—	67	68	—	—	68
Corporate notes and bonds	12	—	—	12	3	—	—	3
Total debt securities	\$ 247	\$ —	\$ —	\$ 247	\$ 569	\$ —	\$ —	\$ 569
Publicly traded equity securities ⁽¹⁾				1,746				1,284
Total debt and publicly traded equity securities				\$ 1,993				\$ 1,853

⁽¹⁾ Unrealized net gains of \$61 million and \$327 million were recorded in Other (income) expense, net in the third quarter and first nine months of 2023, respectively, on equity securities still held at September 30, 2023. Unrealized net losses of \$221 million and \$415 million were recorded in Other (income) expense, net in the third quarter and first nine months of 2022, respectively, on equity securities still held at September 30, 2022.

At September 30, 2023 and September 30, 2022, the Company also had \$863 million and \$705 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 nine months of 2023, the Company recorded unrealized gains of \$7 million and unrealized losses of \$24 million related to certain of these equity investments still held at September 30, 2023. During the first nine months of 2022, the Company recorded unrealized gains of \$21 million and unrealized losses of \$12 million related to certain of these equity investments still held at September 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 September 30, 2023 were \$296 million and \$40 million, respectively.

At September 30, 2023 and September 30, 2022, the Company also had \$467 million and \$655 million, respectively, recorded in *Other Assets* for equity securities held through ownership interests in investment funds. Losses recorded in *Other (income) expense, net* relating to these investment funds were \$93 million and \$141 million for the third quarter of 2023 and 2022, respectively, and were \$66 million and \$952 million for the first nine 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
	September 30, 2023				December 31, 2022			
Assets								
Investments								
Commercial paper	\$ —	\$ 168	\$ —	\$ 168	\$ —	\$ 498	\$ —	\$ 498
Publicly traded equity securities	1,306	—	—	1,306	1,015	—	—	1,015
	1,306	168	—	1,474	1,015	498	—	1,513
Other assets ⁽¹⁾								
U.S. government and agency securities	67	—	—	67	68	—	—	68
Corporate notes and bonds	12	—	—	12	3	—	—	3
Publicly traded equity securities ⁽²⁾	440	—	—	440	269	—	—	269
	519	—	—	519	340	—	—	340
Derivative assets ⁽³⁾								
Forward exchange contracts	—	431	—	431	—	218	—	218
Purchased currency options	—	170	—	170	—	215	—	215
	—	601	—	601	—	433	—	433
Total assets	\$ 1,825	\$ 769	\$ —	\$ 2,594	\$ 1,355	\$ 931	\$ —	\$ 2,286
Liabilities								
Other liabilities								
Contingent consideration	\$ —	\$ —	\$ 345	\$ 345	\$ —	\$ —	\$ 456	\$ 456
Derivative liabilities ⁽³⁾								
Forward exchange contracts	—	160	—	160	—	402	—	402
Written currency options	—	8	—	8	—	7	—	7
Interest rate swaps	—	8	—	8	—	—	—	—
	—	176	—	176	—	409	—	409
Total liabilities	\$ —	\$ 176	\$ 345	\$ 521	\$ —	\$ 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⁾ Balance at September 30, 2023 includes securities with a total fair value of \$132 million, which are subject to a contractual sale restriction that expires in July 2024.

⁽³⁾ 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 September 30, 2023 and December 31, 2022, *Cash and cash equivalents* included \$7.8 billion and \$11.3 billion of cash equivalents, respectively (which would be considered Level 2 in the fair value hierarchy).

Contingent Consideration

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

(\$ in millions)	2023	2022
Fair value January 1	\$ 456	\$ 777
Changes in estimated fair value ⁽¹⁾	6	(156)
Payments	(117)	(119)
Other	—	(3)
Fair value September 30 ⁽²⁾	\$ 345	\$ 499

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

⁽²⁾ At September 30, 2023, \$255 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 September 30, 2023 includes \$126 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 September 30, 2023, was \$29.5 billion compared with a carrying value of \$34.9 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, distributors 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 \$3.5 billion and \$2.5 billion of accounts receivable as of September 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, generally within thirty days after receipt. As of September 30, 2023 and December 31, 2022, the Company had collected \$39 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 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 \$143 million and \$66 million at September 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)	September 30, 2023		December 31, 2022	
Finished goods	\$	1,840	\$	1,841
Raw materials and work in process		7,630		7,063
Supplies		281		238
Total		9,751		9,142
Decrease to LIFO cost		(469)		(293)
	\$	9,282	\$	8,849
Recognized as:				
Inventories	\$	6,131	\$	5,911
Other Assets		3,151		2,938

Amounts recognized as *Other Assets* are comprised almost entirely of raw materials and work in process inventories. At both September 30, 2023 and December 31, 2022, these amounts included \$2.4 billion of inventories not expected to be sold within one year. In addition, these amounts included \$756 million and \$516 million at September 30, 2023 and December 31, 2022, respectively, of inventories produced in preparation for product launches.

8. Other Intangibles

In the third quarter of 2022, the Company recorded \$887 million of impairment charges within *Research and development* expenses related to intangible assets obtained in connection with the 2020 acquisition of ArQule, Inc. Of this amount, \$807 million represents an in-process research and development (IPR&D) impairment charge related to nemtabrutinib (MK-1026), a novel, oral BTK inhibitor currently being evaluated for the treatment of B-cell malignancies. Following discussions with regulatory authorities in the third quarter of 2022, the development period for nemtabrutinib was extended, which constituted a triggering event that required the evaluation of the nemtabrutinib intangible asset for impairment. The Company estimated the fair value of nemtabrutinib utilizing an income approach which uses Level 3 inputs to calculate the present value of projected future cash flows. The market participant assumptions used to derive the forecasted cash flows were updated to reflect a delay in the anticipated launch date for nemtabrutinib, which resulted in lower cumulative revenue forecasts and a reduction in the estimated fair value. The revised estimated fair value of nemtabrutinib when compared with its related carrying value resulted in the IPR&D impairment charge noted above. In December 2022, regulatory authorities provided additional feedback with respect to clinical study design that led to a further reassessment of the development plan for nemtabrutinib, which was expected to result in changes to the clinical study design, and corresponding delays in the anticipated approval and launch timelines, which constituted a triggering event. Utilizing an income approach, the forecasted cash flows were updated to reflect a decline in forecasted revenue coupled with an increase in development cost forecasts, which reduced projected cash flows lowering the estimated current fair value of nemtabrutinib. The revised estimated fair value of nemtabrutinib when compared with its then-related carrying value resulted in a \$780 million impairment charge, which was recorded in the fourth quarter of 2022. The remaining IPR&D intangible asset related to nemtabrutinib is \$418 million. If the assumptions used to estimate the fair value of nemtabrutinib prove to be incorrect and the development of nemtabrutinib does not progress as anticipated thereby adversely affecting projected future cash flows, the Company may record an additional impairment charge in the future and such charge could be material. The remaining \$80 million intangible asset impairment charge in the third quarter of 2022 related to derazantinib and resulted from the termination of the out-licensing agreement and the decision by Merck not to pursue development of derazantinib.

9. 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, including 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.

10. 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

As previously disclosed, 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 September 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

As previously disclosed, 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.

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 financial results for the first nine months of 2023. On October 18, 2023, the court granted final approval of the indirect purchaser class settlement.

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 were 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.

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 have appealed 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. On October 20, 2023, the Company petitioned the Third Circuit for permission to appeal the antitrust decision.

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.

On July 24, 2023, defendants filed a notice of appeal with the Federal Court of Appeals.

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 26 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 Zydus has received FDA approval for a non-automatically substitutable form of sitagliptin that differs from the form in the Company's sitagliptin products.

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 fourth quarter of 2023 with a decision in the first quarter of 2024. 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 nine issued U.S. patents, including a demand for damages.

