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, 2024

OR

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

For the transition period from _____ to _____

Commission File No. 1-6571

Merck & Co., Inc.

(Exact name of registrant as specified in its charter)

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

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

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

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

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

Title of each class	*Trading Symbol(s)*	*Name of each exchange on which registered*
Common Stock ($0.50 par value)	MRK	New York Stock Exchange
1.875% Notes due 2026	MRK/26	New York Stock Exchange
3.250% Notes due 2032	MRK/32	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
3.500% Notes due 2037	MRK/37	New York Stock Exchange
3.700% Notes due 2044	MRK/44	New York Stock Exchange
3.750% Notes due 2054	MRK/54	New York Stock Exchange

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company.

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

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

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

The number of shares of common stock outstanding as of the close of business on October 31, 2024: 2,529,635,645

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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,	
	2024	2023	2024	2023
Sales	$ 16,657	$ 15,962	$ 48,544	$ 45,485
Costs, Expenses and Other				
Cost of sales	4,080	4,264	11,365	12,214
Selling, general and administrative	2,731	2,519	7,952	7,700
Research and development	5,862	3,307	13,354	20,904
Restructuring costs	56	126	258	344
Other (income) expense, net	(162)	126	(151)	388
	12,567	10,342	32,778	41,550
Income Before Taxes	4,090	5,620	15,766	3,935
Taxes on Income	929	870	2,377	2,332
Net Income	3,161	4,750	13,389	1,603
Less: Net Income Attributable to Noncontrolling Interests	4	5	15	12
Net Income Attributable to Merck & Co., Inc.	$ 3,157	$ 4,745	$ 13,374	$ 1,591
Basic Earnings per Common Share Attributable to Merck & Co., Inc. Common Shareholders	$ 1.25	$ 1.87	$ 5.28	$ 0.63
Earnings per Common Share Assuming Dilution Attributable to Merck & Co., Inc. Common Shareholders	$ 1.24	$ 1.86	$ 5.26	$ 0.62

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Net Income Attributable to Merck & Co., Inc.	$ 3,157	$ 4,745	$ 13,374	$ 1,591
Other Comprehensive Loss Net of Taxes:				
Net unrealized (loss) gain on derivatives, net of reclassifications	(296)	159	(99)	171
Benefit plan net (loss) gain and prior service (cost) credit, net of amortization	(13)	—	(28)	(75)
Cumulative translation adjustment	299	(175)	(83)	(244)
	(10)	(16)	(210)	(148)
Comprehensive Income Attributable to Merck & Co., Inc.	$ 3,147	$ 4,729	$ 13,164	$ 1,443

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, 2024	December 31, 2023
Assets		
Current Assets		
Cash and cash equivalents	$ 14,593	$ 6,841
Short-term investments	—	252
Accounts receivable (net of allowance for doubtful accounts of $79 in 2024 and $88 in 2023)	11,381	10,349
Inventories (excludes inventories of $3,995 in 2024 and $3,348 in 2023 classified in Other assets - see Note 6)	6,244	6,358
Other current assets	8,143	8,368
Total current assets	40,361	32,168
Investments	575	252
Property, Plant and Equipment, at cost, net of accumulated depreciation of $19,072 in 2024 and $18,266 in 2023	23,446	23,051
Goodwill	21,697	21,197
Other Intangibles, Net	17,010	18,011
Other Assets	14,443	11,996
	$ 117,532	$ 106,675
Liabilities and Equity		
Current Liabilities		
Loans payable and current portion of long-term debt	$ 3,149	$ 1,372
Trade accounts payable	3,586	3,922
Accrued and other current liabilities	16,539	15,766
Income taxes payable	4,330	2,649
Dividends payable	1,982	1,985
Total current liabilities	29,586	25,694
Long-Term Debt	34,982	33,683
Deferred Income Taxes	864	871
Other Noncurrent Liabilities	7,540	8,792
Merck & Co., Inc. Stockholders' Equity		
Common stock, $0.50 par value Authorized - 6,500,000,000 shares Issued - 3,577,103,522 shares in 2024 and 2023	1,788	1,788
Other paid-in capital	44,530	44,509
Retained earnings	61,384	53,895
Accumulated other comprehensive loss	(5,371)	(5,161)
	102,331	95,031
Less treasury stock, at cost: 1,045,073,377 shares in 2024 and 1,045,470,249 shares in 2023	57,829	57,450
Total Merck & Co., Inc. stockholders' equity	44,502	37,581
Noncontrolling Interests	58	54
Total equity	44,560	37,635
	$ 117,532	$ 106,675

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,	
	2024	2023
Cash Flows from Operating Activities		
Net income	$ 13,389	$ 1,603
Adjustments to reconcile net income to net cash provided by operating activities:		
Amortization	1,720	1,582
Depreciation	1,582	1,326
Income from investments in equity securities, net	(169)	(240)
Charge for the acquisition of Eyebiotech Limited	1,350	—
Charge for the acquisition of MK-1045 (formerly CN201) from Curon Pharmaceutical	750	—
Charge for the acquisition of Harpoon Therapeutics, Inc.	656	—
Charge for the acquisition of Prometheus Biosciences, Inc.	—	10,217
Charge for the acquisition of Imago BioSciences, Inc.	—	1,192
Deferred income taxes	(633)	(968)
Share-based compensation	574	478
Other	611	(81)
Net changes in assets and liabilities	(1,812)	(2,349)
Net Cash Provided by Operating Activities	18,018	12,760
Cash Flows from Investing Activities		
Capital expenditures	(2,435)	(2,874)
Purchases of securities and other investments	(64)	(704)
Proceeds from sales of securities and other investments	370	1,489
Acquisition of Eyebiotech Limited, net of cash acquired	(1,344)	—
Acquisition of Elanco Animal Health Incorporated aqua business	(1,301)	—
Acquisition of Harpoon Therapeutics, Inc., net of cash acquired	(746)	—
Acquisition of MK-1045 (formerly CN201) from Curon Pharmaceutical	(700)	—
Acquisition of Prometheus Biosciences, Inc., net of cash acquired	—	(10,705)
Acquisition of Imago BioSciences, Inc., net of cash acquired	—	(1,327)
Other	(70)	(15)
Net Cash Used in Investing Activities	(6,290)	(14,136)
Cash Flows from Financing Activities		
Proceeds from issuance of debt	3,599	5,939
Payments on debt	(751)	(1,752)
Dividends paid to stockholders	(5,889)	(5,593)
Purchases of treasury stock	(817)	(953)
Proceeds from exercise of stock options	165	119
Other	(330)	(325)
Net Cash Used in Financing Activities	(4,023)	(2,565)
Effect of Exchange Rate Changes on Cash, Cash Equivalents and Restricted Cash	74	(163)
Net Increase (Decrease) in Cash, Cash Equivalents and Restricted Cash	7,779	(4,104)
Cash, Cash Equivalents and Restricted Cash at Beginning of Year (includes restricted cash of $68 and $79 at January 1, 2024 and 2023, respectively, included in *Other current assets*)	6,909	12,773
Cash, Cash Equivalents and Restricted Cash at End of Period (includes restricted cash of $95 and $64 at September 30, 2024 and 2023, respectively, included in *Other current assets*)	$ 14,688	$ 8,669

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.) 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 26, 2024.

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

Recently Adopted Accounting Standard

In August 2023, the Financial Accounting Standards Board (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. The Company adopted the guidance effective July 1, 2024 on a prospective basis. There was no impact to the Company's consolidated financial statements upon adoption.

Recently Issued Accounting Standards Not Yet Adopted

In November 2023, the FASB issued guidance intended to improve reportable segment disclosure requirements, primarily through expanded disclosures for significant segment expenses. The guidance is effective for annual periods beginning in 2024, and interim periods beginning in 2025. The guidance will result in incremental disclosures within the footnotes to the Company's financial statements.

In December 2023, the FASB issued guidance intended to improve the transparency of income tax disclosures by requiring consistent categories and disaggregation of information in the effective income tax rate reconciliation and income taxes paid disclosures by jurisdiction. The guidance also includes other amendments to improve the effectiveness of income tax disclosures by removing certain previously required disclosures. The guidance is effective beginning with 2025 annual reporting. Early adoption is permitted. The guidance will result in incremental disclosures within the footnotes to the Company's financial statements.

2. Acquisitions, Divestitures, 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.

2024 Transactions

In September 2024, Merck acquired MK-1045 (formally CN201), a novel investigational clinical-stage bispecific antibody for the treatment of B-cell associated diseases, from Curon Biopharmaceutical (Curon) for an upfront payment of $700 million. In addition, Curon is eligible to receive future contingent developmental milestone payments of up to $300 million and regulatory milestone payments of up to $300 million. MK-1045 is currently being evaluated in Phase 1 and Phase 1b/2 clinical trials for the treatment of patients with relapsed or refractory non-Hodgkin lymphoma and relapsed or refractory B-cell acute lymphocytic leukemia, respectively. Merck plans to evaluate MK-1045 as a treatment for B-cell malignancies as well as investigate its potential to provide a novel, scalable option for the treatment of autoimmune diseases. The transaction was accounted for as an asset acquisition. Merck recorded a charge of $750 million (reflecting the upfront payment and other related costs) to *Research and development* expenses in the third quarter and first nine months of 2024. In connection with the agreement, Merck is also obligated to pay a third party future contingent developmental, regulatory and sales-based milestone payments of up to $128 million in the aggregate, as well as tiered royalties ranging from a mid-single-digit rate to a low-double-digit rate on future net sales of MK-1045 if approved.

In July 2024, Merck acquired the aqua business of Elanco Animal Health Incorporated (Elanco aqua business) for total consideration of $1.3 billion. The Elanco aqua business consists of an innovative portfolio of medicines and vaccines, nutritionals and supplements for aquatic species; two related aqua manufacturing facilities in Canada and Vietnam; as well as a research facility in Chile. The acquisition broadens Animal Health's aqua portfolio with products such as *Clynav*, a new generation DNA-based vaccine that protects Atlantic salmon against pancreas disease, and *Imvixa*, an anti-parasitic sea lice

treatment. This acquisition also brings a portfolio of water treatment products for warm water production, complementing Animal Health's warm water vaccine portfolio. In addition to these products, the DNA-based vaccine technology that is a part of the business has the potential to accelerate the development of novel vaccines to address the unmet needs of the aqua industry. There are no contingent payments associated with the acquisition, which was accounted for as a business combination.

The estimated fair values of assets acquired and liabilities assumed from the Elanco aqua business (which are considered preliminary subject to the finalization of the tax treatment of the transaction) are as follows:

($ in millions)	July 9, 2024
Inventories	$ 74
Property, plant and equipment	67
Product rights - *Clynav* (useful life 15 years) [(1)]	340
Other product rights (useful lives 15 years) [(1)]	291
Other assets and liabilities, net	24
Total identifiable net assets	796
Goodwill [(2)]	505
Consideration transferred	$ 1,301

[(1)] *The estimated fair values of Clynav and other product rights were determined using an income approach, specifically the multi-period excess earnings method. The future probability-weighted net cash flows were discounted to present value utilizing a discount rate of 8.5%. Actual cash flows are likely to be different than those assumed.*

[(2)] *The goodwill recognized is largely attributable to anticipated synergies expected to arise after the acquisition and was allocated to the Animal Health segment.*

Also in July 2024, Merck acquired Eyebiotech Limited (EyeBio), a privately held ophthalmology-focused biotechnology company for $1.2 billion (including payments to settle share-based equity awards) and also incurred $207 million of transaction costs. The acquisition agreement also provides for former EyeBio shareholders to receive future contingent developmental milestone payments of up to $200 million (of which $100 million was triggered in the third quarter of 2024 as noted below), regulatory milestone payments of up to $1.0 billion and sales-based milestone payments of up to $500 million. EyeBio's development work focused on candidates for the prevention and treatment of vision loss associated with retinal vascular leakage, a known risk factor for retinal diseases. EyeBio's lead candidate, *Restoret (*MK-3000, formerly EYE103), is an investigational, potentially first-in-class tetravalent, tri-specific antibody that acts as an agonist of the Wingless-related integration site signaling pathway, which is in clinical development for the treatment of diabetic macular edema and neovascular age-related macular degeneration. The transaction was accounted for as an asset acquisition since *Restoret* accounted for substantially all of the fair value of the gross assets acquired (excluding cash and deferred income taxes). Merck recorded net assets of $21 million, as well as a charge of $1.35 billion to *Research and development* expenses in the third quarter and first nine months of 2024 related to the acquisition. Additionally, a $100 million developmental milestone was triggered in the third quarter of 2024 upon initiation of a Phase 2/3 clinical trial evaluating *Restoret* for the treatment of diabetic macular edema, which was also recorded to *Research and development* expenses.

Additionally in July 2024, Merck and Orion Corporation (Orion) announced the mutual exercise of an option to convert the companies' ongoing co-development and co-commercialization agreement for opevesostat (MK-5684/ODM-208), an investigational cytochrome P450 11A1 (CYP11A1) inhibitor, and other candidates targeting CYP11A1, into an exclusive global license for Merck. With the exercise of the option, Merck assumed full responsibility for all past and future development and commercialization expenses associated with the candidates covered by the original agreement. In addition, Orion became eligible to receive developmental milestone payments of up to $30 million, regulatory milestone payments of up to $625 million and sales-based milestone payments of up to $975 million, as well as annually tiered royalties ranging from a low double-digit rate up to a rate in the low twenties on net sales for any commercialized licensed product. Orion retained responsibility for the manufacture of clinical and commercial supply for Merck. No payment was associated with the exercise of the option, which became effective in September of 2024.

Also in July 2024, Merck notified Kelun-Biotech (a holding subsidiary of Sichuan Kelun Pharmaceutical Co., Ltd.) it was terminating the license and collaboration agreement entered into in July 2022 in which Merck gained exclusive worldwide rights for the development, manufacture and commercialization of an investigational antibody drug conjugate (ADC) (SKB315/MK-1200) for the treatment of solid tumors. As a result of this termination, which became effective in September 2024, all rights to SKB315 have reverted to Kelun-Biotech.