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

Other Litigation

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

Legal Defense Reserves

Legal defense costs expected to be incurred in connection with a loss contingency are accrued when probable and reasonably estimable. Some of the significant factors considered in the review of these legal defense reserves are as follows: the actual costs incurred by the Company; the development of the Company's legal defense strategy and structure in light of the scope of its litigation; the number of cases being brought against the Company; the costs and outcomes of completed trials and the most current information regarding anticipated timing, progression, and related costs of pre-trial activities and trials in the associated litigation. The amount of legal defense reserves as of September 30, 2023 and December 31, 2022 of approximately \$220 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.

11. Equity

(\$ and shares in millions except per share amounts)	Three Months Ended September 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 July 1, 2022	3,577	\$ 1,788	\$ 44,115	\$ 58,437	\$ (4,327)	1,044	\$ (56,770)	\$ 75	\$ 43,318
Net income attributable to Merck & Co., Inc.	—	—	—	3,248	—	—	—	—	3,248
Other comprehensive loss, net of taxes	—	—	—	—	(416)	—	—	—	(416)
Cash dividends declared on common stock (\$0.69 per share)	—	—	—	(1,757)	—	—	—	—	(1,757)
Share-based compensation plans and other	—	—	128	—	—	—	12	—	140
Net income attributable to noncontrolling interests	—	—	—	—	—	—	—	5	5
Distributions attributable to noncontrolling interests	—	—	—	—	—	—	—	(14)	(14)
Balance at September 30, 2022	3,577	\$ 1,788	\$ 44,243	\$ 59,928	\$ (4,743)	1,044	\$ (56,758)	\$ 66	\$ 44,524
Balance at July 1, 2023	3,577	\$ 1,788	\$ 44,219	\$ 54,198	\$ (4,900)	1,038	\$ (56,612)	\$ 49	\$ 38,742
Net income attributable to Merck & Co., Inc.	—	—	—	4,745	—	—	—	—	4,745
Other comprehensive loss, net of taxes	—	—	—	—	(16)	—	—	—	(16)
Cash dividends declared on common stock (\$0.73 per share)	—	—	—	(1,861)	—	—	—	—	(1,861)
Treasury stock shares purchased	—	—	—	—	—	4	(466)	—	(466)
Share-based compensation plans and other	—	—	139	—	—	—	12	—	151
Net income attributable to noncontrolling interests	—	—	—	—	—	—	—	5	5
Balance at September 30, 2023	3,577	\$ 1,788	\$ 44,358	\$ 57,082	\$ (4,916)	1,042	\$ (57,066)	\$ 54	\$ 41,300

(\$ and shares in millions except per share amounts)	Nine Months Ended September 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.	—	—	—	11,502	—	—	—	—	11,502
Other comprehensive loss, net of taxes	—	—	—	—	(314)	—	—	—	(314)
Cash dividends declared on common stock (\$2.07 per share)	—	—	—	(5,270)	—	—	—	—	(5,270)
Share-based compensation plans and other	—	—	5	—	—	(5)	351	—	356
Net income attributable to noncontrolling interests	—	—	—	—	—	—	—	6	6
Distributions attributable to noncontrolling interests	—	—	—	—	—	—	—	(13)	(13)
Balance at September 30, 2022	3,577	\$ 1,788	\$ 44,243	\$ 59,928	\$ (4,743)	1,044	\$ (56,758)	\$ 66	\$ 44,524
Balance at January 1, 2023	3,577	\$ 1,788	\$ 44,379	\$ 61,081	\$ (4,768)	1,039	\$ (56,489)	\$ 67	\$ 46,058
Net income attributable to Merck & Co., Inc.	—	—	—	1,591	—	—	—	—	1,591
Other comprehensive loss, net of taxes	—	—	—	—	(148)	—	—	—	(148)
Cash dividends declared on common stock (\$2.19 per share)	—	—	—	(5,590)	—	—	—	—	(5,590)
Treasury stock shares purchased	—	—	—	—	—	9	(953)	—	(953)
Share-based compensation plans and other	—	—	(21)	—	—	(6)	376	—	355
Net income attributable to noncontrolling interests	—	—	—	—	—	—	—	12	12
Distributions attributable to noncontrolling interests	—	—	—	—	—	—	—	(25)	(25)
Balance at September 30, 2023	3,577	\$ 1,788	\$ 44,358	\$ 57,082	\$ (4,916)	1,042	\$ (57,066)	\$ 54	\$ 41,300

12. 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 September 30,				Nine Months Ended September 30,			
	2023		2022		2023		2022	
	U.S.	International	U.S.	International	U.S.	International	U.S.	International
Service cost	\$ 88	\$ 48	\$ 91	\$ 66	\$ 239	\$ 148	\$ 289	\$ 213
Interest cost	130	76	123	35	396	225	330	110
Expected return on plan assets	(182)	(131)	(182)	(93)	(553)	(390)	(576)	(292)
Amortization of unrecognized prior service (credit) cost	—	(6)	(8)	(3)	(1)	5	(24)	(10)
Net (gain) loss amortization	—	(1)	10	24	—	(2)	122	73
Termination benefits	1	—	1	—	2	—	2	1
Curtailments	—	—	3	—	5	—	11	—
Settlements	—	—	79	—	26	—	180	—
	\$ 37	\$ (14)	\$ 117	\$ 29	\$ 114	\$ (14)	\$ 334	\$ 95

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 September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Service cost	\$ 8	\$ 11	\$ 24	\$ 36
Interest cost	16	11	47	34
Expected return on plan assets	(16)	(21)	(48)	(64)
Amortization of unrecognized prior service credit	(12)	(14)	(37)	(42)
Net gain amortization	(11)	(11)	(31)	(32)
Curtailments	—	—	(1)	(1)
	\$ (15)	\$ (24)	\$ (46)	\$ (69)

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 third quarter and first nine months of both 2023 and 2022. These partial settlements triggered remeasurements of some of the Company's U.S. pension plans. The third quarter 2023 remeasurement, which was calculated using discount rates and asset values as of September 30, 2023, resulted in a net decrease of \$34 million to net pension liabilities and a related adjustment to AOCL. Remeasurements during the first nine months of 2023 resulted in an increase of \$13 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 13), 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.

13. Other (Income) Expense, Net

Other (income) expense, net, consisted of:

(\$ in millions)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Interest income	\$ (73)	\$ (40)	\$ (295)	\$ (62)
Interest expense	317	244	836	727
Exchange losses	85	96	208	220
Loss (income) from investments in equity securities, net ⁽¹⁾	33	371	(240)	1,361
Net periodic defined benefit plan (credit) cost other than service cost	(138)	(60)	(364)	(208)
Other, net	(98)	(182)	243	(462)
	\$ 126	\$ 429	\$ 388	\$ 1,576

⁽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 nine months of 2023 includes a \$572.5 million charge related to settlements with certain plaintiffs in the Zetia antitrust litigation (see Note 10).

Interest paid for the nine months ended September 30, 2023 and 2022 was \$678 million and \$660 million, respectively.

14. Income Taxes

The effective income tax rate of 15.5% for the third quarter of 2023 reflects the favorable mix of income and expense. The effective income tax rate of 59.3% for the first nine months of 2023 includes a 44.0 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 9.2% for the third quarter of 2022 and 11.0% for the first nine months of 2022 reflect the favorable mix of income and expense, as well as the favorable impact of net unrealized losses from investments in equity securities and intangible asset impairment charges, 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.

15. Earnings Per Share

The calculations of earnings per share are as follows:

(\$ and shares in millions except per share amounts)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Net Income Attributable to Merck & Co., Inc.	\$ 4,745	\$ 3,248	\$ 1,591	\$ 11,502
Average common shares outstanding	2,537	2,533	2,538	2,531
Common shares issuable ⁽¹⁾	9	9	11	9
Average common shares outstanding assuming dilution	2,546	2,542	2,549	2,540
Basic Earnings per Common Share Attributable to Merck & Co., Inc. Common Shareholders	\$ 1.87	\$ 1.28	\$ 0.63	\$ 4.55
Earnings per Common Share Assuming Dilution Attributable to Merck & Co., Inc. Common Shareholders	\$ 1.86	\$ 1.28	\$ 0.62	\$ 4.53

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

For the third quarter of 2023 and 2022, 6 million and 2 million, respectively, and for the first nine months of 2023 and 2022, 5 million and 5 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.

16. Other Comprehensive Income (Loss)

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

(\$ in millions)	Three Months Ended September 30,			
	Derivatives	Employee Benefit Plans	Foreign Currency Translation Adjustment	Accumulated Other Comprehensive Loss
Balance July 1, 2022, net of taxes	\$ 390	\$ (2,465)	\$ (2,252)	\$ (4,327)
Other comprehensive income (loss) before reclassification adjustments, pretax	682	(294)	(618)	(230)
Tax	(143)	62	50	(31)
Other comprehensive income (loss) before reclassification adjustments, net of taxes	539	(232)	(568)	(261)
Reclassification adjustments, pretax	(254) ⁽¹⁾	77 ⁽²⁾	—	(177)
Tax	53	(31)	—	22
Reclassification adjustments, net of taxes	(201)	46	—	(155)
Other comprehensive income (loss), net of taxes	338	(186)	(568)	(416)
Balance September 30, 2022, net of taxes	\$ 728	\$ (2,651)	\$ (2,820)	\$ (4,743)
Balance July 1, 2023, net of taxes	\$ 85	\$ (2,483)	\$ (2,502)	\$ (4,900)
Other comprehensive income (loss) before reclassification adjustments, pretax	247	29	(252)	24
Tax	(52)	(7)	77	18
Other comprehensive income (loss) before reclassification adjustments, net of taxes	195	22	(175)	42
Reclassification adjustments, pretax	(45) ⁽¹⁾	(27) ⁽²⁾	—	(72)
Tax	9	5	—	14
Reclassification adjustments, net of taxes	(36)	(22)	—	(58)
Other comprehensive income (loss), net of taxes	159	—	(175)	(16)
Balance September 30, 2023, net of taxes	\$ 244	\$ (2,483)	\$ (2,677)	\$ (4,916)

(\$ in millions)	Nine Months Ended September 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	1,233	(125)	(1,001)	107
Tax	(259)	25	11	(223)
Other comprehensive income (loss) before reclassification adjustments, net of taxes	974	(100)	(990)	(116)
Reclassification adjustments, pretax	(493) ⁽¹⁾	266 ⁽²⁾	—	(227)
Tax	103	(74)	—	29
Reclassification adjustments, net of taxes	(390)	192	—	(198)
Other comprehensive income (loss), net of taxes	584	92	(990)	(314)
Balance September 30, 2022, net of taxes	\$ 728	\$ (2,651)	\$ (2,820)	\$ (4,743)
Balance January 1, 2023, net of taxes	\$ 73	\$ (2,408)	\$ (2,433)	\$ (4,768)
Other comprehensive income (loss) before reclassification adjustments, pretax	375	(24)	(288)	63
Tax	(79)	(4)	35	(48)
Other comprehensive income (loss) before reclassification adjustments, net of taxes	296	(28)	(253)	15
Reclassification adjustments, pretax	(158) ⁽¹⁾	(57) ⁽²⁾	9	(206)
Tax	33	10	—	43
Reclassification adjustments, net of taxes	(125)	(47)	9	(163)
Other comprehensive income (loss), net of taxes	171	(75)	(244)	(148)
Balance September 30, 2023, net of taxes	\$ 244	\$ (2,483)	\$ (2,677)	\$ (4,916)

⁽¹⁾ Primarily relates to foreign currency cash flow hedges that were reclassified from AOCL to Sales.⁽²⁾ Includes net amortization of prior service cost/credit, actuarial gains and losses, settlements and curtailments included in net periodic benefit cost (see Note 12).

17. 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 September 30,						Nine Months Ended September 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	\$ 3,795	\$ 2,543	\$ 6,338	\$ 3,331	\$ 2,095	\$ 5,426	\$ 11,142	\$ 7,261	\$ 18,403	\$ 9,307	\$ 6,180	\$ 15,487
Alliance revenue-Lynparza ⁽¹⁾	153	146	299	144	140	284	439	445	884	427	397	825
Alliance revenue-Lenvima ⁽¹⁾	160	100	260	142	60	202	476	258	734	426	235	660
Welireg	51	3	54	38	—	38	141	6	146	83	—	83
Alliance revenue-Reblozyl ⁽²⁾	43	10	52	32	7	39	108	33	142	87	37	124
Vaccines												
Gardasil/Gardasil 9	838	1,746	2,585	957	1,337	2,294	1,718	5,297	7,015	1,803	3,624	5,428
ProQuad/M-M-R II/Varivax	567	146	713	532	136	668	1,435	388	1,823	1,337	379	1,716
RotaTeq	108	48	156	154	102	256	381	203	584	427	218	644
Vaxneuvance	182	33	214	15	1	16	423	65	488	31	1	32
Pneumovax 23	42	98	140	68	63	131	105	223	327	280	177	457
Vaqta	32	37	69	27	36	64	91	60	151	72	62	134
Hospital Acute Care												
Bridion	265	159	424	233	190	423	841	572	1,413	665	579	1,244
Prevymis	70	87	157	49	64	114	186	244	430	136	174	310
Difcid	69	5	74	72	6	77	199	16	215	184	12	196
Primaxin	—	41	41	—	63	63	2	173	174	1	185	185
Noxafil	4	47	51	13	49	62	29	138	167	39	141	180
Zerbaxa	29	24	53	24	19	43	86	71	157	64	55	120
Cardiovascular												
Alliance revenue-Adempas/Verquvo ⁽³⁾	96	(4)	92	85	3	88	249	10	259	244	14	258
Adempas	—	65	65	—	57	57	—	189	189	—	181	181
Virology												
Lagevrio	—	640	640	—	436	436	—	1,236	1,236	1,523	3,336	4,859
Isentress/Isentress HD	58	61	119	68	93	161	165	212	377	196	270	466
Neuroscience												
Belsomra	23	35	58	20	42	62	60	117	176	60	139	199
Immunology												
Simponi	—	179	179	—	173	173	—	539	539	—	540	540
Remicade	—	45	45	—	49	49	—	144	144	—	163	163
Diabetes												
Januvia	328	252	581	332	385	717	842	800	1,642	958	1,294	2,252
Janumet	43	211	255	90	327	417	182	755	937	258	1,089	1,347
Other pharmaceutical ⁽⁴⁾	197	353	549	194	410	603	540	1,147	1,690	511	1,225	1,736
Total Pharmaceutical segment sales	7,153	7,110	14,263	6,620	6,343	12,963	19,840	20,602	40,442	19,119	20,707	39,826
Animal Health:												
Livestock	205	669	874	186	643	829	543	1,987	2,530	521	1,965	2,486
Companion Animal	257	269	526	289	253	542	875	942	1,817	904	929	1,834
Total Animal Health segment sales	462	938	1,400	475	896	1,371	1,418	2,929	4,347	1,425	2,894	4,320
Total segment sales	7,615	8,048	15,663	7,095	7,239	14,334	21,258	23,531	44,789	20,544	23,601	44,146
Other ⁽⁵⁾	100	199	299	227	398	625	135	561	696	383	925	1,307
	\$ 7,715	\$ 8,247	\$ 15,962	\$ 7,322	\$ 7,637	\$ 14,959	\$ 21,393	\$ 24,092	\$ 45,485	\$ 20,927	\$ 24,526	\$ 45,453

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

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

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

⁽⁵⁾ Other is primarily comprised of miscellaneous corporate revenue, including revenue hedging activities which increased sales by \$173 million and \$533 million for the nine months ended September 30, 2023 and 2022, respectively, as well as revenue from third-party manufacturing arrangements (including sales to Organon). Other for the nine months ended September 30, 2023 and 2022 also includes \$118 million and \$156 million, respectively, related to upfront and milestone payments received by Merck for out-licensing arrangements.

Product sales are recorded net of the provision for discounts, including chargebacks, which are customer discounts that occur when a contracted customer purchases through an intermediary wholesale purchaser, and rebates that are owed based upon definitive contractual agreements or legal requirements with private sector and public sector (Medicaid and Medicare Part D) benefit providers, after the final dispensing of the product by a pharmacy to a benefit plan participant. These discounts, in the aggregate, reduced U.S. sales by \$3.1 billion and \$3.3 billion for the three months ended September 30, 2023 and 2022, respectively, and \$9.4 billion and \$9.1 billion for the nine months ended September 30, 2023 and 2022, respectively.