In March 2024, Merck acquired Harpoon Therapeutics, Inc. (Harpoon), a clinical-stage immunotherapy company developing a novel class of T-cell engagers designed to harness the power of the body's immune system to treat patients suffering from cancer and other diseases, for $765 million and also incurred $56 million of transaction costs. Harpoon's lead candidate, MK-6070 (formerly HPN328), is a T-cell engager targeting delta-like ligand 3 (DLL3), an inhibitory canonical Notch ligand that is expressed at high levels in small-cell lung cancer (SCLC) and neuroendocrine tumors. MK-6070 is currently being evaluated as monotherapy in a Phase 1/2 clinical trial in certain patients with advanced cancers associated with expression of DLL3. The study is also evaluating MK-6070 in combination with atezolizumab in certain patients with SCLC. The transaction was accounted for as an asset acquisition since MK-6070 represented substantially all of the fair value of the gross assets acquired (excluding cash and deferred income taxes). Merck recorded net assets of $165 million, as well as a charge of $656 million to *Research and development* expenses in the first nine months of 2024 related to the transaction. There are no future contingent payments associated with the acquisition. In August 2024, Merck and Daiichi Sankyo expanded their existing global

co-development and co-commercialization agreement to include MK-6070. See Note 3 for more information on Merck's collaboration with Daiichi Sankyo.

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) ADC candidates: patritumab deruxtecan (HER3-DXd) (MK-1022), ifinatamab deruxtecan (I-DXd) (MK-2400) and raludotatug deruxtecan (R-DXd) (MK-5909) (see Note 3).

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, tulisokibart (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. Tulisokibart is being developed for the treatment of immune-mediated diseases including ulcerative colitis, Crohn's disease, and other autoimmune conditions. A Phase 3 clinical trial evaluating tulisokibart for ulcerative colitis commenced in 2023. The transaction was accounted for as an asset acquisition since tulisokibart 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 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 as a charge to *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. Subsequently, in April 2024, Merck notified Kelun-Biotech it was terminating one additional candidate under the agreement. In July 2024, Merck notified Kelun-Biotech that it was exercising an existing license option for one of the candidates under the agreement, granting Merck a license for the development, manufacture and commercialization worldwide excluding China. There are now three candidates licensed under the original agreement and one candidate for which the license option remains unexercised. Merck paid Kelun-Biotech $38 million in connection with the July option exercise, following which Kelun-Biotech remains eligible to receive future contingent payments aggregating up to $540 million in development-related payments, $1.5 billion in regulatory milestones, and $3.1 billion in sales-based milestones if Kelun-Biotech does not retain Chinese mainland, Hong Kong and Macau rights for the remaining option ADC 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 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 clinical trials for the treatment of essential thrombocythemia, myelofibrosis, and polycythemia vera, in addition to other indications. A Phase 3 clinical trial evaluating bomedemstat for the treatment of certain patients with essential thrombocythemia is underway. The transaction was accounted for as an asset acquisition 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.

Spin-Off of Organon & Co.

In connection with the 2021 spin-off of Organon & Co. (Organon), Merck and Organon 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 continued to market, import and distribute such products on behalf of Organon until such time as the relevant licenses and permits transferred to Organon, with Organon receiving all of the economic benefits and burdens of such activities. As of September 30, 2024, only one jurisdiction remains under an interim operating agreement. Additionally, Merck and Organon entered into a number of manufacturing and supply agreements (MSAs) with terms ranging from four years to ten years. The amounts included in the condensed consolidated statement of operations for the above MSAs include sales of $109 million and $100 million and related cost of sales of $108 million and $106 million for the third quarter of 2024 and 2023, respectively, and sales of $309 million and $290 million and related cost of sales of $310 million and $314 million for the first nine months of 2024 and 2023, respectively. The amounts due from Organon for all spin-off related agreements were $370 million and $632 million at September 30, 2024 and December 31, 2023, respectively, and are reflected in *Other current assets*. The amounts due to Organon under these agreements were $130 million and $598 million at September 30, 2024 and December 31, 2023, respectively, and are included in *Accrued and other current liabilities*.

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 are developing and commercializing 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 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 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, 2024) and a corresponding increase to the intangible asset related to Lynparza. 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. Lynparza received regulatory approvals triggering capitalized milestone payments from Merck to AstraZeneca of $245 million and $105 million in the first nine months of 2024 and 2023, respectively (each of which had been previously accrued for). In the second quarter of 2024, the partners agreed that no future regulatory milestone payments from Merck to AstraZeneca are likely under the agreement.

The intangible asset balance related to Lynparza (which includes capitalized sales-based and regulatory milestone payments) was $1.3 billion at September 30, 2024 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:

	Three Months Ended September 30,		Nine Months Ended September 30,	
($ in millions)	2024	2023	2024	2023
Alliance revenue - Lynparza	$ 337	$ 299	$ 947	$ 884
Alliance revenue - Koselugo	39	26	114	74
Total alliance revenue	$ 376	$ 325	$ 1,061	$ 958
Cost of sales [1]	82	82	245	230
Selling, general and administrative	39	44	121	143
Research and development	19	23	57	65

($ in millions)	September 30, 2024	December 31, 2023
Receivables from AstraZeneca included in *Other current assets*	$ 375	$ 341
Payables to AstraZeneca included in *Accrued and other current liabilities* [2]	615	256
Payables to AstraZeneca included in *Other Noncurrent Liabilities* [2]	—	600

[1] *Represents amortization of capitalized milestone payments.*

[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 are developing and commercializing 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 by the Company to be probable of payment. Accordingly, Merck recorded $250 million of liabilities for these payments (one of which was paid in the second quarter of 2023 and the other was paid in the second quarter of 2024) 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. 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. 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 $502 million at September 30, 2024 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:

	Three Months Ended September 30,		Nine Months Ended September 30,	
($ in millions)	2024	2023	2024	2023
Alliance revenue - Lenvima	$ 251	$ 260	$ 755	$ 734
Cost of sales [1]	60	137	181	320
Selling, general and administrative	40	46	120	145
Research and development	4	5	18	61

($ in millions)	September 30, 2024	December 31, 2023
Receivables from Eisai included in *Other current assets*	$ 252	$ 226
Payables to Eisai included in *Accrued and other current liabilities* [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) and Verquvo (vericiguat). The two companies have implemented a joint development and commercialization strategy. 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. There are no sales-based milestone payments remaining under this collaboration.

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 $431 million and $47 million, respectively, at September 30, 2024 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, 2024	Three Months Ended September 30, 2023	Nine Months Ended September 30, 2024	Nine Months Ended September 30, 2023
Alliance revenue - Adempas/Verquvo	$ 102	$ 92	$ 306	$ 259
Net sales of Adempas recorded by Merck	72	65	214	189
Net sales of Verquvo recorded by Merck	11	8	25	24
Total sales	$ 185	$ 165	$ 545	$ 472
Cost of sales [1]	59	53	182	165
Selling, general and administrative	29	33	88	100
Research and development	27	26	82	76

($ in millions)	September 30, 2024	December 31, 2023
Receivables from Bayer included in *Other current assets*	$ 166	$ 156
Payables to Bayer included in *Accrued and other current liabilities*	82	80

[1] *Includes amortization of intangible assets, cost of products sold by Merck, as well as Bayer's share of profits from sales in Merck's marketing territories.*

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.

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, 2024	Three Months Ended September 30, 2023	Nine Months Ended September 30, 2024	Nine Months Ended September 30, 2023
Net sales of *Lagevrio* recorded by Merck	$ 383	$ 640	$ 843	$ 1,236
Cost of sales [1]	204	348	491	762
Selling, general and administrative	11	21	43	72
Research and development	5	8	7	33

($ in millions)	September 30, 2024	December 31, 2023
Payables to Ridgeback included in *Accrued and other current liabilities* [2]	$ 176	$ 113

[1] *Includes cost of products sold by Merck, Ridgeback's share of profits, royalty expense, amortization of capitalized milestone payments and inventory reserves.*

[2] *Includes accrued royalties.*

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 in 2023. 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 provided for a continuation payment of $750 million related to patritumab deruxtecan, which Merck paid in October 2024, and a continuation payment of $750 million related to raludotatug deruxtecan due from Merck in October 2025. If Merck does not make the remaining continuation payment for raludotatug deruxtecan, the rights for that program will revert to Daiichi Sankyo and the non-refundable upfront payments already paid will be retained by 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. In conjunction with this transaction, Merck recorded an aggregate pretax charge of $5.5 billion to *Research and development* expenses in the fourth quarter of 2023 for the $4.0 billion of upfront payments and the $1.5 billion of continuation payments.

Merck and Daiichi Sankyo equally share research and development costs, except for raludotatug deruxtecan, where Merck is responsible for 75% of the first $2.0 billion of research and development expenses. Merck includes its share of development costs associated with the collaboration as part of *Research and development* expenses. 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 5% sales-based royalty. Merck will record its share of product sales, net of cost of sales and commercialization costs, as alliance revenue.

In August 2024, Merck and Daiichi Sankyo expanded their agreement to include MK-6070, an investigational delta-like ligand 3 (DLL3) targeting T-cell engager, which Merck obtained through its acquisition of Harpoon (see Note 2). The companies are planning to evaluate MK-6070 in combination with ifinatamab deruxtecan in certain patients with SCLC, as well as other potential combinations. Merck received an upfront cash payment of $170 million from Daiichi Sankyo (recorded within *Other (income) expense, net)* and has also satisfied a contingent quid obligation from the original collaboration agreement. The companies will jointly develop and commercialize MK-6070 worldwide and share research and development and commercialization expenses. Research and development expenses related to MK-6070 in combination with ifinatamab deruxtecan will be shared in a manner consistent with the original agreement for ifinatamab deruxtecan. Merck will be solely responsible for manufacturing and supply of MK-6070. If approved, Merck will generally record sales for MK-6070 worldwide (Merck will be the principal on sales transactions) and the companies will equally share expenses as well as profits worldwide, except for Japan where Merck retains exclusive rights and Daiichi Sankyo will receive a 5% sales-based royalty.

Summarized financial information related to this collaboration is as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
($ in millions)	2024	2023	2024	2023
Selling, general and administrative	$ 5	$ —	$ 21	$ —
Research and development	94	—	227	—

($ in millions)	September 30, 2024	December 31, 2023
Payables to Daiichi Sankyo included in *Accrued and other current liabilities*	$ 811	$ 800
Payables to Daiichi Sankyo included in *Other Noncurrent Liabilities*	750	750

Moderna, Inc.

In 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). V940 (mRNA-4157) is currently being evaluated in combination with *Keytruda* in multiple Phase 3 clinical trials. Merck and Moderna share costs and will share any profits equally under this worldwide collaboration. Merck records its share of development costs associated with the collaboration as part of *Research and development* expenses. Any reimbursements received from Moderna for research and development expenses are recognized as reductions to *Research and development* costs. Merck has also capitalized certain of the shared costs, which aggregated $172 million at September 30, 2024 and will be amortized over the assets' estimated useful lives.

Summarized financial information related to this collaboration is as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
($ in millions)	2024	2023	2024	2023
Selling, general and administrative	$ 5	$ 2	$ 11	$ 3
Research and development	93	66	255	153

($ in millions)	September 30, 2024	December 31, 2023
Payables to Moderna included in *Accrued and other current liabilities*	$ 68	$ 63

Bristol-Myers Squibb Company

Reblozyl (luspatercept-aamt) is a first-in-class erythroid maturation recombinant fusion protein that is being commercialized through a global collaboration with Bristol-Myers Squibb Company (BMS). Reblozyl is approved in the U.S., Europe and certain other markets for the treatment of anemia in certain rare blood disorders and is also being evaluated for additional indications for hematology therapies. BMS is the principal on sales transactions for Reblozyl; however, Merck co-promotes Reblozyl (and may co-promote any future products approved under this collaboration) in North America, which is

reimbursed by BMS. Merck receives tiered royalties ranging from 20% to 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, consisting of royalties (recorded within *Sales*) was $100 million and $261 million in the third quarter and first nine months of 2024, respectively, compared with $52 million and $142 million in the third quarter and first nine months of 2023, respectively.

4. Restructuring

In January 2024, the Company approved a new restructuring program (2024 Restructuring Program) intended to continue the optimization of the Company's Human Health global manufacturing network as the future pipeline shifts to new modalities and also optimize the Animal Health global manufacturing network to improve supply reliability and increase efficiency. The actions contemplated under the 2024 Restructuring Program are expected to be substantially completed by the end of 2031, with the cumulative pretax costs to be incurred by the Company to implement the program estimated to be approximately $4.0 billion. Approximately 60% of the cumulative pretax costs will be non-cash, relating primarily to the accelerated depreciation of facilities to be closed or divested. The remainder of the costs will result in cash outlays, relating primarily to facility shut-down costs. The Company recorded total pretax costs of $279 million and $701 million in the third quarter and first nine months of 2024, respectively, related to the 2024 Restructuring Program, bringing total cumulative pretax costs incurred through September 30, 2024 to $892 million.

In 2019, Merck approved a global restructuring program (2019 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 Company recorded total pretax costs of $199 million and $532 million in the third quarter and first nine months of 2023, respectively, related to the 2019 Restructuring Program. The actions under the 2019 Restructuring Program were substantially complete at the end of 2023 and, as of January 1, 2024, any remaining activities are being accounted for as part of the 2024 Restructuring Program.

For segment reporting, restructuring charges are unallocated expenses.

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

	Three Months Ended September 30, 2024				Nine Months Ended September 30, 2024			
($ in millions)	Accelerated Depreciation	Separation Costs	Other Exit Costs	Total	Accelerated Depreciation	Separation Costs	Other	Total
2024 Restructuring Program								
Cost of sales	$ 40	$ —	$ 152	$ 192	$ 171	$ —	$ 203	$ 374
Selling, general and administrative	—	—	31	31	—	—	67	67
Research and development	—	—	—	—	—	—	2	2
Restructuring costs	—	11	45	56	—	122	136	258
	$ 40	$ 11	$ 228	$ 279	$ 171	$ 122	$ 408	$ 701

	Three Months Ended September 30, 2023				Nine Months Ended September 30, 2023			
($ in millions)	Accelerated Depreciation	Separation Costs	Other Exit Costs	Total	Accelerated Depreciation	Separation Costs	Other	Total
2019 Restructuring Program								
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
	$ 36	$ 95	$ 68	$ 199	$ 79	$ 246	$ 207	$ 532

Accelerated depreciation costs primarily relate to manufacturing, research and administrative facilities and equipment to be sold or closed as part of the programs. 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 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.

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

Other exit costs in 2024 and 2023 include asset impairment, facility shut-down and other related costs, as well as pretax gains and losses resulting from the sales of facilities and related assets. Additionally, other activity includes certain

employee-related costs associated with pension and other postretirement benefit plans (see Note 10) and share-based compensation.