Consolidated sales by geographic area where derived are as follows:

(\$ in millions)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
United States	\$ 7,715	\$ 7,322	\$ 21,393	\$ 20,927
Europe, Middle East and Africa	3,327	3,286	9,978	11,228
China	1,694	1,442	5,322	3,957
Japan	1,081	673	2,514	2,776
Asia Pacific (other than China and Japan)	781	854	2,475	2,792
Latin America	895	684	2,298	1,933
Other	469	698	1,505	1,840
	\$ 15,962	\$ 14,959	\$ 45,485	\$ 45,453

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

(\$ in millions)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Segment profits:				
Pharmaceutical segment	\$ 10,407	\$ 9,590	\$ 29,400	\$ 28,263
Animal Health segment	421	515	1,453	1,672
Total segment profits	10,828	10,105	30,853	29,935
Other profits	190	377	374	831
Unallocated:				
Interest income	73	40	295	62
Interest expense	(317)	(244)	(836)	(727)
Amortization	(562)	(460)	(1,582)	(1,623)
Depreciation	(401)	(448)	(1,175)	(1,257)
Research and development	(3,183)	(4,277)	(20,523)	(9,374)
Restructuring costs	(126)	(94)	(344)	(288)
Charge for Zetia antitrust litigation settlements	—	—	(573)	—
Other unallocated, net	(882)	(1,416)	(2,554)	(4,628)
	\$ 5,620	\$ 3,583	\$ 3,935	\$ 12,931

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 October 2023, Merck and Daiichi Sankyo entered into a global development and commercialization agreement for three of Daiichi Sankyo's deruxtecan (DXd) antibody drug conjugate (ADC) candidates: patritumab deruxtecan (HER3-DXd) (MK-1022), ifinatamab deruxtecan (I-DXd) (MK-2400) and raludotatug deruxtecan (R-DXd) (MK-5909). All three potentially first-in-class DXd ADCs are in various stages of clinical development for the treatment of multiple solid tumors both as monotherapy and/or in combination with other treatments. The companies will jointly develop and potentially commercialize these ADC candidates worldwide, except in Japan where Daiichi Sankyo will maintain exclusive rights. Daiichi Sankyo will be solely responsible for manufacturing and supply. Under the terms of the agreement, Merck made upfront payments of \$4.0 billion and will make continuation payments of \$1.5 billion to Daiichi Sankyo and Daiichi Sankyo is eligible to receive future contingent sales-based milestone payments. In conjunction with this transaction, Merck will record an aggregate pretax charge of \$5.5 billion to *Research and development* expenses, or approximately \$1.70 per share, in the fourth quarter of 2023. In addition, Merck will invest in the pipeline assets and incur costs to finance the transaction, resulting in a negative impact to earnings per share (EPS) of approximately \$0.25 in the first 12 months following the close of the transaction.

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 a charge of \$10.2 billion to *Research and development* expenses, or \$4.00 per share, in the first nine 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 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 nine months of 2023. In October 2023, Merck notified Kelun-Biotech it was terminating two of the seven candidates under the agreement. Kelun-Biotech remains 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 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 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 a charge of \$1.2 billion to *Research and development* expenses in the first nine 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 nine 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). In August 2023, the U.S. Department of Health and Human Services (HHS), through the Centers for Medicare & Medicaid Services (CMS), announced that *Januvia* (sitagliptin) will be included in the first year of the IRA's "Drug Price Negotiation Program" (Program). Pursuant to the IRA's Program, discussions with the government will occur in 2023 and 2024, with government price-setting becoming effective on January 1, 2026. The Company has sued the U.S. government regarding the IRA's Program (see Note 10 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 September 30,		% Change	% Change Excluding Foreign Exchange	Nine Months Ended September 30,		% Change	% Change Excluding Foreign Exchange
	2023	2022			2023	2022		
United States	\$ 7,715	\$ 7,322	5 %	5 %	\$ 21,393	\$ 20,927	2 %	2 %
International	8,247	7,637	8 %	12 %	24,092	24,526	(2)%	4 %
Total	\$ 15,962	\$ 14,959	7 %	9 %	\$ 45,485	\$ 45,453	— %	3 %

Worldwide sales grew 7% to \$16.0 billion in the third 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 third quarter were higher sales in the virology franchise largely due to *Lagevrio* (molnupiravir). Revenue growth in the third quarter of 2023 was partially offset by lower sales in the diabetes franchise attributable to *Januvia* and *Janumet* (sitagliptin and metformin HCl), lower sales of *RotaTeq* (Rotavirus Vaccine, Live Oral, Pentavalent) and lower revenue from third-party manufacturing arrangements.

Worldwide sales were nearly flat in the first nine months of 2023 compared with the corresponding prior year period. Sales performance reflects higher sales in the oncology franchise, largely 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* (sugammadex) and *Prevymis* (letermovir). These increases were offset by lower sales in the virology franchise, largely attributable to *Lagevrio*, as well as lower sales in the diabetes franchise due to *Januvia* and *Janumet*, lower sales of *Pneumovax* 23 (pneumococcal vaccine polyvalent), and lower revenue from third-party manufacturing arrangements.

See Note 17 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 September 30,		% Change	% Change Excluding Foreign Exchange	Nine Months Ended September 30,		% Change	% Change Excluding Foreign Exchange
	2023	2022			2023	2022		
<i>Keytruda</i>	\$ 6,338	\$ 5,426	17 %	17 %	\$ 18,403	\$ 15,487	19 %	21 %
Alliance Revenue - Lynparza ⁽¹⁾	299	284	5 %	6 %	884	825	7 %	10 %
Alliance Revenue - Lenvima ⁽¹⁾	260	202	29 %	30 %	734	660	11 %	13 %
<i>Welireg</i>	54	38	43 %	43 %	146	83	77 %	77 %
Alliance Revenue - Reblozyl ⁽²⁾	52	39	35 %	35 %	142	124	14 %	14 %

⁽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 nine 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. *Keytruda* is also 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. Additionally, *Keytruda* is approved for patients with certain types of resectable NSCLC in combination with chemotherapy as neoadjuvant treatment, and then continued as a single agent as adjuvant treatment after surgery. *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 for certain types of advanced biliary tract cancer, 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 17% and 19% in the third quarter and first nine 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, HNSCC, endometrial and bladder cancers, as well as higher pricing. *Keytruda* sales growth in international markets reflects higher demand for the HNSCC and RCC metastatic indications, as well as uptake in TNBC and RCC 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 ≥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.
August 2023	European Commission (EC) approval in combination with trastuzumab, fluoropyrimidine- and platinum-containing chemotherapy, for the first-line treatment of locally advanced unresectable or metastatic human epidermal growth factor receptor 2 (HER2)-positive gastric or GEJ adenocarcinoma in adults whose tumors express PD-L1, based on the KEYNOTE-811 trial.
October 2023	EC approval as a monotherapy for the adjuvant treatment of adults with NSCLC who are at high risk of recurrence following complete resection and platinum-based chemotherapy, based on the KEYNOTE-091 trial.
October 2023	FDA approval for the treatment of patients with resectable (tumors ≥4cm or node positive) NSCLC in combination with platinum-containing chemotherapy as neoadjuvant treatment, and then continued as a single agent as adjuvant treatment after surgery, based on the KEYNOTE-671 trial.
October 2023	FDA full approval for the treatment of adult and pediatric patients with recurrent locally advanced or metastatic Merkel cell carcinoma. The conversion from an accelerated to a full (regular) approval is based on the KEYNOTE-913 and KEYNOTE-017 trials.
October 2023	FDA approval in combination with gemcitabine and cisplatin for the treatment of patients with locally advanced unresectable or metastatic biliary tract cancer, based on the KEYNOTE-966 trial.