The following table summarizes the charges and spending relating to restructuring program activities for the nine months ended September 30, 2024:

($ in millions)	Accelerated Depreciation	Separation Costs	Other Exit Costs	Total
Restructuring reserves January 1, 2024	$ —	$ 681	$ 31	$ 712
Expenses	171	122	408	701
(Payments) receipts, net	—	(177)	(122)	(299)
Non-cash activity	(171)	—	(292)	(463)
Restructuring reserves September 30, 2024	$ —	$ 626	$ 25	$ 651

5. 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 foreign 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 foreign 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 foreign 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 foreign exchange rate and the cost of the hedging instrument (primarily the euro, Swiss franc, Japanese yen, and Chinese renminbi). 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 foreign 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. A portion of 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 Income are shown below:

	Amount of Pretax (Gain) Loss Recognized in Other Comprehensive Income [1]				Amount of Pretax (Gain) Loss Recognized in *Other (income) expense, net* for Amounts Excluded from Effectiveness Testing			
	Three Months Ended September 30,		Nine Months Ended September 30,		Three Months Ended September 30,		Nine Months Ended September 30,	
($ in millions)	2024	2023	2024	2023	2024	2023	2024	2023
Net Investment Hedging Relationships								
Foreign exchange contracts	$ 1	$ (1)	$ 4	$ —	$ —	$ —	$ (2)	$ 1
Euro-denominated notes	169	(100)	73	(26)	—	—	—	—

[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, 2024, the Company was a party to six 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.

	September 30, 2024		
($ in millions)	Par Value of Debt	Number of Interest Rate Swaps Held	Total Swap Notional Amount
4.50% notes due 2033	$ 1,500	6	$ 1,500

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 changes 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. 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 in the Condensed Consolidated Balance Sheet related to cumulative basis adjustments for fair value hedges:

	Carrying Amount of Hedged Liabilities		Cumulative Amount of Fair Value Hedging Adjustment Increase Included in the Carrying Amount	
($ in millions)	September 30, 2024	December 31, 2023	September 30, 2024	December 31, 2023
Balance Sheet Caption				
Long-Term Debt	$ 1,589	$ 1,056	$ 98	$ 56

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:

		September 30, 2024			December 31, 2023		
		Fair Value of Derivative		U.S. Dollar Notional	Fair Value of Derivative		U.S. Dollar Notional
($ in millions)		Asset	Liability		Asset	Liability	
Derivatives Designated as Hedging Instruments	*Balance Sheet Caption*						
Interest rate swap contracts	Other Assets	$ 99	$ —	$ 1,500	$ 57	$ —	$ 1,000
Foreign exchange contracts	Other current assets	30	—	4,635	106	—	6,138
Foreign exchange contracts	Other Assets	28	—	2,170	26	—	1,929
Foreign exchange contracts	Accrued and other current liabilities	—	118	5,022	—	76	3,680
Foreign exchange contracts	Other Noncurrent Liabilities	—	1	54	—	1	7
		157	119	13,381	189	77	12,754
Derivatives Not Designated as Hedging Instruments	*Balance Sheet Caption*						
Foreign exchange contracts	Other current assets	183	—	10,298	153	—	9,693
Foreign exchange contracts	Accrued and other current liabilities	—	179	11,635	—	162	8,104
		183	179	21,933	153	162	17,797
		$ 340	$ 298	$ 35,314	$ 342	$ 239	$ 30,551

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:

	September 30, 2024		December 31, 2023	
($ in millions)	Asset	Liability	Asset	Liability
Gross amounts recognized in the condensed consolidated balance sheet	$ 340	$ 298	$ 342	$ 239
Gross amounts subject to offset in master netting arrangements not offset in the condensed consolidated balance sheet	(225)	(225)	(215)	(215)
Cash collateral received	—	—	(3)	—
Net amounts	$ 115	$ 73	$ 124	$ 24

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

	Three Months Ended September 30,						Nine Months Ended September 30,					
($ in millions)	2024	2023	2024	2023	2024	2023	2024	2023	2024	2023	2024	2023
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)	
	$16,657	$15,962	$ (162)	$ 126	$ (10)	$ (16)	$48,544	$45,485	$ (151)	$ 388	$ (210)	$ (148)
Loss (gain) on fair value hedging relationships:												
Interest rate swap contracts												
Hedged items	—	—	68	(7)	—	—	—	—	42	(7)	—	—
Derivatives designated as hedging instruments	—	—	(69)	8	—	—	—	—	(43)	8	—	—
Impact of cash flow hedging relationships:												
Foreign exchange contracts												
Amount of (loss) gain recognized in *OCI* on derivatives	—	—	—	—	(325)	247	—	—	—	—	22	375
Increase in *Sales* as a result of *AOCL* reclassifications	48	45	—	—	(48)	(45)	146	170	—	—	(146)	(170)
Interest rate contracts												
Amount of gain recognized in *Other (income) expense, net* on derivatives	—	—	—	—	—	—	—	—	(1)	(1)	—	—
Amount of (loss) gain recognized in *OCI* on derivatives	—	—	—	—	—	—	—	—	—	—	(1)	13

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

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

		Amount of Derivative Pretax (Gain) Loss Recognized in Income			
		Three Months Ended September 30,		Nine Months Ended September 30,	
($ in millions)		2024	2023	2024	2023
Derivatives Not Designated as Hedging Instruments	*Income Statement Caption*				
Foreign exchange contracts [1]	Other (income) expense, net	$ (139)	$ 60	$ (65)	$ 32
Foreign exchange contracts [2]	Sales	10	—	(10)	(3)

[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, 2024, the Company estimates $161 million of pretax net unrealized losses on derivatives maturing within the next 12 months that hedge foreign currency denominated sales over that same period will be reclassified from *AOCL* to *Sales*. The amount ultimately reclassified to *Sales* may differ as foreign exchange rates change. Realized gains and losses are ultimately determined by actual foreign exchange rates at maturity.

Investments in Debt and Equity Securities

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

	September 30, 2024				December 31, 2023			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
($ in millions)								
U.S. government and agency securities	$ 81	$ —	$ —	$ 81	$ 72	$ —	$ —	$ 72
Commercial paper	—	—	—	—	252	—	—	252
Corporate notes and bonds	—	—	—	—	13	—	—	13
Total debt securities	$ 81	$ —	$ —	$ 81	$ 337	$ —	$ —	$ 337
Publicly traded equity securities [1]				984				764
Total debt and publicly traded equity securities				$ 1,065				$ 1,101

[1] *Unrealized net losses (gains) of $42 million and $(82) million were recorded in* Other (income) expense, net *in the third quarter and first nine months of 2024, respectively, on equity securities still held at September 30, 2024. 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.*

At September 30, 2024 and September 30, 2023, the Company also had $848 million and $863 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 2024, the Company recorded unrealized gains of $12 million and unrealized losses of $25 million related to certain of these equity investments still held at September 30, 2024. 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. 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, 2024 were $302 million and $89 million, respectively.

At September 30, 2024 and September 30, 2023, the Company also had $328 million and $467 million, respectively, recorded in *Other Assets* for equity securities held through ownership interests in investment funds. (Gains) losses recorded in *Other (income) expense, net* relating to these investment funds were $(21) million and $93 million for the third quarter of 2024 and 2023, respectively, and $(26) million and $66 million for the first nine months of 2024 and 2023, respectively.

Fair Value Measurements

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

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

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

Level 3 - Unobservable inputs that are supported by little or no market activity. Level 3 assets or liabilities are those whose values are determined using pricing models, discounted cash flow methodologies, or similar techniques with significant

unobservable inputs, as well as assets or liabilities for which the determination of fair value requires significant judgment or estimation.

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

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

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

	Fair Value Measurements Using				Fair Value Measurements Using			
	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3	Total
($ in millions)	September 30, 2024				December 31, 2023			
Assets								
Investments								
Commercial paper	$ —	$ —	$ —	$ —	$ —	$ 252	$ —	$ 252
Publicly traded equity securities	575	—	—	575	252	—	—	252
	575	—	—	575	252	252	—	504
Other assets [1]								
U.S. government and agency securities	81	—	—	81	72	—	—	72
Corporate notes and bonds	—	—	—	—	13	—	—	13
Publicly traded equity securities	409	—	—	409	512	—	—	512
	490	—	—	490	597	—	—	597
Derivative assets [2]								
Forward exchange contracts	—	180	—	180	—	202	—	202
Interest rate swaps	—	99	—	99	—	57	—	57
Purchased currency options	—	61	—	61	—	83	—	83
	—	340	—	340	—	342	—	342
Total assets	$ 1,065	$ 340	$ —	$ 1,405	$ 849	$ 594	$ —	$ 1,443
Liabilities								
Other liabilities								
Contingent consideration	$ —	$ —	$ 208	$ 208	$ —	$ —	$ 354	$ 354
Derivative liabilities [2]								
Forward exchange contracts	—	291	—	291	—	239	—	239
Written currency options	—	7	—	7	—	—	—	—
	—	298	—	298	—	239	—	239
Total liabilities	$ —	$ 298	$ 208	$ 506	$ —	$ 239	$ 354	$ 593

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

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

As of September 30, 2024 and December 31, 2023, *Cash and cash equivalents* included $13.6 billion and $6.0 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)	2024	2023
Fair value January 1	$ 354	$ 456
Changes in estimated fair value [1]	2	6
Payments	(148)	(117)
Fair value September 30 [2]	$ 208	$ 345

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

[2] *Balance at September 30, 2024, includes $163 million of current liabilities, of which $136 million relates 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.*

The payments of contingent consideration during the first nine months of 2024 include $126 million related to the Sanofi Pasteur MSD liabilities described above and $22 million related to the first commercial sale of *Lyfnua* (gefapixant) in the European Union. The payments of contingent consideration during the first nine months of 2023 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, 2024, was $35.2 billion compared with a carrying value of $38.1 billion and at December 31, 2023, was $32.0 billion compared with a carrying value of $35.1 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 $3.1 billion and $3.0 billion of accounts receivable as of September 30, 2024 and December 31, 2023, 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, 2024 and December 31, 2023, the Company had collected $42 million and $44 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 is recorded in *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 $3 million at December 31, 2023. The obligation to return such collateral is recorded in *Accrued and other current liabilities*.

6. Inventories

Inventories consisted of:

($ in millions)	September 30, 2024	December 31, 2023
Finished goods	$ 1,939	$ 1,954
Raw materials and work in process	8,780	8,037
Supplies	282	277
Total	11,001	10,268
Decrease to LIFO cost	(762)	(562)
	$ 10,239	$ 9,706
Recognized as:		
Inventories	$ 6,244	$ 6,358
Other Assets	3,995	3,348

Amounts recognized as *Other Assets* are comprised almost entirely of raw materials and work in process inventories. At September 30, 2024 and December 31, 2023, these amounts included $3.7 billion and $2.6 billion, respectively, of inventories not expected to be sold within one year. In addition, these amounts included $334 million and $790 million at September 30, 2024 and December 31, 2023, respectively, of inventories produced in preparation for product launches.

7. Long-Term Debt

In May 2024, MSD Netherlands Capital B.V., a wholly-owned finance subsidiary of Merck, completed a registered public offering of €3.4 billion in aggregate principal amount of euro-dominated senior notes comprised of €850 million of 3.25% senior notes due 2032, €850 million of 3.50% senior notes due 2037, €850 million of 3.70% senior notes due 2044 and €850 million of 3.75% senior notes due 2054 (collectively, the Euronotes). The Company has fully and unconditionally guaranteed all of MSD Netherlands Capital B.V.'s obligations under the Euronotes and no other subsidiary of the Company will guarantee these obligations. MSD Netherlands Capital B.V. is a "finance subsidiary" as defined in Rule 13-01(a)(4)(vi) of Regulation S-X of the Exchange Act, with no assets or operations other than those related to the issuance, administration and repayment of the Euronotes. The financial condition, results of operations and cash flows of MSD Netherlands Capital B.V. are consolidated in the financial statements of the Company. The net cash proceeds from the offering were used for general corporate purposes.

8. Contingencies

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

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

The Company records accruals for contingencies when it is probable that a liability has been incurred and the amount can be reasonably estimated. These accruals are adjusted periodically as assessments change or additional information becomes available. Generally, 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

Dr. Scholl's Foot Powder

As previously disclosed, Merck is a defendant in product liability lawsuits in the U.S. arising from consumers' alleged exposure to talc in Dr. Scholl's foot powder, which Merck acquired through its merger with Schering-Plough Corporation and sold as part of the divestiture of Merck's consumer care business to Bayer in 2014. In these actions, plaintiffs allege that they were exposed to asbestos-contaminated talc and developed mesothelioma as a result. As of September 30, 2024, approximately 330 cases were pending against Merck in various state courts.

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, 2024, approximately 210 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 U.S. 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. In February 2024, the multidistrict litigation was reassigned to Judge Kenneth D. Bell. One state court action in Los Angeles County is now scheduled to commence trial on January 21, 2025. As previously disclosed, there are fewer than 15 product liability cases pending outside the U.S.

Commercial and Other Litigation

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 July 2023, 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 appealed that decision, and on August 6, 2024, the Third Circuit affirmed the district court's decision.

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. 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. The Company appealed the antitrust decision, and on October 7, 2024, the Third Circuit reversed-in-part the district court's order and remanded the case with instructions to enter summary judgment for the Company.

340B Program Litigation

As previously disclosed, Merck filed a complaint in the U.S. District Court for the District of Columbia to challenge the letter Merck received from the U.S. Health Resources and Services Administration (HRSA) in May 2022 regarding Merck's 340B Program integrity initiative. On September 17, 2024, the court entered a consent judgment granting Merck the relief it had sought in the litigation, including declarations that HRSA's May 2022 letter was unlawful and that the version of Merck's 340B Program integrity initiative at issue in the litigation did not violate Section 340B on its face.

Governmental Proceedings

Civil Investigative Demand

As previously disclosed, in June 2024, Merck received a Civil Investigative Demand (CID) from the U.S. Department of Justice, pursuant to a False Claims Act investigation, seeking documents and materials related to *Steglatro*, *Januvia* and certain related drugs. The CID states that it is investigating Merck's price reporting under the Medicaid Drug Rebate Program as well as compliance with anti-kickback requirements in connection with patient assistance programs. The Company is cooperating with the investigation.

Other Matters

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.

Patent Litigation

From time to time, generic manufacturers of pharmaceutical products file abbreviated New Drug Applications (ANDAs) 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 had 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 in August 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.

As previously disclosed, in June 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 five-year extension. This ruling affirms and validates Merck's U.S. patent protection for *Bridion* through at least January 2026. Also in June 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.

In July 2023, defendants filed a notice of appeal with the U.S. Court of Appeals for the Federal Circuit. The appeal is currently pending.

While the New Jersey action was pending, the Company settled with five of these 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 other 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 February 5, 2024, the Company received another Paragraph IV Certification Letter under the Hatch-Waxman Act notifying the Company that Hikma Pharmaceuticals USA Inc. (Hikma) had filed an application to the FDA seeking pre-patent expiry approval to sell a generic version of *Bridion* Injection. On March 15, 2024, the Company filed a patent infringement lawsuit in the U.S. District Court for the District of New Jersey against Hikma, postponing FDA approval of the Hikma generic drug for 30 months or until expiration of the sugammadex patent (January 27, 2026) and any potentially applicable pediatric exclusivity or an adverse court decision, if any, whichever may occur earlier. Expiration of the patent, and any potentially applicable pediatric exclusivity, will occur earlier than expiry of the 30-month stay. On April 16, 2024, the district court stayed the case during the pendency of the Federal Circuit appeal noted above.