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 5% in the third quarter of 2023 primarily driven by higher pricing in the U.S. and higher demand in Latin America. Alliance revenue related to Lynparza grew 7% in the first nine months of 2023 primarily driven by higher pricing and demand in the U.S., as well as higher demand in several international markets. 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. In August 2023, Japan's MHLW approved Lynparza in combination with abiraterone and prednisolone for treatment of adult patients with *BRCAm* mCRPC with distant metastasis, 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 29% in the third quarter of 2023 largely reflecting higher demand in the U.S. and certain international markets, as well as the timing of purchases in China. Alliance revenue related to Lenvima grew 11% in the first nine months of 2023 largely reflecting higher demand in the U.S. and Europe, 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, grew 43% and 77% in the third quarter and first nine months of 2023, respectively. Sales growth in both periods is due to continued uptake in the U.S. following launch in 2021. In September 2023, the FDA accepted and granted priority review for a

supplemental new drug application (NDA) seeking approval for *Welireg* for the treatment of adult patients with advanced RCC following immune checkpoint and anti-angiogenic therapies. The supplemental NDA is based on data from the LITESPARK-005 trial. The FDA set a Prescription Drug User Fee Act (PDUFA), or target action, date of January 17, 2024.

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) (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 nine months of 2022, also includes the receipt of a regulatory approval milestone payment of \$20 million. Alliance revenue increased 35% and 14% in the third quarter and first nine months of 2023, respectively, due to strong underlying sales performance. The increase in alliance revenue in the first nine 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 September 30,		% Change	% Change Excluding Foreign Exchange	Nine Months Ended September 30,		% Change	% Change Excluding Foreign Exchange
	2023	2022			2023	2022		
<i>Gardasil/Gardasil 9</i>	\$ 2,585	\$ 2,294	13 %	16 %	\$ 7,015	\$ 5,428	29 %	34 %
<i>ProQuad</i>	267	264	1 %	1 %	678	640	6 %	6 %
<i>M-M-R II</i>	122	124	(2)%	(4)%	329	330	— %	(1)%
<i>Varivax</i>	325	280	16 %	15 %	816	746	9 %	10 %
<i>RotaTeq</i>	156	256	(39)%	(39)%	584	644	(9)%	(8)%
<i>Vaxneuvance</i>	214	16	*	*	488	32	*	*
<i>Pneumovax 23</i>	140	131	6 %	4 %	327	457	(28)%	(27)%

* > 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 13% and 29% in the third quarter and first nine months of 2023, respectively, driven primarily by strong demand outside of the U.S., 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. Sales growth in both periods was partially offset by lower sales in the U.S. due to public sector buying patterns, partially offset by higher pricing and demand.

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, were nearly flat in the third quarter of 2023 compared with the third quarter of 2022. Worldwide sales of *ProQuad* increased 6% in the first nine months of 2023 primarily reflecting higher pricing in the U.S.

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 third quarter and first nine 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), increased 16% in the third quarter of 2023 primarily attributable to higher pricing and demand in the U.S., as well as higher demand in Latin America. Global sales of *Varivax* grew 9% in the first nine months of 2023 largely due to higher pricing and demand in the U.S., as well as higher demand in the Asia Pacific region, partially offset by lower demand in Latin America.

Global sales of *RotaTeq*, a vaccine to help protect against rotavirus gastroenteritis in infants and children, declined 39% in the third quarter of 2023 and decreased 9% in first nine months of 2023 primarily due to public sector buying patterns in the U.S., as well as lower sales in China reflecting the continued buy-out of first quarter 2023 inventory stocking.

Worldwide sales of *Vaxneuvance*, a vaccine to help prevent invasive pneumococcal disease, increased to \$214 million and \$488 million in the third quarter and first nine months of 2023, respectively, primarily due to continued uptake in the pediatric indication in the U.S. and launches in European markets.

Worldwide sales of *Pneumovax 23*, a vaccine to help prevent pneumococcal disease, grew 6% in the third quarter of 2023 primarily reflecting higher demand in certain ex-U.S. markets that was largely offset by lower demand in the U.S. Global sales of *Pneumovax 23* declined 28% in the first nine months of 2023 due to lower demand in the U.S., partially offset by higher demand in several ex-U.S. markets. Lower demand for *Pneumovax 23* in the U.S. is being driven by the continued market 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 September 30,		% Change	% Change Excluding Foreign Exchange	Nine Months Ended September 30,		% Change	% Change Excluding Foreign Exchange
	2023	2022			2023	2022		
<i>Bridion</i>	\$ 424	\$ 423	— %	— %	\$ 1,413	\$ 1,244	14 %	15 %
<i>Prevymis</i>	157	114	38 %	38 %	430	310	39 %	41 %

Worldwide sales of *Bridion*, for the reversal of two types of neuromuscular blocking agents used during surgery, were essentially flat in the third quarter of 2023 reflecting higher demand in the U.S., due in part to *Bridion*'s growing market share among neuromuscular blockade reversal agents, offset by lower demand in ex-U.S. markets due to generic competition, particularly in Europe. The patent that provided market exclusivity for *Bridion* in the European Union (EU) expired in July 2023. Accordingly, the Company is experiencing sales declines of *Bridion* in these markets and expects the declines to continue. Global sales of *Bridion* grew 14% in the first nine months of 2023 primarily due to higher demand and pricing in the U.S.

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 38% and 39% in the third quarter and first nine months of 2023, respectively, 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. In October 2023, the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) recommended approval of *Prevymis* for this new indication. The CHMP's recommendation will be reviewed by the EC for marketing authorization in the EU and a final decision is expected later in 2023.

Cardiovascular

(\$ in millions)	Three Months Ended September 30,		% Change	% Change Excluding Foreign Exchange	Nine Months Ended September 30,		% Change	% Change Excluding Foreign Exchange
	2023	2022			2023	2022		
Alliance Revenue - Adempas/ Verquvo ⁽¹⁾	\$ 92	\$ 88	5 %	5 %	\$ 259	\$ 258	— %	— %
Adempas	65	57	15 %	11 %	189	181	5 %	7 %

⁽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 (PAH) 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 in the third quarter and first nine months of 2023 was relatively consistent compared with the corresponding prior year periods. Revenue also includes sales of Adempas and Verquvo in Merck's marketing territories. Sales of Adempas in Merck's marketing territories grew 15% and 5% in the third quarter and first nine months of 2023, respectively, due to higher demand.

Virology

(\$ in millions)	Three Months Ended September 30,		% Change	% Change Excluding Foreign Exchange	Nine Months Ended September 30,		% Change	% Change Excluding Foreign Exchange
	2023	2022			2023	2022		
<i>Lagevrio</i>	\$ 640	\$ 436	47 %	51 %	\$ 1,236	\$ 4,859	(75)%	(73)%
<i>Isentress/Isentress HD</i>	119	161	(27)%	(27)%	377	466	(19)%	(17)%

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* grew 47% in the third quarter of 2023 primarily due to higher demand in Japan, partially offset by lower demand in Australia and the nonrecurrence of sales in the UK. Sales of *Lagevrio* declined 75% in the first nine months of 2023 primarily due to sales of *Lagevrio* in the U.S. and the UK in the first nine months of 2022 that did not recur in 2023, coupled with lower demand in Japan and Australia. The Company expects full-year 2023 *Lagevrio* sales to be approximately \$1.3 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 27% and 19% in the third quarter and first nine months of 2023, respectively, primarily due to competitive pressure in Europe and the U.S. The patent that provided market exclusivity for

Isentress/Isentress HD in the EU expired in July 2023. Accordingly, the Company is experiencing sales declines of *Isentress/Isentress HD* in these markets and expects the declines to continue. The Company also expects competitive pressure for *Isentress/Isentress HD* in the U.S. to continue.