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).

As previously disclosed, beginning in 2019, a number of generic drug companies filed ANDAs seeking approval of generic forms of *Januvia* and *Janumet* along with paragraph IV certifications challenging the validity of the 2027 salt/polymorph patent. The Company responded by filing infringement lawsuits which have all been settled. The Company has settled with a total of 26 generic companies providing that these generic companies can bring their generic versions of *Januvia* and *Janumet* to the market in the U.S. 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 a form of sitagliptin that is a different form than that used in *Januvia*. 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.

In January 2023, the Company received a Paragraph IV Certification Letter under the Hatch-Waxman Act notifying the Company that Zydus filed an ANDA 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.* In November 2023, the Company received a Paragraph IV Certification Letter under the Hatch-Waxman Act notifying the Company that Zydus filed an ANDA seeking approval of sitagliptin/metformin HCl Extended Release tablets. In January 2024, the parties reached settlement enabling Zydus to seek final approval of a non-automatically substitutable version containing a different form of sitagliptin than that used in *Janumet XR*.

As a result of these 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.

In March 2024, the Company received another Paragraph IV Certification Letter under the Hatch-Waxman Act from Azurity Pharmaceuticals, Inc. (Azurity) asserting that a different sitagliptin product subject to its ANDA does not infringe the salt patent. On May 3, 2024, Merck filed a civil action in the U.S. District Court of Delaware alleging infringement. The case was dismissed without prejudice on July 26, 2024. Following the dismissal, the Company granted Azurity a covenant not to assert the salt patent against the Azurity product that is the subject of such ANDA.

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 in March 2023 and an Advocate General Opinion was received on June 6, 2024, with a decision expected later in 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.

In October 2023, the Company filed a patent infringement lawsuit against Sawai Pharmaceuticals Co., Ltd. and Medisa Shinyaku Co., Ltd (collectively, Defendants) in the Tokyo District Court seeking an injunction to stop the manufacture, sale and offer for sale of the Defendants' sitagliptin dihydrogen phosphate product, while the Company's patents and patent term extensions are in force. The lawsuit is in response to the Defendants' application for marketing authorization to sell a generic sitagliptin dihydrogen phosphate product, in the anhydrate form, which was approved on August 15, 2023. Merck asserts that the Defendants' activity infringes a patent term extension associated with Merck's patent directed to the sitagliptin compound patent.

Keytruda — As previously disclosed, in November 2022, the Company filed a complaint against The Johns Hopkins University (JHU) 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 in April and May 2023, denying Merck's claims, and counterclaiming for willful infringement of nine issued U.S. patents, including a demand for damages. Between November 30, 2023, and March 13, 2024, the Company filed *inter partes* review (IPR) petitions with the United States Patent & Trademark Office Patent Trial and Appeal Board (PTAB), challenging the validity of all nine patents asserted in the case. Between June 13, 2024 and October 3, 2024, the PTAB instituted a review of all nine asserted patents. On July 1, 2024, the district court granted Merck's motion to stay the case in its entirety pending the outcome of the PTAB proceeding instituted on June 13, 2024.

Lynparza — As previously disclosed, 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/ Delaware 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. In May and July 2024, AstraZeneca and the Company filed additional patent infringement lawsuits in the U.S. District Court for the District of New Jersey against Natco asserting additional patents covering olaparib.

In December 2023, AstraZeneca Pharmaceuticals LP received a second Paragraph IV Certification Letter under the Hatch-Waxman Act notifying AstraZeneca that Sandoz Inc. (Sandoz) has filed an application to the FDA seeking pre-patent expiry approval to sell generic versions of Lynparza (olaparib) tablet. In February 2024, AstraZeneca and the Company filed a patent infringement lawsuit in the U.S. District Court for the District of New Jersey against Sandoz. This lawsuit, which asserts one or more patents covering olaparib, automatically stays FDA approval of the generic application until June 2026 or until an adverse court decision, if any, whichever may occur earlier. In May and July 2024, AstraZeneca and the Company filed additional patent infringement lawsuits in the U.S. District Court for the District of New Jersey against Sandoz asserting additional patents covering olaparib.

In May 2024, AstraZeneca Pharmaceuticals LP received a third Paragraph IV Certification Letter under the Hatch-Waxman Act notifying AstraZeneca that Cipla USA, Inc. and Cipla Limited (collectively, Cipla) filed an application to the FDA seeking pre-patent expiry approval to sell generic versions of Lynparza (olaparib) tablet. In June 2024, AstraZeneca and the Company filed a patent infringement lawsuit in the U.S. District Court for the District of New Jersey against Cipla. This lawsuit, which asserts one or more patents covering olaparib, automatically stays FDA approval of the generic application until November 2026 or until an adverse court decision, if any, whichever may occur earlier. In June and July 2024, AstraZeneca and the Company filed additional patent infringement lawsuits in the U.S. District Court for the District of New Jersey against Cipla asserting additional patents covering olaparib.

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, 2024 and December 31, 2023 of approximately $210 million represents the Company's best estimate of the minimum amount of defense costs to be incurred in connection with its outstanding litigation; however, events such as additional trials and other events that could arise in the course of its litigation could affect the ultimate amount of legal defense costs to be incurred by the Company. The Company will continue to monitor its legal defense costs and review the adequacy of the associated reserves and may determine to increase the reserves at any time in the future if, based upon the factors set forth, it believes it would be appropriate to do so.

9. Equity

	Three Months Ended September 30,								
	Common Stock		Other Paid-In Capital	Retained Earnings	Accumulated Other Comprehensive Loss	Treasury Stock		Non-controlling Interests	Total
($ and shares in millions except per share amounts)	Shares	Par Value				Shares	Cost		
Balance at 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
Balance at July 1, 2024	3,577	$ 1,788	$ 44,362	$ 60,187	$ (5,361)	1,041	$ (57,394)	$ 66	$ 43,648
Net income attributable to Merck & Co., Inc.	—	—	—	3,157	—	—	—	—	3,157
Other comprehensive loss, net of taxes	—	—	—	—	(10)	—	—	—	(10)
Cash dividends declared on common stock ($0.77 per share)	—	—	—	(1,960)	—	—	—	—	(1,960)
Treasury stock shares purchased	—	—	—	—	—	4	(444)	—	(444)
Share-based compensation plans and other	—	—	168	—	—	—	9	—	177
Net income attributable to noncontrolling interests	—	—	—	—	—	—	—	4	4
Distributions attributable to noncontrolling interests	—	—	—	—	—	—	—	(12)	(12)
Balance at September 30, 2024	3,577	$ 1,788	$ 44,530	$ 61,384	$ (5,371)	1,045	$ (57,829)	$ 58	$ 44,560

($ 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, 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
Balance at January 1, 2024	3,577	$ 1,788	$ 44,509	$ 53,895	$ (5,161)	1,045	$ (57,450)	$ 54	$ 37,635
Net income attributable to Merck & Co., Inc.	—	—	—	13,374	—	—	—	—	13,374
Other comprehensive loss, net of taxes	—	—	—	—	(210)	—	—	—	(210)
Cash dividends declared on common stock ($2.31 per share)	—	—	—	(5,885)	—	—	—	—	(5,885)
Treasury stock shares purchased	—	—	—	—	—	7	(817)	—	(817)
Share-based compensation plans and other	—	—	21	—	—	(7)	438	1	460
Net income attributable to noncontrolling interests	—	—	—	—	—	—	—	15	15
Distributions attributable to noncontrolling interests	—	—	—	—	—	—	—	(12)	(12)
Balance at September 30, 2024	3,577	$ 1,788	$ 44,530	$ 61,384	$ (5,371)	1,045	$ (57,829)	$ 58	$ 44,560

10. Pension and Other Postretirement Benefit Plans

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

($ in millions)	Three Months Ended September 30,				Nine Months Ended September 30,			
	2024		2023		2024		2023	
	U.S.	International	U.S.	International	U.S.	International	U.S.	International
Service cost	$ 100	$ 60	$ 88	$ 48	$ 273	$ 182	$ 239	$ 148
Interest cost	134	74	130	76	403	220	396	225
Expected return on plan assets	(206)	(139)	(182)	(131)	(621)	(416)	(553)	(390)
Amortization of unrecognized prior service (credit) cost	—	(3)	—	(6)	—	(10)	(1)	5
Net loss (gain) amortization	12	1	—	(1)	30	4	—	(2)
Termination benefits	1	—	1	—	5	—	2	—
Curtailments	—	—	—	—	—	—	5	—
Settlements	—	—	—	—	—	—	26	—
	$ 41	$ (7)	$ 37	$ (14)	$ 90	$ (20)	$ 114	$ (14)

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
($ in millions)	2024	2023	2024	2023
Service cost	$ 7	$ 8	$ 23	$ 24
Interest cost	14	16	42	47
Expected return on plan assets	(20)	(16)	(60)	(48)
Amortization of unrecognized prior service credit	(11)	(12)	(32)	(37)
Net gain amortization	(14)	(11)	(38)	(31)
Curtailments	—	—	—	(1)
	$ (24)	$ (15)	$ (65)	$ (46)

In connection with restructuring actions (see Note 4), 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 2023. 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 a net increase of $13 million to net pension liabilities and also resulted in a related adjustment to *AOCL*.

The components of net periodic benefit cost (credit) other than the service cost component are included in *Other (income) expense, net* (see Note 11), with the exception of certain amounts for termination benefits, 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.

11. Other (Income) Expense, Net

Other (income) expense, net, consisted of:

	Three Months Ended September 30,		Nine Months Ended September 30,	
($ in millions)	2024	2023	2024	2023
Interest income	$ (127)	$ (73)	$ (269)	$ (295)
Interest expense	330	317	943	836
Exchange losses	33	85	177	208
Loss (income) from investments in equity securities, net [(1)]	31	33	(169)	(240)
Net periodic defined benefit plan (credit) cost other than service cost	(157)	(138)	(476)	(364)
Other, net	(272)	(98)	(357)	243
	$ (162)	$ 126	$ (151)	$ 388

[(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.

Interest paid for the nine months ended September 30, 2024 and 2023 was $822 million and $678 million, respectively.

12. Income Taxes

The effective income tax rate of 22.7% for the third quarter of 2024 reflects a 7.2 percentage point combined unfavorable impact of charges related to the acquisitions of EyeBio and MK-1045, which had minimal tax benefits. The effective income tax rate of 15.1% for the first nine months of 2024 reflects a 2.1 percentage point combined unfavorable impact of charges related to the acquisitions of Harpoon, EyeBio and MK-1045, which had minimal tax benefits. The effective income tax rate for the first nine months of 2024 also reflects a 1.6 percentage point favorable impact due to a $259 million reduction in reserves for unrecognized income tax benefits resulting from the expiration in June 2024 of the statute of limitations for assessments related to the 2019 federal tax return year.

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 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. The statute of limitations for assessments with respect to the 2019 and 2020 federal tax return years expired in June 2024 (as noted above) and October 2024, respectively. Merck expects to record a benefit of approximately $270 million in the fourth quarter of 2024 due to a reduction in reserves for unrecognized tax benefits resulting from the expiration of the statute of limitations related to the 2020 federal tax return year.

13. Earnings Per Share

The calculations of earnings per share are as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
($ and shares in millions except per share amounts)	2024	2023	2024	2023
Net Income Attributable to Merck & Co., Inc.	$ 3,157	$ 4,745	$ 13,374	$ 1,591
Average common shares outstanding	2,534	2,537	2,534	2,538
Common shares issuable [(1)]	7	9	9	11
Average common shares outstanding assuming dilution	2,541	2,546	2,543	2,549
Basic Earnings per Common Share Attributable to Merck & Co., Inc. Common Shareholders	$ 1.25	$ 1.87	$ 5.28	$ 0.63
Earnings per Common Share Assuming Dilution Attributable to Merck & Co., Inc. Common Shareholders	$ 1.24	$ 1.86	$ 5.26	$ 0.62

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

For the third quarter of 2024 and 2023, 7 million and 6 million, respectively, and for the first nine months of 2024 and 2023, 6 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.

14. Other Comprehensive Income (Loss)

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

	Three Months Ended September 30,			
($ in millions)	Derivatives	Employee Benefit Plans	Foreign Currency Translation Adjustment	Accumulated Other Comprehensive Loss
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)
Balance July 1, 2024, net of taxes	$ 173	$ (2,808)	$ (2,726)	$ (5,361)
Other comprehensive income (loss) before reclassification adjustments, pretax	(325)	—	279	(46)
Tax	68	(3)	20	85
Other comprehensive income (loss) before reclassification adjustments, net of taxes	(257)	(3)	299	39
Reclassification adjustments, pretax	(49) [(1)]	(14) [(2)]	—	(63)
Tax	10	4	—	14
Reclassification adjustments, net of taxes	(39)	(10)	—	(49)
Other comprehensive income (loss), net of taxes	(296)	(13)	299	(10)
Balance September 30, 2024, net of taxes	$ (123)	$ (2,821)	$ (2,427)	$ (5,371)

($ in millions)	Derivatives	Employee Benefit Plans	Foreign Currency Translation Adjustment	Accumulated Other Comprehensive Loss
	Nine Months Ended September 30,			
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)
Balance January 1, 2024, net of taxes	$ (24)	$ (2,793)	$ (2,344)	$ (5,161)
Other comprehensive income (loss) before reclassification adjustments, pretax	22	6	(103)	(75)
Tax	(5)	(5)	—	(10)
Other comprehensive income (loss) before reclassification adjustments, net of taxes	17	1	(103)	(85)
Reclassification adjustments, pretax	(147) [1]	(44) [2]	20	(171)
Tax	31	15	—	46
Reclassification adjustments, net of taxes	(116)	(29)	20	(125)
Other comprehensive income (loss), net of taxes	(99)	(28)	(83)	(210)
Balance September 30, 2024, net of taxes	$ (123)	$ (2,821)	$ (2,427)	$ (5,371)

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

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

15. Segment Reporting

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

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

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

Sales of the Company's products were as follows:

	Three Months Ended September 30,						Nine Months Ended September 30,					
	2024			2023			2024			2023		
($ in millions)	U.S.	Int'l	Total	U.S.	Int'l	Total	U.S.	Int'l	Total	U.S.	Int'l	Total
Pharmaceutical:												
Oncology												
Keytruda	$ 4,500	$ 2,929	$ 7,429	$ 3,795	$ 2,543	$ 6,338	$ 13,031	$ 8,614	$ 21,646	$ 11,142	$ 7,261	$ 18,403
Alliance revenue-Lynparza [(1)]	161	177	337	153	146	299	449	498	947	439	445	884
Alliance revenue-Lenvima [(1)]	173	78	251	160	100	260	523	233	755	476	258	734
Welireg	127	12	139	51	3	54	320	29	349	141	6	146
Alliance revenue-Reblozyl [(2)]	82	18	100	43	10	52	215	45	261	108	33	142
Vaccines												
Gardasil/Gardasil 9	1,020	1,285	2,306	838	1,746	2,585	2,045	4,988	7,032	1,718	5,297	7,015
ProQuad/M-M-R II*/Varivax*	572	131	703	567	146	713	1,500	391	1,891	1,435	388	1,823
Vaxneuvance	137	103	239	182	33	214	397	251	647	423	65	488
RotaTeq	131	62	193	108	48	156	388	185	572	381	203	584
Pneumovax 23	19	49	68	42	98	140	36	152	188	105	223	327
Hospital Acute Care												
Bridion	339	81	420	265	159	424	1,020	296	1,315	841	572	1,413
Prevymis	101	107	208	70	87	157	265	305	570	186	244	430
Dificid	83	13	96	69	5	74	231	30	261	199	16	215
Zerbaxa	39	26	64	29	24	53	106	77	182	86	71	157
Noxafil	1	40	41	4	47	51	9	132	141	29	138	167
Cardiovascular												
Alliance revenue-Adempas/ Verquvo [(3)]	96	7	102	96	(4)	92	283	22	306	249	10	259
Adempas	—	72	72	—	65	65	—	214	214	—	189	189
Winrevair	147	3	149	—	—	—	216	3	219	—	—	—
Virology												
Lagevrio	84	299	383	—	640	640	144	699	843	—	1,236	1,236
Isentress/Isentress HD	54	48	102	58	61	119	147	155	302	165	212	377
Delstrigo	15	50	65	13	40	54	42	139	180	37	110	148
Pifeltro	31	12	42	27	10	37	86	37	123	78	31	109
Neuroscience												
Belsomra	20	58	78	23	35	58	53	124	177	60	117	176
Immunology												
Simponi	—	189	189	—	179	179	—	545	545	—	539	539
Remicade	—	41	41	—	45	45	—	115	115	—	144	144
Diabetes												
Januvia	67	211	278	328	252	581	428	674	1,102	842	800	1,642
Janumet	15	190	204	43	211	255	70	610	679	182	755	937
Other pharmaceutical [(4)]	213	426	644	189	381	568	559	1,232	1,796	518	1,239	1,758
Total Pharmaceutical segment sales	8,227	6,717	14,943	7,153	7,110	14,263	22,563	20,795	43,358	19,840	20,602	40,442
Animal Health:												
Livestock	194	692	886	205	669	874	529	2,044	2,573	543	1,987	2,530
Companion Animal	293	307	601	257	269	526	888	1,019	1,907	875	942	1,817
Total Animal Health segment sales	487	999	1,487	462	938	1,400	1,417	3,063	4,480	1,418	2,929	4,347
Total segment sales	8,714	7,716	16,430	7,615	8,048	15,663	23,980	23,858	47,838	21,258	23,531	44,789
Other [(5)]	22	206	227	100	199	299	109	597	706	135	561	696
	$8,736	$7,922	$ 16,657	$7,715	$8,247	$ 15,962	$ 24,089	$ 24,455	$ 48,544	$ 21,393	$ 24,092	$ 45,485

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 (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 $156 million and $173 million for the nine months ended September 30, 2024 and 2023, respectively, as well as revenue from third-party manufacturing arrangements (including sales to Organon as discussed in Note 2). Other for the nine months ended September 30, 2024 and 2023 also includes $91 million and $118 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 $3.6 billion and $3.1 billion for the three months ended September 30, 2024 and 2023, respectively, and $10.1 billion and $9.4 billion for the nine months ended September 30, 2024 and September 30, 2023, respectively.

Consolidated sales by geographic area where derived are as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
($ in millions)	2024	2023	2024	2023
United States	$ 8,736	$ 7,715	$ 24,089	$ 21,393
Europe, Middle East and Africa	3,583	3,327	10,661	9,978
China	1,017	1,694	4,606	5,322
Latin America	936	895	2,591	2,298
Japan	938	1,081	2,445	2,514
Asia Pacific (other than China and Japan)	823	781	2,294	2,475
Other	624	469	1,858	1,505
	$ 16,657	$ 15,962	$ 48,544	$ 45,485

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
($ in millions)	2024	2023	2024	2023
Segment profits:				
Pharmaceutical segment	$ 11,547	$ 10,407	$ 33,651	$ 29,400
Animal Health segment	510	421	1,574	1,453
Total segment profits	12,057	10,828	35,225	30,853
Other profits	117	190	391	374
Unallocated:				
Interest income	127	73	269	295
Interest expense	(330)	(317)	(943)	(836)
Amortization	(633)	(562)	(1,720)	(1,582)
Depreciation	(467)	(401)	(1,368)	(1,175)
Research and development	(5,716)	(3,183)	(12,926)	(20,523)
Restructuring costs	(56)	(126)	(258)	(344)
Charge for Zetia antitrust litigation settlements	—	—	—	(573)
Other unallocated, net	(1,009)	(882)	(2,904)	(2,554)
	$ 4,090	$ 5,620	$ 15,766	$ 3,935

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 by Merck Research Laboratories, the Company's research and development division that focuses on human health-related activities, or general and administrative expenses not directly incurred by the segments, 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 amortization of purchase accounting adjustments are not allocated to segments.

Other profits are primarily comprised of miscellaneous corporate profits, as well as operating profits (losses) 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 Development Transactions

Below is a summary of significant business development activity thus far in 2024.

In September 2024, Merck acquired MK-1045 (formally CN201), a novel investigational clinical-stage bispecific antibody for the treatment of B-cell associated diseases, from Curon Biopharmaceutical (Curon) for an upfront payment of $700 million. In addition, Curon is eligible to receive future contingent developmental and regulatory milestone payments. MK-1045 is currently being evaluated in Phase 1 and Phase 1b/2 clinical trials for the treatment of patients with relapsed or refractory non-Hodgkin lymphoma and relapsed or refractory B-cell acute lymphocytic leukemia, respectively. Merck plans to evaluate MK-1045 as a treatment for B-cell malignancies as well as investigate its potential to provide a novel, scalable option for the treatment of autoimmune diseases. The transaction was accounted for as an asset acquisition. Merck recorded a charge of $750 million (reflecting the upfront payment and other related costs) to *Research and development* expenses, or approximately $0.29 per share in the third quarter and first nine months of 2024. In connection with the agreement, Merck is also obligated to pay a third party future contingent developmental, regulatory and sales-based milestone payments and tiered royalties on future net sales of MK-1045 if approved.

In July 2024, Merck acquired the aqua business of Elanco Animal Health Incorporated (Elanco aqua business) for total consideration of $1.3 billion. The Elanco aqua business consists of an innovative portfolio of medicines and vaccines, nutritionals and supplements for aquatic species; two related aqua manufacturing facilities in Canada and Vietnam; as well as a research facility in Chile. The acquisition broadens Animal Health's aqua portfolio with products such as *Clynav*, a new generation DNA-based vaccine that protects Atlantic salmon against pancreas disease, and *Imvixa*, an anti-parasitic sea lice treatment. This acquisition also brings a portfolio of water treatment products for warm water production, complementing Animal Health's warm water vaccine portfolio. In addition to these products, the DNA-based vaccine technology that is a part of the business has the potential to accelerate the development of novel vaccines to address the unmet needs of the aqua industry. There are no contingent payments associated with the acquisition, which was accounted for as a business combination.

Also in July 2024, Merck acquired Eyebiotech Limited (EyeBio), a privately held ophthalmology-focused biotechnology company for $1.2 billion (including payments to settle share-based equity awards) and also incurred $207 million of transaction costs. The acquisition agreement also provides for former EyeBio shareholders to receive future contingent developmental, regulatory and sales-based milestone payments. EyeBio's development work focused on candidates for the prevention and treatment of vision loss associated with retinal vascular leakage, a known risk factor for retinal diseases. EyeBio's lead candidate, *Restoret* (MK-3000, formerly EYE103), is an investigational, potentially first-in-class tetravalent, tri-specific antibody that acts as an agonist of the Wingless-related integration site signaling pathway, which is in clinical development for the treatment of diabetic macular edema and neovascular age-related macular degeneration. The transaction was accounted for as an asset acquisition. Merck recorded net assets of $21 million, as well as a charge of $1.35 billion to *Research and development* expenses, or $0.52 per share, in the third quarter and first nine months of 2024 related to the acquisition. Additionally, a $100 million developmental milestone was triggered in the third quarter of 2024 upon initiation of a Phase 2/3 clinical trial evaluating *Restoret* for the treatment of diabetic macular edema, which was also recorded to *Research and development* expenses.

Additionally in July 2024, Merck and Orion Corporation (Orion) announced the mutual exercise of an option to convert the companies' ongoing co-development and co-commercialization agreement for opevesostat (MK-5684/ODM-208), an investigational cytochrome P450 11A1 (CYP11A1) inhibitor, and other candidates targeting CYP11A1, into an exclusive global license for Merck. With the exercise of the option, Merck assumed full responsibility for all past and future development and commercialization expenses associated with the candidates covered by the original agreement. In addition, Orion became eligible to receive developmental, regulatory and sales-based milestone payments, as well as annually tiered royalties on net sales for any commercialized licensed product. Orion retained responsibility for the manufacture of clinical and commercial supply for Merck. No payment was associated with the exercise of the option, which became effective in September of 2024.

In March 2024, Merck acquired Harpoon Therapeutics, Inc. (Harpoon), a clinical-stage immunotherapy company developing a novel class of T-cell engagers designed to harness the power of the body's immune system to treat patients suffering from cancer and other diseases, for $765 million and also incurred $56 million of transaction costs. Harpoon's lead candidate, MK-6070 (formerly HPN328), is a T-cell engager targeting delta-like ligand 3 (DLL3), an inhibitory canonical Notch ligand that is expressed at high levels in small-cell lung cancer (SCLC) and neuroendocrine tumors. MK-6070 is currently being evaluated as monotherapy in a Phase 1/2 clinical trial in certain patients with advanced cancers associated with expression of DLL3. The study is also evaluating MK-6070 in combination with atezolizumab in certain patients with SCLC. The transaction was accounted for as an asset acquisition. Merck recorded net assets of $165 million, as well as a charge of $656 million, or $0.26 per share, to *Research and development* expenses in the first nine months of 2024 related to the transaction. There are no future contingent payments associated with the acquisition. In August 2024, Merck and Daiichi Sankyo expanded their existing global co-development and co-commercialization agreement to include MK-6070.

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 2021, the U.S. Congress passed the American Rescue Plan Act, which included a provision that eliminates the statutory cap on rebates drug manufacturers pay to Medicaid beginning in January 2024. Accordingly, manufacturers may have to pay state Medicaid programs more in rebates than they receive on sales of particular products. As a result of this provision, the Company has recognized increased discounts for *Januvia* (sitagliptin) and *Janumet* (sitagliptin and metformin HCl) in the first nine months of 2024. In 2022, the U.S. Congress passed the Inflation Reduction Act (IRA), which made 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* would 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 have now concluded, with government price-setting becoming effective on January 1, 2026. The Company has sued the U.S. government regarding the IRA's Program. Additionally, increased utilization of the 340B Federal Drug Discount Program and restrictions on the Company's ability to identify inappropriate discounts are having a negative impact on Company performance. Furthermore, the Biden Administration and Congress continue to discuss legislation designed to control health care costs, including the cost of drugs. 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 2024 was negatively affected by other cost-reduction measures taken by governments and other third parties to lower health care costs. The Company anticipates all of these actions and additional actions in the future will negatively affect sales and profits.

Operating Results

Sales

	Three Months Ended September 30,			% Change Excluding Foreign Exchange	Nine Months Ended September 30,			% Change Excluding Foreign Exchange
($ in millions)	2024	2023	% Change		2024	2023	% Change	
United States	$ 8,736	$ 7,715	13 %	13 %	$ 24,089	$ 21,393	13 %	13 %
International	7,922	8,247	(4)%	2 %	24,455	24,092	2 %	8 %
Total	$ 16,657	$ 15,962	4 %	7 %	$ 48,544	$ 45,485	7 %	10 %

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

Worldwide sales were $16.7 billion in the third quarter of 2024, representing growth of 4% compared with the third quarter of 2023, or 7% excluding the unfavorable effect of foreign exchange. Approximately 2 percentage points of the negative impact of foreign exchange was due to the devaluation of the Argentine peso, which was largely offset by inflation-related price increases consistent with practice in that market. Global sales growth in the third quarter of 2024 was primarily due to higher sales in the oncology franchise, largely due to strong growth of *Keytruda* (pembrolizumab) and *Welireg* (belzutifan). Also contributing to revenue growth were higher sales in the cardiovascular franchise, largely attributable to the launch of *Winrevair* (sotatercept-csrk), and increased sales in the hospital acute care franchise, reflecting in part strong performance of *Prevymis* (letermovir). Higher sales of animal health products also contributed to revenue growth in the third quarter of 2024. Sales growth in the third quarter of 2024 was partially offset by lower sales in the diabetes franchise attributable to *Januvia* and *Janumet*, and lower sales in the vaccines franchise largely due to combined *Gardasil* (Human Papillomavirus Quadrivalent [Types 6, 11, 16 and 18] Vaccine and Recombinant)*/Gardasil* 9 (Human Papillomavirus 9-valent Vaccine, Recombinant) sales. Lower sales in the virology franchise largely due to *Lagevrio* (molnupiravir) also partially offset revenue growth in the third quarter of 2024.

Worldwide sales were $48.5 billion in the first nine months of 2024, an increase of 7% compared with the same period of 2023, or 10% excluding the unfavorable effect of foreign exchange. Approximately 2 percentage points of the negative impact of foreign exchange was due to the devaluation of the Argentine peso, which was largely offset by inflation-related price increases consistent with practice in that market. Global sales growth in the first nine months of 2024 was primarily due to higher sales in the oncology franchise largely due to *Keytruda* and *Welireg*, higher sales in the cardiovascular franchise largely attributable to the launch of *Winrevair*, and increased sales in the vaccines franchise, reflecting continued uptake of *Vaxneuvance* (Pneumococcal 15-valent Conjugate Vaccine) for pediatric use. Also contributing to revenue growth in the first nine months of 2024 were higher sales of animal health products. Revenue growth in the first nine months of 2024 was partially offset by lower sales in the diabetes franchise attributable to *Januvia* and *Janumet*, as well as lower sales in the virology franchise largely due to *Lagevrio*.