Diabetes

(\$ in millions)	Three Months Ended September 30,		% Change	% Change Excluding Foreign Exchange	Nine Months Ended September 30,		% Change	% Change Excluding Foreign Exchange
	2023	2022			2023	2022		
<i>Januvia/Janumet</i>	\$ 835	\$ 1,133	(26)%	(25)%	\$ 2,579	\$ 3,599	(28)%	(26)%

Worldwide combined sales of *Januvia* and *Janumet*, medicines that help lower blood sugar levels in adults with type 2 diabetes, declined 26% and 28% in the third quarter and first nine 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, for the year-to-date period, lower 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 10 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 a non-automatically substitutable form of sitagliptin that differs from the form in the Company's sitagliptin products has been approved by the FDA. 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. In August 2023, the U.S. Department of HHS, through the CMS, announced that *Januvia* will be included in the first year of the IRA's Program. Pursuant to the IRA's Program, discussions with the government will occur in 2023 and 2024, with government price-setting becoming effective on January 1, 2026. The Company has sued the U.S. government regarding the IRA's Program (see Note 10 to the condensed consolidated financial statements).

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. Accordingly, the Company is experiencing sales declines in these markets and expects the declines to continue. 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 10%, 14% and 40%, respectively, of total combined *Januvia* and *Janumet* sales for the first nine 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 September 30,		% Change	% Change Excluding Foreign Exchange	Nine Months Ended September 30,		% Change	% Change Excluding Foreign Exchange
	2023	2022			2023	2022		
Livestock	\$ 874	\$ 829	5 %	7 %	\$ 2,530	\$ 2,486	2 %	6 %
Companion Animal	526	542	(3)%	(4)%	1,817	1,834	(1)%	— %

Sales of livestock products grew 5% and 2% in the third quarter and first nine months of 2023, respectively. Sales growth in both periods was primarily due to higher pricing, as well as higher demand for poultry, swine and ruminant products. Sales of companion animal products declined 3% and 1% in the third quarter and first nine months of 2023, respectively, primarily due to fewer vet visits in the U.S., partially offset by higher pricing. Sales of the *Bravecto* (fluralaner) parasiticide line of products were \$235 million for the third quarter of 2023, representing a decline of 3% compared with the third quarter of 2022. Sales of *Bravecto* products were \$875 million for the first nine months of 2023, representing growth of 1% compared with the corresponding prior year period, or 3% excluding the unfavorable effect of foreign exchange.

Costs, Expenses and Other

(\$ in millions)	Three Months Ended September 30,			Nine Months Ended September 30,		
	2023	2022	% Change	2023	2022	% Change
Cost of sales	\$ 4,264	\$ 3,934	8 %	\$ 12,214	\$ 13,530	(10)%
Selling, general and administrative	2,519	2,520	— %	7,700	7,355	5 %
Research and development	3,307	4,399	(25)%	20,904	9,773	*
Restructuring costs	126	94	34 %	344	288	19 %
Other (income) expense, net	126	429	(71)%	388	1,576	(75)%
	\$ 10,342	\$ 11,376	(9)%	\$ 41,550	\$ 32,522	28 %

* > 100%

Cost of Sales

Cost of sales increased 8% in the third quarter of 2023 and declined 10% in the first nine months of 2023 compared with the corresponding prior year periods. Cost of sales includes \$348 million and \$244 million in the third quarter of 2023 and 2022, respectively, and \$762 million and \$2.6 billion in the first nine months of 2023 and 2022, respectively, related to sales of *Lagevrio*, which is being developed in a collaboration with Ridgeback. Cost of sales also includes the amortization of intangible assets recorded in connection with acquisitions, collaborations, and licensing arrangements, which totaled \$552 million and \$445 million in the third quarter of 2023 and 2022, respectively, and \$1.6 billion in both the first nine months of 2023 and 2022. Amortization expense in the third quarter of 2023 includes \$81 million of cumulative catch-up amortization related to Merck's collaboration with Eisai. Amortization expense in the first nine months of 2023 and 2022 includes \$154 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 for more information on Merck's collaborative arrangements. Also included in cost of sales are expenses associated with restructuring activities, which amounted to \$33 million and \$54 million in the third quarter of 2023 and 2022, respectively, and \$94 million and \$167 million in the first nine 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 73.3% in the third quarter of 2023 compared with 73.7% in the third quarter of 2022. The gross margin decline was primarily due to the unfavorable impacts of foreign exchange, higher *Lagevrio* sales (which have a low gross margin) and higher amortization of intangible assets, partially offset by lower revenue from third-party manufacturing arrangements (which have a low gross margin), lower manufacturing-related costs and the favorable effect of product mix. Gross margin was 73.1% in the first nine months of 2023 compared with 70.2% in the first nine months of 2022. The gross margin improvement primarily reflects the favorable impacts of lower *Lagevrio* sales, lower revenue from third-party manufacturing arrangements, lower manufacturing-related costs and product mix, partially offset by the unfavorable impact of foreign exchange.

Selling, General and Administrative

Selling, general and administrative (SG&A) expenses were flat in the third quarter of 2023 compared with the third quarter of 2022 reflecting higher promotional spending that was offset by lower administrative costs. SG&A expenses rose 5% in the first nine months of 2023 primarily due to higher administrative costs, including compensation and benefit costs, as well as increased promotional spending and higher selling costs, partially offset by lower acquisition-related costs and the favorable effect of foreign exchange.

Research and Development

Research and development (R&D) expenses declined 25% in the third quarter of 2023 primarily due to charges recorded in 2022 for intangible asset impairments coupled with lower upfront and option payments in 2023 for collaborations and licensing agreements. The decline in R&D expenses was partially offset by higher compensation and benefit costs in 2023 (reflecting in part increased headcount), higher investments in discovery research and early drug development, as well as higher clinical development spending. R&D expenses were \$20.9 billion in the first nine months of 2023 compared with \$9.8 billion in the first nine months of 2022. The increase was primarily due to a \$10.2 billion charge for the acquisition of Prometheus, a \$1.2 billion charge for the acquisition of Imago, higher compensation and benefit costs, 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 nine months of 2023 was partially offset by charges recorded in 2022 for intangible asset impairments, as well as lower upfront and option payments in 2023 related to collaborations and licensing arrangements.

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 \$2.0 billion for the third quarter of 2023 and 2022, respectively, and \$6.6 billion and \$5.6 billion for the first nine 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 \$1.0 billion and \$1.5 billion for the third quarter of 2023 and 2022, respectively, and \$14.3 billion and \$3.2 billion for the first nine months of 2023 and 2022, respectively.

The decline in these non-MRL R&D expenses in the third quarter of 2023 largely reflects \$690 million of upfront and option payments in the aggregate made in 2022 for collaborations and licensing agreements with Orion Corporation (Orion), Moderna, Inc. (Moderna) and Orna Therapeutics (Orna). The increase in these non-MRL R&D expenses in the first nine months of 2023 was largely attributable to a \$10.2 billion charge for the acquisition of Prometheus (as noted above), 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, partially offset by the \$690 million of charges in 2022 for the transactions with Orion, Moderna and Orna. See Note 2 to the condensed consolidated financial statements for additional information related to business development activity. Additionally, R&D expenses in the third quarter and first nine months of 2022 include \$887 million of intangible asset impairment charges largely related to nemtabrutinib. See Note 8 to the condensed consolidated financial statements for more information on the intangible asset impairment charges.

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 \$4.0 billion. Merck expects to record charges of approximately \$650 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 \$126 million and \$94 million for the third quarter of 2023 and 2022, respectively, and \$344 million and \$288 million for the first nine 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 \$199 million and \$175 million in the third quarter of 2023 and 2022, respectively, and \$532 million and \$559 million for the first nine 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 \$126 million of expense in the third quarter of 2023 compared with \$429 million of expense in the third quarter of 2022, primarily due to lower losses from investments in equity securities. Other (income) expense, net, was \$388 million of expense for the first nine months of 2023 compared with \$1.6 billion of expense for the first nine 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 10 to the condensed consolidated financial statements).

For details on the components of Other (income) expense, net, see Note 13 to the condensed consolidated financial statements.

Segment Profits

(\$ in millions)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Pharmaceutical segment profits	\$ 10,407	\$ 9,590	\$ 29,400	\$ 28,263
Animal Health segment profits	421	515	1,453	1,672
Other	(5,208)	(6,522)	(26,918)	(17,004)
Income Before Taxes	\$ 5,620	\$ 3,583	\$ 3,935	\$ 12,931

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 9% and 4% in the third quarter and first nine months of 2023, respectively, primarily due to 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 13% in the third quarter and first nine months of 2023, respectively, reflecting higher manufacturing costs, higher inventory write-offs, increased administrative and promotional costs, as well as the unfavorable effect of foreign exchange.