See Note 15 to the condensed consolidated financial statements for details on sales of the Company's products. A discussion of performance for select products in the franchises follows. All product or service marks appearing in type form different from that of the surrounding text are trademarks or service marks owned, licensed to, promoted or distributed by Merck, its subsidiaries or affiliates, except as noted. All other trademarks or service marks are those of their respective owners.

Pharmaceutical Segment

Oncology

($ in millions)	Three Months Ended September 30, 2024	2023	% Change	% Change Excluding Foreign Exchange	Nine Months Ended September 30, 2024	2023	% Change	% Change Excluding Foreign Exchange
Keytruda	$ 7,429	$ 6,338	17 %	21 %	$ 21,646	$ 18,403	18 %	22 %
Alliance Revenue - Lynparza [(1)]	337	299	13 %	13 %	947	884	7 %	8 %
Alliance Revenue - Lenvima [(1)]	251	260	(3)%	(4)%	755	734	3 %	3 %
Welireg	139	54	*	*	349	146	*	*
Alliance Revenue - Reblozyl [(2)]	100	52	91 %	91 %	261	142	84 %	84 %

** > 100%*

[(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 to the condensed consolidated financial statements).*

[(2)] *Alliance revenue for Reblozyl represents royalties (see Note 3 to the condensed consolidated financial statements).*

Keytruda is an anti-PD-1 (programmed death receptor-1) therapy that has been approved in over 40 indications in the U.S., including 18 tumor types and 2 tumor-agnostic indications, and has similarly been approved in markets worldwide for many of these indications. 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% in the third quarter of 2024 and rose 18% in the first nine months of 2024, or 21% and 22%, respectively, excluding the unfavorable effect of foreign exchange. Approximately 3 percentage points and 4 percentage points of the negative impact of foreign exchange in the third quarter and first nine months of 2024, respectively, was due to the devaluation of the Argentine peso, which was largely offset by inflation-related price increases consistent with practice in that market. *Keytruda* sales growth in the U.S. reflects increased uptake across earlier-stage indications, including in certain types of non-small-cell lung cancer (NSCLC), high-risk early-stage triple-negative breast cancer (TNBC), and certain types of renal cell carcinoma (RCC), as well as higher demand across the multiple approved metastatic indications, in particular for the treatment of certain types of urothelial, endometrial, and head and neck cancers, and higher pricing. *Keytruda* sales growth in international markets reflects higher demand predominately for the TNBC, melanoma and RCC earlier-stage indications, as well as uptake in cervical, gastric and renal cancer metastatic indications, particularly in Europe and Latin America.

Keytruda has received the following regulatory approvals thus far in 2024.

Date	Approval
January 2024	U.S. Food and Drug Administration (FDA) approval in combination with chemoradiotherapy for the treatment of patients with FIGO (International Federation of Gynecology and Obstetrics) 2014 Stage III-IVA cervical cancer, based on the KEYNOTE-A18 trial.
January 2024	FDA full approval for the treatment of patients with hepatocellular carcinoma (HCC) secondary to hepatitis B who have received prior systemic therapy other than a PD-1/PD-L1 containing regimen. The conversion from an accelerated to full (regular) approval is based on the KEYNOTE-394 trial.
February 2024	China's National Medical Products Administration (NMPA) approval in combination with gemcitabine and cisplatin for the first-line treatment of patients with locally advanced or metastatic biliary tract carcinoma, based on the KEYNOTE-966 trial.
March 2024	European Commission (EC) approval in combination with platinum-containing chemotherapy as neoadjuvant treatment, and then continued as monotherapy as adjuvant treatment, for resectable NSCLC at high risk of recurrence in adults, based on the KEYNOTE-671 trial.
May 2024	Japan's Ministry of Health, Labor and Welfare (MHLW) approval in combination with fluoropyrimidine- and platinum-containing chemotherapy for the first-line treatment of patients with locally advanced unresectable or metastatic gastric or gastroesophageal junction (GEJ) adenocarcinoma, based on the KEYNOTE-859 trial.
May 2024	Japan's MHLW approval 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 the KEYNOTE-966 trial.
June 2024	FDA approval in combination with carboplatin and paclitaxel, followed by *Keytruda* as a single agent, for the treatment of adult patients with primary advanced or recurrent endometrial carcinoma, based on the KEYNOTE-868 trial.
June 2024	China's NMPA approval in combination with trastuzumab, fluoropyrimidine- and platinum-containing chemotherapy for the first-line treatment of patients with locally advanced unresectable or metastatic human epidermal growth factor receptor 2 (HER2) positive gastric or GEJ adenocarcinoma whose tumors express PD-L1 as determined by a fully validated test, based on the KEYNOTE-811 trial.
September 2024	EC approval in combination with Padcev (enfortumab vedotin-ejfv), an antibody-drug conjugate, for the first-line treatment of unresectable or metastatic urothelial carcinoma in adults, based on the KEYNOTE-A39 trial that was conducted in collaboration with Seagen (now Pfizer Inc.) and Astellas.
September 2024	FDA approval in combination with pemetrexed and platinum chemotherapy for the first-line treatment of adult patients with unresectable advanced or metastatic malignant pleural mesothelioma based on the IND.227/ KEYNOTE-483 trial.

September 2024	Japan's MHLW approval in combination with chemotherapy as a neoadjuvant treatment, then continued as monotherapy as an adjuvant treatment, for patients with NSCLC based on the KEYNOTE-671 trial.
September 2024	Japan's MHLW approval in combination with Padcev for the first-line treatment of patients with radically unresectable urothelial carcinoma based on the KEYNOTE-A39 trial.
September 2024	Japan's MHLW approval as monotherapy in patients with radically unresectable urothelial carcinoma who are not eligible for any platinum-containing chemotherapy based on the KEYNOTE-052 trial.
September 2024	China's NMPA approval for the first-line treatment of adult patients with unresectable or metastatic melanoma, and conversion from conditional to full approval for the second-line treatment of adult patients with unresectable or metastatic melanoma following failure of one prior line of therapy, based on the LEAP-003 trial.
October 2024	EC approval in combination with chemoradiotherapy for the treatment of FIGO 2014 Stage III-IVA locally advanced cervical cancer in adults who have not received prior definitive therapy, based on the KEYNOTE-A18 trial.
October 2024	EC approval in combination with carboplatin and paclitaxel followed by *Keytruda* as a single agent for the first-line treatment of primary advanced or recurrent endometrial carcinoma in adults who are candidates for systemic therapy, based on the KEYNOTE-868 trial.

The Company is a party to certain third-party license agreements pursuant to which the Company pays royalties on sales of *Keytruda*. Under the terms of the more significant of these agreements, Merck paid a royalty of 6.5% on worldwide sales of *Keytruda* through December 2023 to one third party; this royalty declined to 2.5% in 2024 and will continue through 2026, terminating thereafter. The Company pays an additional 2% royalty on worldwide sales of *Keytruda* to another third party, the termination date of which varies by country; this royalty expired in the U.S. in September 2024 and will expire on varying dates in major European markets in the second half of 2025. The royalty expenses are included in *Cost of sales*.

Lynparza (olaparib) is an oral poly (ADP-ribose) polymerase (PARP) inhibitor being developed as part of a collaboration with AstraZeneca PLC (AstraZeneca) (see Note 3 to the condensed consolidated financial statements). Lynparza is approved for the treatment of certain types of advanced or recurrent ovarian, early or metastatic breast, metastatic pancreatic and metastatic castration-resistant prostate cancers. Alliance revenue related to Lynparza increased 13% and 7% in the third quarter and first nine months of 2024, respectively, primarily due to higher global demand.

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 declined 3% in the third quarter of 2024 primarily reflecting the timing of sales in China in the prior year, partially offset by higher demand in the U.S. Alliance revenue related to Lenvima grew 3% in the first nine months of 2024 primarily reflecting higher demand and pricing in the U.S., partially offset by the timing of sales in China in the prior year.

Sales of *Welireg*, for the treatment of adult patients with certain von Hippel-Lindau (VHL) disease-associated tumors and certain adult patients with previously treated advanced RCC, more than doubled in both the third quarter and first nine months of 2024. Sales growth in both periods was primarily due to higher demand in the U.S. largely attributable to the continued uptake of a new indication for previously treated advanced RCC following approval by the FDA in December 2023. *Welireg* is under review in the European Union (EU) and Japan both for the treatment of previously treated advanced RCC based on the LITESPARK-005 clinical trial and for the treatment of VHL disease based on the LITESPARK-004 clinical trial.

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 (consisting of royalties) increased 91% and 84% in the third quarter and first nine months of 2024, respectively, due to strong underlying sales performance.

Vaccines

($ in millions)	Three Months Ended September 30, 2024	2023	% Change	% Change Excluding Foreign Exchange	Nine Months Ended September 30, 2024	2023	% Change	% Change Excluding Foreign Exchange
Gardasil/Gardasil 9	$ 2,306	$ 2,585	(11)%	(10)%	$ 7,032	$ 7,015	— %	3 %
ProQuad	274	267	3 %	3 %	717	678	6 %	6 %
M-M-R II	129	122	5 %	6 %	346	329	5 %	6 %
Varivax	301	325	(7)%	(7)%	828	816	2 %	2 %
Vaxneuvance	239	214	12 %	13 %	647	488	33 %	34 %
RotaTeq	193	156	24 %	25 %	572	584	(2)%	(1)%
Pneumovax 23	68	140	(51)%	(51)%	188	327	(42)%	(40)%

Combined worldwide sales of *Gardasil* and *Gardasil* 9, vaccines to help prevent certain cancers and other diseases caused by certain types of human papillomavirus (HPV), declined 11% in the third quarter of 2024 primarily driven by lower demand in China, partially offset by higher sales in the U.S. due to public sector buying patterns, higher pricing and demand, as well as higher demand in most international regions. Combined worldwide sales of *Gardasil* and *Gardasil* 9 were nearly flat in the

first nine months of 2024 primarily due to higher sales in the U.S. reflecting public sector buying patterns, higher pricing and demand, as well as higher demand in most international regions, offset by lower demand in China. In the second quarter of 2024, the Company observed a significant decline in shipments from its distributor and commercialization partner in China, Zhifei Biological Products Co., Ltd. (Zhifei), to disease and control prevention institutions and correspondingly into the points of vaccination compared with prior quarters, resulting in above normal inventory levels in China. This lower level of Zhifei shipments continued in the third quarter of 2024. Accordingly, the Company will ship less than its full year 2024 contracted doses to Zhifei and combined sales of *Gardasil/Gardasil* 9 in China will decline in 2024 compared with 2023, and such sales are also expected to decline in 2025 compared with 2024.

The Company is a party to certain third-party license agreements pursuant to which the Company pays royalties on sales of *Gardasil/Gardasil* 9. Under the terms of the more significant of these agreements, Merck pays a 7% royalty on sales of *Gardasil/Gardasil* 9 in the U.S. to one third party (this royalty expires in December 2028); Merck paid an additional 7% royalty on worldwide sales of *Gardasil/Gardasil* 9 to another third party, which expired in December 2023. The royalty expenses are included in *Cost of sales*.

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, grew 3% and 6% in the third quarter and first nine months of 2024, respectively, 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 prevent measles, mumps and rubella, grew 5% in both the third quarter and first nine months of 2024 largely reflecting timing of tenders in certain international markets, partially offset by lower demand and pricing in the U.S.

Global sales of *Varivax* (Varicella Virus Vaccine Live), a vaccine to help prevent chickenpox (varicella), declined 7% in the third quarter of 2024 primarily attributable to the timing of sales in Latin America. Global sales of *Varivax* grew 2% in the first nine months of 2024 primarily due to higher pricing in the U.S., partially offset by the timing of sales in Latin America.

Worldwide sales of *Vaxneuvance*, a vaccine to help protect against invasive pneumococcal disease, grew 12% and 33% in the third quarter and first nine months of 2024, respectively, primarily reflecting continued uptake following launches in the pediatric indication in Europe, Japan, and other countries in the Asia Pacific region. Lower demand in the U.S. due to competition partially offset *Vaxneuvance* sales growth in both periods.

Global sales of *RotaTeq* (Rotavirus Vaccine, Live Oral, Pentavalent), a vaccine to help protect against rotavirus gastroenteritis in infants and children, grew 24% in the third quarter of 2024 largely due to the beneficial impact of public sector buying patterns in the U.S. coupled with the timing of sales in China. Worldwide sales of *RotaTeq* declined 2% in the first nine months of 2024 primarily due to lower tenders in Europe and the timing of sales in China. The sales decline in the year-to-date period was partially offset by higher sales in the U.S. due to public sector buying patterns and higher pricing, offset in part by lower demand.

Worldwide sales of *Pneumovax* 23 (pneumococcal vaccine polyvalent), a vaccine to help prevent pneumococcal disease, declined 51% and 42% in the third quarter and first nine months of 2024, respectively, driven by lower global demand, particularly in the U.S. as the market has shifted toward newer adult pneumococcal conjugate vaccines.

In June 2024, the FDA approved *Capvaxive* (Pneumococcal 21-valent Conjugate Vaccine) for the prevention of invasive pneumococcal disease and pneumococcal pneumonia in individuals 18 years of age and older. The approval was supported by results from multiple Phase 3 clinical studies evaluating *Capvaxive* in both vaccine-naïve and vaccine-experienced adult patient populations, including STRIDE-3, STRIDE-4, STRIDE-5 and STRIDE-6. In June 2024, the U.S. Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) unanimously voted to recommend *Capvaxive* as an option for adults age 65 and older, among other cohorts, for pneumococcal vaccination. In October 2024, the CDC's ACIP voted to update the adult age-based pneumococcal vaccination guidelines and recommended *Capvaxive* for pneumococcal vaccination in adults 50 years of age and older. These provisional recommendations were adopted by the CDC director and are now official. Merck is a party to certain third-party license agreements pursuant to which the Company pays royalties on sales of *Capvaxive*. Under the more significant of these agreements, Merck pays a royalty of 7.25% on net sales of *Capvaxive* through 2026; this royalty will decline to 2.5% on net sales from 2027 through 2035.