Income Taxes

The effective income tax rate of 15.5% for the third quarter of 2023 reflects the favorable mix of income and expense. The effective income tax rate of 59.3% for the first nine months of 2023 includes a 44.0 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 9.2% for the third quarter of 2022 and 11.0% for the first nine months of 2022 reflect the favorable mix of income and expense, as well as the favorable impact of net unrealized losses from investments in equity securities and intangible asset impairment charges, which were taxed at the U.S. tax rate.

Non-GAAP Income and Non-GAAP EPS

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

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

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

(\$ in millions except per share amounts)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Income before taxes as reported under GAAP	\$ 5,620	\$ 3,583	\$ 3,935	\$ 12,931
Increase (decrease) for excluded items:				
Acquisition- and divestiture-related costs	555	1,344	1,643	2,512
Restructuring costs	199	175	532	559
Loss (income) from investments in equity securities, net	17	350	(218)	1,268
Other items:				
Charge for Zetia antitrust litigation settlements	—	—	573	—
Non-GAAP income before taxes	6,391	5,452	6,465	17,270
Income tax provision as reported under GAAP	870	330	2,332	1,423
Estimated tax benefit on excluded items ⁽¹⁾	89	414	350	965
Non-GAAP income tax provision	959	744	2,682	2,388
Non-GAAP net income	5,432	4,708	3,783	14,882
Less: Net income attributable to noncontrolling interests as reported under GAAP	5	5	12	6
Non-GAAP net income attributable to Merck & Co., Inc.	\$ 5,427	\$ 4,703	\$ 3,771	\$ 14,876
EPS assuming dilution as reported under GAAP ⁽²⁾	\$ 1.86	\$ 1.28	\$ 0.62	\$ 4.53
EPS difference	0.27	0.57	0.86	1.33
Non-GAAP EPS assuming dilution ⁽²⁾	\$ 2.13	\$ 1.85	\$ 1.48	\$ 5.86

⁽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⁾ GAAP and non-GAAP EPS were negatively affected in the first nine months of 2023 by \$4.52, and in both the third quarter and first nine months of 2022 by \$0.22, of charges for certain upfront and pre-approval milestone payments related to collaborations and licensing agreements, as well as charges related to pre-approval assets obtained in transactions accounted for as asset acquisitions.

Acquisition- and Divestiture-Related Costs

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

Restructuring Costs

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

Income and Losses from Investments in Equity Securities

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

Certain Other Items

Non-GAAP income and non-GAAP EPS exclude certain other items. These items are adjusted for after evaluating them on an individual basis, considering their quantitative and qualitative aspects. Typically, these consist of items that are unusual in nature, significant to the results of a particular period or not indicative of future operating results. Excluded from non-GAAP income and non-GAAP EPS in 2023 is a charge related to settlements with certain plaintiffs in the Zetia antitrust litigation (see Note 10 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. The marketing application for gefapixant is based on results from the COUGH-1 and COUGH-2 clinical trials. In September 2023, the FDA announced it will hold a Pulmonary-Allergy Drugs Advisory Committee meeting on November 17, 2023 to discuss gefapixant. In January 2022, Merck received a Complete Response Letter (CRL) for the original 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 FDA accepted Merck's resubmission of the NDA for gefapixant and assigned a PDUFA date of December 27, 2023. In September 2023, the EC approved *Lyfnua* (gefapixant).

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 priority review by the FDA in combination with external beam radiotherapy plus concurrent chemotherapy, followed by brachytherapy (also known as concurrent chemoradiotherapy) as treatment with definitive intent for newly diagnosed patients with high-risk locally advanced cervical cancer. The submission is based on the KEYNOTE-A18 trial. The FDA set a PDUFA date of January 20, 2024.

Additionally, *Keytruda* is 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 October 2023, the CHMP of the EMA adopted a positive opinion recommending approval of *Keytruda* in combination with chemotherapy, for the first-line treatment of locally advanced unresectable or metastatic HER2-negative gastric or GEJ adenocarcinoma in adults whose tumors express PD-L1. 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 fourth quarter of 2023.

Keytruda is under review in the EU and Japan in combination with standard of care chemotherapy (gemcitabine and cisplatin) for the treatment of patients with locally advanced unresectable or metastatic biliary tract cancer, based on data from the KEYNOTE-966 trial.

Keytruda is also under review in the EU and Japan 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).

In September 2023, the FDA accepted and granted priority review for a supplemental NDA seeking approval for *Welireg* for the treatment of adult patients with advanced RCC following immune checkpoint and anti-angiogenic therapies. The supplemental NDA is based on data from the LITESPARK-005 trial. The FDA set a PDUFA date of January 17, 2024.

Also in September 2023, the FDA accepted for priority review a Biologics License Application for sotatercept (MK-7962), Merck's novel investigational activin signaling inhibitor for the treatment of adult patients with PAH (World Health Organization Group 1). The application is based on the results from the Phase 3 STELLAR trial. The FDA set a PDUFA date of March 26, 2024. Merck has also submitted a marketing authorization application to the EMA. Sotatercept was granted Breakthrough Therapy Designation and Orphan Drug designation by the FDA, as well as Priority Medicines (PRIME) scheme and Orphan Drug designation by the EMA for the treatment of PAH. Sotatercept is the subject of a licensing agreement with BMS.

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.

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 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.

In August 2023, Merck announced the initiation of the Phase 3 clinical program, CORALreef, for MK-0616, an investigational, oral proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor, being evaluated for the treatment of adults with hypercholesterolemia. This is the first Phase 3 clinical program for an oral PCSK9 inhibitor. The first participants have enrolled in two registrational Phase 3 studies evaluating low-density lipoprotein (LDL) cholesterol reduction and a Phase 3 cardiovascular outcomes study.

In October 2023, Merck initiated a Phase 3 clinical trial for MK-7240 for the treatment of ulcerative colitis. MK-7240 is a humanized monoclonal antibody directed to tumor necrosis factor-like ligand 1A, a target associated with both intestinal inflammation and fibrosis. MK-7240, which was obtained as part of Merck's acquisition of Prometheus in June 2023, is being developed for the treatment of immune-mediated diseases including ulcerative colitis, Crohn's disease, and other autoimmune conditions.

Also in October 2023, Merck and Daiichi Sankyo entered into a global development and commercialization agreement for three of Daiichi Sankyo's DXd ADC candidates: patritumab deruxtecan (HER3-DXd) (MK-1022), ifinatamab deruxtecan (I-DXd) (MK-2400) and raludotatug deruxtecan (R-DXd) (MK-5909). The companies will jointly develop and potentially commercialize these ADC candidates worldwide, except in Japan where Daiichi Sankyo will maintain exclusive rights. All three potentially first-in-class DXd ADCs are in various stages of clinical development for the treatment of multiple solid tumors both as monotherapy and/or in combination with other treatments. Patritumab deruxtecan was granted Breakthrough Therapy Designation by the FDA in December 2021 for the treatment of patients with *epidermal growth factor receptor (EGFR)*-mutated locally advanced or metastatic NSCLC with disease progression on or after treatment with a third-generation tyrosine kinase inhibitor and platinum-based therapies. The submission of a BLA in the U.S. is planned by the end of March 2024 for patritumab deruxtecan, which is based on data from the HERTHENA-Lung01 Phase 2 trial. Ifinatamab deruxtecan is currently being evaluated as monotherapy in IDEate-01, a Phase 2 clinical trial in patients with previously treated extensive-stage small-cell lung cancer (SCLC). Raludotatug deruxtecan is currently being evaluated in a first-in-human Phase 1 clinical trial. Designed using Daiichi Sankyo's proprietary DXd ADC technology to target and deliver a cytotoxic payload inside cancer cells that express a specific cell surface antigen, each ADC consists of a monoclonal antibody attached to a number of topoisomerase I inhibitor

payloads (an exatecan derivative, DXd) via tetrapeptide-based cleavable linkers. See Note 3 to the condensed consolidated financial statements for additional information related to this collaboration.

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.

In August 2023, Merck and Eisai provided an update on the Phase 3 LEAP-010 trial evaluating *Keytruda* plus Lenvima as a first-line treatment for patients with recurrent or metastatic HNSCC whose tumors express PD-L1. Two planned interim analyses were conducted by an independent Data Monitoring Committee. In the first analysis, *Keytruda* plus Lenvima showed a statistically significant improvement in progression-free survival and objective response rate versus *Keytruda* plus placebo. At the second analysis, *Keytruda* plus Lenvima did not demonstrate an improvement in overall survival compared to *Keytruda* plus placebo. Accordingly, the study will be closed, and the companies informed investigators of this decision. A full evaluation of the data from this study, including pre-planned subgroup analyses, is ongoing. The companies will work with investigators to share the results with the scientific community.

In September 2023, Merck and Eisai provided updates on two Phase 3 trials, LEAP-006 and LEAP-008, evaluating *Keytruda* plus Lenvima in patients with certain types of metastatic NSCLC. The LEAP-006 trial evaluating *Keytruda* plus Lenvima in combination with pemetrexed and platinum-containing chemotherapy versus *Keytruda* with pemetrexed and platinum-containing chemotherapy as a first-line treatment for adult patients with metastatic, nonsquamous NSCLC who have confirmation that *EGFR*-, *anaplastic lymphoma kinase (ALK)*- or *c-ros oncogene 1 (ROS1)*-directed therapies are not indicated, did not meet its dual primary endpoints of overall survival and progression free survival. The LEAP-008 trial evaluating *Keytruda* plus Lenvima versus docetaxel, a current second line standard of care option, as a treatment for patients with metastatic NSCLC who progressed on or after platinum-containing chemotherapy and one prior anti-PD-1/-L1 immunotherapy, and have confirmation that *EGFR*-, *ALK*- or *ROS1*-directed therapies are not indicated, did not meet its dual primary endpoints of overall survival and progression free survival. The companies are working with investigators to share the results of both trials with the scientific community.

The charts below reflect the Company's research pipeline as of November 1, 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-1308 (quavonlimab) ⁽²⁾ Non-Small-Cell Lung MK-1308A (quavonlimab+pembrolizumab) Colorectal Small-Cell Lung MK-2140 (zilovertamab vedotin) Bladder Breast Gastric Hematological Malignancies Non-Small-Cell Lung Ovarian Pancreatic MK-2400 (ifinatamab deruxtecán) ⁽¹⁾ Small-Cell Lung MK-2870 ⁽¹⁾⁽³⁾ Neoplasm Malignant MK-3475 <i>Keytruda</i> Advanced Solid Tumors Prostate MK-3475A (pembrolizumab+hyaluronidase subcutaneous) Cutaneous Squamous Cell MK-3543 (bomedemstat) Myeloproliferative Disorders MK-4280 (favezelimab) ⁽²⁾ Non-Small-Cell Lung MK-4280A (favezelimab+pembrolizumab) Bladder Cutaneous Squamous Cell 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 Tukysa ⁽¹⁾ Advanced Solid Tumors Biliary Bladder Cervical Endometrial Gastric Non-Small-Cell Lung MK-7339 Lynparza ⁽¹⁾⁽³⁾ Advanced Solid Tumors MK-7684A (vibostolimab+pembrolizumab) Biliary Bladder Breast Cervical Colorectal Endometrial Esophageal Gastric Head and Neck Hepatocellular Ovarian Prostate	Cancer MK-7902 Lenvima ⁽¹⁾⁽²⁾ Biliary Head and Neck Pancreatic Prostate Small-Cell Lung Dengue Fever Virus Vaccine V181 HIV-1 Infection MK-8591B (islatravir+MK-8507) ⁽⁴⁾ MK-8591D (islatravir+lenacapavir) ⁽¹⁾⁽⁵⁾ 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

Phase 3 (Phase 3 entry date)	Under Review	
Antiviral COVID-19 MK-4482 <i>Lagevrio</i> (U.S.) (May 2021) ⁽¹⁾⁽⁷⁾ Cancer MK-1022 (patritumab deruxetecan) ⁽¹⁾ Non-Small-Cell Lung (May 2022) MK-1026 (nemtubrutinib) 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 (EU) (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) V940 ⁽¹⁾⁽²⁾ Melanoma (July 2023) HIV-1 Infection MK-8591A (doravirine+islatravir) (February 2020) ⁽⁵⁾ Hypercholesterolemia MK-0616 (August 2023) Pneumococcal Vaccine Adult V116 (July 2022) Pulmonary Arterial Hypertension MK-7962 (sotatercept) (EU) (January 2021) Respiratory Syncytial Virus MK-1654 (clesrovimab) (November 2021) Ulcerative Colitis MK-7240 (October 2023)	New Molecular Entities Cough MK-7264 (gefapixant) (U.S.) ⁽⁸⁾ Pulmonary Arterial Hypertension MK-7962 (sotatercept) U.S.	Certain Supplemental Filings Cancer MK-3475 <i>Keytruda</i> • Second-Line Hepatocellular Carcinoma (KEYNOTE-394) (U.S.) • High-Risk Locally Advanced Cervical Cancer (KEYNOTE-A18) (U.S.) • First-Line HER2 Negative Locally Advanced Unresectable or Metastatic Gastric Cancer (KEYNOTE-859) (U.S.) (EU) (JPN) • First-Line Locally Advanced Unresectable or Metastatic Biliary Tract Cancer (KEYNOTE-966) (EU) (JPN) • Resectable Stage II, IIIA or IIIB NSCLC (KEYNOTE-671) (EU) (JPN) MK-6482 <i>Welireg</i> • Previously Treated Advanced Renal Cell Carcinoma (LIGHTSPARK-005) (U.S.)
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)	September 30, 2023	December 31, 2022
Cash and investments	\$ 10,079	\$ 14,207
Working capital	8,860	11,483
Total debt to total liabilities and equity	32.7 %	28.1 %

Cash provided by operating activities was \$12.8 billion in the first nine months of 2023 compared with \$14.7 billion in the first nine months of 2022. Cash provided by operating activities in the first nine months of 2023 was reduced by payments of \$567 million related to the previously disclosed Zetia antitrust settlement of \$572.5 million. Cash provided by operating activities was reduced by milestone and option payments related to certain collaborations of \$240 million and \$2.0 billion in the first nine 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 \$14.1 billion in the first nine months of 2023 compared with \$3.2 billion in the first nine 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, as well as lower capital expenditures.

Cash used in financing activities was \$2.6 billion in the first nine months of 2023 compared with \$7.6 billion in the first nine months of 2022. The change was primarily due to proceeds from the issuance of debt (see below) and lower payments on long-term debt (see below), partially offset by 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 \$3.5 billion and \$2.5 billion of accounts receivable at September 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, including 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. In September 2022, the Company's \$1.0 billion, 2.40% notes matured in accordance with their terms and were repaid.

Dividends paid to stockholders were \$5.6 billion and \$5.3 billion for the first nine 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 was 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 nine months of 2023, the Company purchased \$953 million (9 million shares) of its common stock for its treasury under this program. As of September 30, 2023, the Company's remaining share repurchase authorization was \$4.1 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 September 30, 2023, the Company's disclosure controls and procedures are effective. For the third 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 10 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 September 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⁾	
July 1 - July 31	1,918,488	\$108.79	1,918,488		\$4,351
August 1 - August 31	1,450,550	\$106.99	1,450,550		\$4,196
September 1 - September 30	950,239	\$107.33	950,239		\$4,094
Total	4,319,277	\$107.86	4,319,277		

⁽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 September 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.

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: November 3, 2023

/s/ Jennifer Zachary

JENNIFER ZACHARY

Executive Vice President and General Counsel

Date: November 3, 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: November 3, 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: November 3, 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 September 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: November 3, 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 September 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: November 3, 2023

/s/ Caroline Litchfield

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