Hospital Acute Care

	Three Months Ended September 30,				Nine Months Ended September 30,			
($ in millions)	2024	2023	% Change	% Change Excluding Foreign Exchange	2024	2023	% Change	% Change Excluding Foreign Exchange
Bridion	$ 420	$ 424	(1)%	— %	$ 1,315	$ 1,413	(7)%	(6)%
Prevymis	208	157	32 %	36 %	570	430	33 %	36 %

Worldwide sales of *Bridion* (sugammadex), for the reversal of two types of neuromuscular blocking agents used during surgery, declined 1% and 7% in the third quarter and first nine months of 2024, respectively, primarily driven by lower demand in certain international markets due to generic competition, particularly in the EU and the Asia Pacific region including in Japan, largely offset by higher demand and pricing in the U.S. The patents that provided market exclusivity for *Bridion* in the EU and Japan expired in July 2023 and January 2024, respectively. Accordingly, the Company is experiencing sales declines of *Bridion* in these markets and expects the declines to continue.

Worldwide sales of *Prevymis*, a medicine for prophylaxis (prevention) of cytomegalovirus (CMV) infection and disease in certain high risk adult and pediatric recipients of an allogenic hematopoietic stem cell transplant and for prophylaxis of CMV disease in certain high risk adult and pediatric recipients of a kidney transplant, grew 32% and 33% in the third quarter and first nine months of 2024, respectively, largely due to higher global demand, particularly in the U.S., China, Europe and Japan.

Cardiovascular

($ in millions)	Three Months Ended September 30, 2024	2023	% Change	% Change Excluding Foreign Exchange	Nine Months Ended September 30, 2024	2023	% Change	% Change Excluding Foreign Exchange
Alliance Revenue - Adempas/ Verquvo [1]	$ 102	$ 92	11 %	11 %	$ 306	$ 259	18 %	18 %
Adempas	72	65	11 %	13 %	214	189	13 %	15 %
Winrevair	149	—	—	—	219	—	—	—

[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 (PH). 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. Alliance revenue from the collaboration grew 11% and 18% in the third quarter and first nine months of 2024, respectively, primarily due to higher demand in Bayer's marketing territories. Revenue also includes sales of Adempas and Verquvo in Merck's marketing territories. Sales of Adempas in Merck's marketing territories grew 11% and 13% in the third quarter and first nine months of 2024, respectively, primarily due to higher demand.

In March 2024, the FDA approved *Winrevair* for the treatment of adults with PAH (World Health Organization [WHO] Group 1) to increase exercise capacity, improve WHO functional class (FC), and reduce the risk of clinical worsening events. In August 2024, the EC approved *Winrevair*, in combination with other PAH therapies, for the treatment of PAH in adult patients with WHO FC II to III, to improve exercise capacity. The FDA and EC approvals were based on the STELLAR trial. *Winrevair* has since launched in Germany. Timing for commercial availability of *Winrevair* in the remaining EU countries will depend on multiple factors, including the completion of national reimbursement procedures, which should occur in most other major EU markets in the second half of 2025. Additional worldwide regulatory filings for *Winrevair* are underway. *Winrevair* is the subject of a licensing agreement with BMS pursuant to which Merck pays a 22% royalty on sales of *Winrevair* to BMS. The royalty expenses are included in *Cost of sales*.

Virology

($ in millions)	Three Months Ended September 30, 2024	2023	% Change	% Change Excluding Foreign Exchange	Nine Months Ended September 30, 2024	2023	% Change	% Change Excluding Foreign Exchange
Lagevrio	$ 383	$ 640	(40)%	(36)%	$ 843	$ 1,236	(32)%	(27)%

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). Sales of *Lagevrio* declined 40% in the third quarter of 2024 primarily due to lower demand and pricing in Japan, partially offset by uptake from commercial distribution in the U.S. Sales of *Lagevrio* declined 32% in the first nine months of 2024 primarily due to lower demand and pricing in several markets in the Asia Pacific region, particularly in Japan and China, partially offset by uptake from commercial distribution in the U.S.

Immunology

($ in millions)	Three Months Ended September 30, 2024	2023	% Change	% Change Excluding Foreign Exchange	Nine Months Ended September 30, 2024	2023	% Change	% Change Excluding Foreign Exchange
Simponi	$ 189	$ 179	5 %	7 %	$ 545	$ 539	1 %	2 %
Remicade	41	45	(9)%	(5)%	115	144	(20)%	(16)%

Simponi (golimumab) and *Remicade* (infliximab) are treatments for certain inflammatory diseases that the Company marketed in Europe, Russia and Türkiye. The Company's marketing rights with respect to these products reverted to Johnson & Johnson Innovative Medicine on October 1, 2024.

Diabetes

($ in millions)	Three Months Ended September 30, 2024	2023	% Change	% Change Excluding Foreign Exchange	Nine Months Ended September 30, 2024	2023	% Change	% Change Excluding Foreign Exchange
Januvia/Janumet	$ 482	$ 835	(42)%	(38)%	$ 1,781	$ 2,579	(31)%	(27)%

Worldwide combined sales of *Januvia* and *Janumet*, medicines that help lower blood sugar levels in adults with type 2 diabetes, declined 42% and 31% in the third quarter and first nine months of 2024, respectively, primarily due to lower sales in the U.S., largely reflecting lower pricing and lower demand due to competitive pressures, as well as the ongoing impact of the loss of exclusivity in most markets in Europe and the Asia Pacific region, as well as in Canada.

The American Rescue Plan Act enacted in the U.S. in 2021 included a provision that eliminated the statutory cap on rebates drug manufacturers pay to Medicaid beginning in January 2024. Accordingly, manufacturers may have to pay state Medicaid programs more in rebates than they receive on sales of particular products. As a result of this provision, the Company has recognized increased discounts for *Januvia* and *Janumet* in the first nine months of 2024. In August 2023, the U.S. Department of HHS, through the CMS, announced that *Januvia* would be included in the first year of the IRA's Program. Pursuant to the IRA's Program, discussions with the government have now concluded, with government price-setting becoming effective on January 1, 2026. The Company has sued the U.S. government regarding the IRA's Program.

While the key U.S. patent for *Januvia* and *Janumet* claiming the sitagliptin compound expired in January 2023, as a result of favorable court rulings and settlement agreements related to a later expiring patent directed to the specific sitagliptin salt form of the products (see Note 8 to the condensed consolidated financial statements), the Company expects that *Januvia* and *Janumet* will not lose market exclusivity in the U.S. until May 2026 and *Janumet XR* will not lose market exclusivity in the U.S. until July 2026, although a non-automatically substitutable form of sitagliptin that differs from the form in the Company's sitagliptin products has been approved by the FDA. The Company anticipates pricing and volume declines for *Januvia* and *Janumet* in the U.S. for the remainder of 2024.

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. Generic equivalents of *Januvia* and *Janumet* have also launched in China.

Animal Health Segment

($ in millions)	Three Months Ended September 30, 2024	2023	% Change	% Change Excluding Foreign Exchange	Nine Months Ended September 30, 2024	2023	% Change	% Change Excluding Foreign Exchange
Livestock	$ 886	$ 874	1 %	7 %	$ 2,573	$ 2,530	2 %	7 %
Companion Animal	601	526	14 %	17 %	1,907	1,817	5 %	7 %
	$ 1,487	$ 1,400	6 %	11 %	$ 4,480	$ 4,347	3 %	7 %

Animal Health sales grew 6% in the third quarter of 2024, or 11% excluding the unfavorable effect of foreign exchange, and increased 3% in the first nine months of 2024, or 7% excluding the unfavorable effect of foreign exchange. Approximately 2 percentage points and 3 percentage points of the negative impact of foreign exchange in the third quarter and first nine months of 2024, respectively, was due to the devaluation of the Argentine peso, which was largely offset by inflation-related price increases consistent with practice in that market.

Sales of livestock products grew 1% and 2% in the third quarter and first nine months of 2024, respectively, primarily due to higher pricing, increased demand for poultry and swine products, as well as the inclusion of sales from the July 2024 acquisition of the Elanco aqua business. Lower sales of ruminant products due to timing partially offset livestock sales growth in both the third quarter and first nine months of 2024.

Sales of companion animal products grew 14% in the third quarter of 2024 primarily due to uptake from new product launches, including the injectable formulation of *Bravecto* (fluralaner) in certain international markets, as well as higher pricing across the product portfolio. Sales of companion animal products grew 5% in the first nine months of 2024 primarily due to higher pricing. Sales of *Bravecto*, a line of oral, topical and injectable parasitic control products, were $266 million for the third quarter of 2024, representing growth of 13% compared with the third quarter of 2023, or 16% excluding the unfavorable effect of foreign exchange. Sales of *Bravecto* were $929 million for the first nine months of 2024, representing growth of 6% compared with the corresponding prior year period, or 8% excluding the unfavorable effect of foreign exchange.

Costs, Expenses and Other

($ in millions)	Three Months Ended September 30, 2024	2023	% Change	Nine Months Ended September 30, 2024	2023	% Change
Cost of sales	$ 4,080	$ 4,264	(4)%	$ 11,365	$ 12,214	(7)%
Selling, general and administrative	2,731	2,519	8 %	7,952	7,700	3 %
Research and development	5,862	3,307	77 %	13,354	20,904	(36)%
Restructuring costs	56	126	(56)%	258	344	(25)%
Other (income) expense, net	(162)	126	*	(151)	388	*
	$ 12,567	$ 10,342	22 %	$ 32,778	$ 41,550	(21)%

**>100%*

Cost of Sales

Cost of sales declined 4% and 7% in the third quarter and first nine months of 2024, respectively. *Cost of sales* includes the amortization of intangible assets recorded in connection with acquisitions, collaborations, and licensing arrangements, which totaled $625 million and $552 million in the third quarter of 2024 and 2023, respectively, and $1.7 billion and $1.6 billion in the first nine months of 2024 and 2023, respectively. Amortization expense in the third quarter and first nine months of 2023 includes $81 million and $154 million, respectively, of cumulative catch-up amortization related to Merck's collaboration with Eisai. 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 $192 million and $33 million in the third quarter of 2024 and 2023, respectively, and $374 million and $94 million in the first nine months of 2024 and 2023, respectively, primarily reflecting accelerated depreciation and asset impairments 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 75.5% in the third quarter of 2024 compared with 73.3% in the third quarter of 2023. Gross margin was 76.6% in the first nine months of 2024 compared with 73.1% in the first nine months of 2023. The gross margin improvement in both periods was primarily due to the favorable effect of product mix (including lower royalty rates related to *Keytruda* and *Gardasil/Gardasil 9* sales), partially offset by higher restructuring costs (primarily reflecting asset impairment charges), as well as increased amortization of intangible assets.

Selling, General and Administrative

Selling, general and administrative (SG&A) expenses increased 8% and 3% in the third quarter and first nine months of 2024, respectively, primarily due to higher administrative, selling, promotional and acquisition-related costs, partially offset by the favorable effect of foreign exchange and lower restructuring costs.

Research and Development

Research and development (R&D) expenses grew 77% in the third quarter of 2024 primarily due to higher charges related to business development transactions, which included charges of $1.35 billion for the acquisition of EyeBio and $100 million for a related developmental milestone, as well as $750 million for the acquisition of MK-1045 (formerly CN201) from Curon. Also contributing to the increase in R&D expenses in the third quarter of 2024 were higher compensation and benefit costs, as well as higher clinical development spending. The increase in R&D expenses in the third quarter of 2024 was partially offset by the favorable effect of foreign exchange.

R&D expenses declined 36% in the first nine months 2024 primarily due to lower charges related business development transactions, which in 2024 included charges of $1.35 billion for the acquisition of EyeBio and $100 million for a related developmental milestone, $750 million for the acquisition of MK-1045, as well as $656 million for the acquisition of Harpoon, compared with charges in 2023 of $10.2 billion for the acquisition of Prometheus Biosciences, Inc. (Prometheus), $1.2 billion for the acquisition of Imago BioSciences, Inc. (Imago) and $175 million for a license and collaboration agreement with Kelun-Biotech. The favorable effect of foreign exchange also contributed to the decline in R&D expenses in the first nine months of 2024. The decline in R&D expenses in the first nine months of 2024 was partially offset by increased clinical development spending, as well as higher compensation and benefit costs.

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 $2.5 billion and $2.3 billion for the third quarter of 2024 and 2023, respectively, and $7.4 billion and $6.6 billion for the first nine months of 2024 and 2023, respectively. Also included in R&D expenses are Animal Health research costs, upfront payments for collaboration and licensing agreements, charges for transactions accounted for as asset acquisitions (including charges for the acquisitions of EyeBio, MK-1045, Harpoon, Prometheus and Imago as noted above), and costs incurred by other divisions in support of R&D activities, including depreciation, production and general and administrative, which in the aggregate were $3.3 billion and $1.0 billion for the third quarter of 2024 and 2023, respectively, and $5.9 billion and $14.3 billion for the first nine months of 2024 and 2023, respectively.

Restructuring Costs

In January 2024, the Company approved a new restructuring program (2024 Restructuring Program) intended to continue the optimization of the Company's Human Health global manufacturing network as the future pipeline shifts to new modalities and also optimize the Animal Health global manufacturing network to improve supply reliability and increase efficiency. The actions contemplated under the 2024 Restructuring Program are expected to be substantially completed by the end of 2031, with the cumulative pretax costs to be incurred by the Company to implement the program estimated to be approximately $4.0 billion. Approximately 60% of the cumulative pretax costs will be non-cash, relating primarily to the accelerated depreciation of facilities to be closed or divested. The remainder of the costs will result in cash outlays, relating primarily to facility shut-down costs. The Company expects to record charges of approximately $900 million in 2024 related to the 2024 Restructuring Program. The Company anticipates the actions under the 2024 Restructuring Program will result in cumulative annual net cost savings of approximately $750 million by the end of 2031.

In 2019, Merck approved a global restructuring program (2019 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 under the 2019 Restructuring Program were substantially complete at the end of 2023 and, as of January 1, 2024, any remaining activities are being accounted for as part of the 2024 Restructuring Program.

Restructuring costs, primarily representing separation and other costs associated with these restructuring activities, were $56 million and $126 million for the third quarter of 2024 and 2023, respectively, and $258 million and $344 million for the first nine months of 2024 and 2023, 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. Other expenses in *Restructuring costs* include 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 $279 million and $199 million in the third quarter of 2024 and 2023, respectively, and $701 million and $532 million for the first nine months of 2024 and 2023, respectively, related to restructuring program activities (see Note 4 to the condensed consolidated financial statements).

Other (Income) Expense, Net

Other (income) expense, net was $162 million of income in the third quarter of 2024 compared with $126 million of expense in the third quarter of 2023 primarily due to the receipt of a $170 million upfront payment from Daiichi Sankyo in 2024 related to the expansion of the existing development and commercialization agreement. The favorability in *Other (income) expense, net* in the third quarter of 2024 also reflects lower exchange losses and lower net interest expense in 2024. *Other (income) expense, net* was $151 million of income in the first nine months of 2024 compared with $388 million of expense in the first nine months of 2023. The favorability was primarily due to a $572.5 million charge in 2023 related to settlements with certain plaintiffs in the Zetia antitrust litigation and the receipt of an upfront payment in 2024 from Daiichi Sankyo as noted above, partially offset by higher net interest expense in 2024.

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

Segment Profits

	Three Months Ended September 30,		Nine Months Ended September 30,	
($ in millions)	2024	2023	2024	2023
Pharmaceutical segment profits	$ 11,547	$ 10,407	$ 33,651	$ 29,400
Animal Health segment profits	510	421	1,574	1,453
Other	(7,967)	(5,208)	(19,459)	(26,918)
Income Before Taxes	$ 4,090	$ 5,620	$ 15,766	$ 3,935

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 not directly incurred by the segments, 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 11% and 14% in the third quarter and first nine months of 2024, 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 rose 21% and 8% in the third quarter and first nine months of 2024, respectively, primarily due to higher sales and lower manufacturing-related costs, partially offset by increased administrative and promotional costs, as well as the unfavorable effect of foreign exchange.

Taxes on Income

The effective income tax rate of 22.7% for the third quarter of 2024 reflects a 7.2 percentage point combined unfavorable impact of charges related to the acquisitions of EyeBio and MK-1045, which had minimal tax benefits. The effective income tax rate of 15.1% for the first nine months of 2024 reflects a 2.1 percentage point combined unfavorable impact of charges related to the acquisitions of Harpoon, EyeBio and MK-1045, which had minimal tax benefits. The effective income tax rate for the first nine months of 2024 also reflects a 1.6 percentage point favorable impact due to a $259 million reduction in reserves for unrecognized income tax benefits resulting from the expiration in June 2024 of the statute of limitations for assessments related to the 2019 federal tax return year.

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 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. The statute of limitations for assessments with respect to the 2019 and 2020 federal tax return years expired in June 2024 (as noted above) and October 2024, respectively. Merck expects to record a benefit of approximately $270 million in the fourth quarter of 2024 due to a reduction in reserves for unrecognized tax benefits resulting from the expiration of the statute of limitations related to the 2020 federal tax return year.

While many jurisdictions in which Merck operates have adopted the global minimum tax provision of the Organisation for Economic Co-operation and Development (OECD) Pillar 2, effective for tax years beginning in January 2024, the Company anticipates there will be a reduced impact to its 2024 tax rate due to the accounting for the tax effects of intercompany transactions. The Company expects the impact of the global minimum tax will increase its tax rate to a greater extent in 2025 and thereafter. Also, in the event that the provision of the TCJA requiring capitalization and amortization of R&D expenses for tax purposes is repealed along the lines proposed in the Tax Relief for American Families and Workers Act of 2024, the Company will again be able to realize the benefit of U.S. R&D expenses as incurred but expects no material impact to its effective income tax rate.

Non-GAAP Income and Non-GAAP EPS

Non-GAAP income and non-GAAP earnings per share (EPS) are alternative views of the Company’s performance that Merck is providing because management believes this information enhances investors’ understanding of the Company’s results since management uses non-GAAP measures to assess performance. Non-GAAP 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, annual employee compensation, including senior management’s 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, 2024	Three Months Ended September 30, 2023	Nine Months Ended September 30, 2024	Nine Months Ended September 30, 2023
Income before taxes as reported under GAAP	$ 4,090	$ 5,620	$15,766	$ 3,935
Increase (decrease) for excluded items:				
Acquisition- and divestiture-related costs	679	555	1,808	1,643
Restructuring costs	279	199	701	532
Loss (income) from investments in equity securities, net	58	17	(107)	(218)
Other items:				
Charge for Zetia antitrust litigation settlements	—	—	—	573
Non-GAAP income before taxes	5,106	6,391	18,168	6,465
Income tax provision as reported under GAAP	929	870	2,377	2,332
Estimated tax benefit on excluded items [1]	188	89	445	350
Tax benefit resulting from the expiration of the statute of limitations for assessments related to the 2019 federal tax return year	—	—	259	—
Non-GAAP income tax provision	1,117	959	3,081	2,682
Non-GAAP net income	3,989	5,432	15,087	3,783
Less: Net income attributable to noncontrolling interests as reported under GAAP	4	5	15	12
Non-GAAP net income attributable to Merck & Co., Inc.	$ 3,985	$ 5,427	$15,072	$ 3,771
EPS assuming dilution as reported under GAAP [2]	$ 1.24	$ 1.86	$ 5.26	$ 0.62
EPS difference	0.33	0.27	0.67	0.86
Non-GAAP EPS assuming dilution [2]	$ 1.57	$ 2.13	$ 5.93	$ 1.48

[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 third quarter of 2024 by $0.79 per share, and for the first nine months of 2024 and 2023 by $1.05 per share and $4.52 per share, respectively, of net charges for certain upfront payments and receipts related to collaborations and licensing agreements, as well as charges related to pre-approval assets (including milestone payments) 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, 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 4 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 impairment, 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 items 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 2024 is a benefit due to a reduction in reserves for unrecognized income tax benefits resulting from the expiration of the statute of limitations for assessments related to the 2019 federal tax return year. 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.

Research and Development Update

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

MK-1022, patritumab deruxtecan, is a potential first-in-class HER3 directed DXd antibody drug conjugate (ADC), under review by the FDA for the treatment of adult patients with locally advanced or metastatic EGFR-mutated NSCLC previously treated with two or more systemic therapies. The Biologics License Application (BLA) is based on the primary results from the HERTHENA-Lung01 pivotal Phase 2 trial and data results presented at the IASLC 2023 World Conference on Lung Cancer, which were simultaneously published in the Journal of Clinical Oncology. In June 2024, the FDA issued a complete response letter (CRL) for the BLA due to findings pertaining to an inspection of a third-party manufacturing facility. The CRL did not identify any issues with the efficacy or safety data submitted. Patritumab deruxtecan (HER3-DXd) was discovered by Daiichi Sankyo and is being jointly developed by Daiichi Sankyo and Merck. Merck is working with Daiichi Sankyo to address FDA feedback.

MK-6482, *Welireg* is under review in the EU and Japan both for the treatment of VHL disease based on the LITESPARK-004 clinical trial and for the treatment of previously treated advanced RCC based on the LITESPARK-005 clinical trial.

V116, *Capvaxive*, the Company's 21-valent pneumococcal conjugate vaccine designed to help prevent invasive pneumococcal disease and pneumococcal pneumonia in adults, is under review in the EU and Japan. The applications are supported by results from multiple Phase 3 clinical studies evaluating V116 in both vaccine-naïve and vaccine-experienced adult patient populations, including STRIDE-3, STRIDE-4, STRIDE-5 and STRIDE-6.

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 studies encompass 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, several of which are currently in Phase 3 clinical development. Further trials are being planned for other cancers.

Keytruda is under review in the EU and Japan for the first-line treatment of adult patients with unresectable advanced or metastatic malignant pleural mesothelioma, based on the Phase 2/3 IND.227/KEYNOTE-483 trial.

Additionally, *Keytruda* is under review in Japan in combination with chemotherapy (carboplatin and paclitaxel), followed by *Keytruda* as a single agent, for the first-line treatment of adult patients with primary advanced or recurrent endometrial carcinoma, based on the KEYNOTE-868 trial.

Keytruda is also under review in Japan in combination with chemoradiotherapy for the treatment of patients with high-risk locally advanced cervical cancer, based on the KEYNOTE-A18 trial.

In July 2024, Merck acquired EyeBio, a privately held ophthalmology-focused biotechnology company. EyeBio's lead candidate, *Restoret* (MK-3000, formerly EYE103), is an investigational, potentially first-in-class tetravalent, tri-specific antibody that acts as an agonist of the Wingless-related integration site signaling pathway, which is in clinical development for the treatment of diabetic macular edema and neovascular age-related macular degeneration.

MK-7264, gefapixant, is a non-narcotic, oral selective P2X3 receptor antagonist for the treatment of refractory or unexplained chronic cough in adults. In December 2023, the FDA issued a second CRL regarding the resubmission of Merck's New Drug Application for gefapixant. In the CRL, the FDA concluded that Merck's application did not meet substantial evidence of effectiveness for treating refractory or unexplained chronic cough. The CRL was not related to the safety of gefapixant. Merck has withdrawn its application for gefapixant from the FDA and does not plan to refile.

The Phase 2b clinical trial for MK-8189 as a monotherapy for acute schizophrenia did not meet its primary efficacy endpoint and further development in schizophrenia, bipolar, and dementia indications has stopped. Potential alternative indications for MK-8189 are being explored.

Merck is currently working to incorporate guidance from regulatory authorities into the Company's clinical trial design for its two prospective *Gardasil* 9 single-dose trials. Consequently, the trials will not be started in 2024. The Company will continue to engage with regulatory authorities along with the broader network of critical stakeholders as its clinical development plan matures.

In August 2024, Merck provided updates on two Phase 3 trials, KEYNOTE-867 and KEYNOTE-630. Merck is discontinuing the KEYNOTE-867 trial evaluating *Keytruda*, in combination with stereotactic body radiotherapy (SBRT) for the treatment of patients with stage I or II (stage IIB N0, M0) NSCLC, including those who are medically inoperable or have refused surgery. This decision is based on the recommendation of an independent Data Monitoring Committee (DMC), which reviewed data from a planned interim analysis. At the pre-specified interim analysis, *Keytruda* in combination with SBRT did not demonstrate an improvement in event-free survival or overall survival, the study's primary endpoint and key secondary endpoint, respectively, compared to placebo plus SBRT, and the benefit/risk profile of the combination did not support continuing the trial. Merck is also discontinuing the KEYNOTE-630 trial evaluating *Keytruda* for the adjuvant treatment of patients with high-risk locally advanced cutaneous squamous cell carcinoma (cSCC) following surgery and radiation, based on the recommendation of an independent DMC. The DMC recommended that the study should be stopped for futility as the risk/benefit profile did not support continuing the trial.

Also in August 2024, Merck announced the discontinuation of the Phase 3 KeyVibe-008 trial based on the recommendation of an independent DMC. The trial was evaluating the investigational fixed-dose combination (coformulation) of vibostolimab, an anti-TIGIT antibody, and pembrolizumab (*Keytruda*) in combination with chemotherapy compared to atezolizumab in combination with chemotherapy, for the first-line treatment of patients with extensive-stage SCLC. At a pre-planned analysis, data showed that the primary endpoint of overall survival met the pre-specified futility criteria. Additionally, when compared to patients in the control arm, patients in the vibostolimab and pembrolizumab fixed-dose combination arm experienced a higher rate of adverse events and immune-related adverse events. A comprehensive analysis of this study is ongoing and Merck will work with investigators to share the results with the scientific community.

In September 2024, Merck announced that the Phase 3 KEYFORM-007 trial evaluating the investigational fixed-dose combination of favezelimab, Merck's anti-LAG-3 antibody, and *Keytruda* did not meet its primary endpoint of overall survival for the treatment of patients with previously treated PD-L1 positive microsatellite stable metastatic colorectal cancer. At the final pre-specified analysis, the favezelimab and pembrolizumab fixed-dose combination did not demonstrate an improvement in overall survival compared to standard of care (regorafenib or TAS-102 [trifluridine and tipiracil hydrochloride]). A full evaluation of the data is ongoing and Merck will work with investigators to share the results with the scientific community.

The chart below reflects the Company's research pipeline as of November 1, 2024. 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-1022 (patritumab deruxtecan)[1]
  - Bladder
  - Cervical
  - Endometrial
  - Esophageal
  - Gastric
  - Head and Neck
  - Melanoma
  - Ovarian
  - Pancreatic
  - Prostate
- MK-1308 (quavonlimab)[2]
  - Non-Small-Cell Lung
- MK-1308A (quavonlimab+pembrolizumab)
  - Colorectal
- MK-2400 (ifinatamab deruxtecan)[1]
  - Biliary
  - Bladder
  - Breast
  - Cervical
  - Colorectal
  - Endometrial
  - Esophageal
  - Head and Neck
  - Ovarian
- MK-2870 (sacituzumab tirumotecan)[1][3]
  - Biliary
  - Colorectal
  - Neoplasm Malignant
  - Pancreatic
- MK-3475 *Keytruda*
  - Advanced Solid Tumors
  - Prostate
- MK-3475A (pembrolizumab+hyaluronidase subcutaneous)
  - Cutaneous Squamous Cell
  - Hematological Malignancies
- MK-4280 (favezelimab)[2]
  - Non-Small-Cell Lung
- MK-4280A (favezelimab+pembrolizumab)
  - Bladder
  - Colorectal
  - Cutaneous Squamous Cell
  - Endometrial
  - Esophageal
  - Melanoma
  - Renal Cell
- MK-5890 (boserolimab)[2]
  - Neoplasm Malignant

Cancer
- MK-5909 (raludotatug deruxtecan)[1]
  - Ovarian
- MK-6482 *Welireg*[3]
  - Endometrial
  - Esophageal
  - Hepatocellular
  - Prostate
  - Rare cancers
- MK-7339 Lynparza[1][3]
  - Advanced Solid Tumors
- MK-7684A (vibostolimab+pembrolizumab)
  - Bladder
  - Colorectal
  - Endometrial
  - Melanoma
  - Ovarian
  - Prostate
  - Renal Cell
- V940[1][2]
  - Bladder
  - Cutaneous Squamous Cell
  - Renal Cell

Dengue Fever Virus Vaccine
- V181

HIV-1 Infection
- MK-8591B (islatravir+MK-8507)[4]

HIV-1 Pre-Exposure Prophylaxis
- MK-8527

Nonalcoholic Steatohepatitis (NASH)
- MK-6024 (efinopegdutide)

Pulmonary Hypertension-Chronic Obstructive Pulmonary Disease
- MK-5475

Pulmonary Hypertension Due To Left Heart Disease
- MK-7962 *Winrevair*

Thrombosis
- MK-2060

Vitiligo
- MK-6194

Phase 3 (Phase 3 entry date)	Under Review	
Antiviral COVID-19 MK-4482 *Lagevrio* (U.S.) (May 2021)[(1)(6)] **Cancer** MK-1022 (patritumab deruxtecan)[(1)] Non-Small-Cell Lung (May 2022) (EU) MK-1026 (nemtabrutinib) Hematological Malignancies (March 2023) MK-1084[(2)] Non-Small-Cell Lung (May 2024) MK-1308A (quavonlimab+pembrolizumab) Renal Cell (April 2021) MK-2140 (zilovertamab vedotin) Hematological Malignancies (September 2024) MK-2400 (ifinatamab deruxtecan)[(1)] Small-Cell Lung (July 2024) MK-2870 (sacituzumab tirumotecan)[(1)(3)] Breast (April 2024) Cervical (July 2024) Endometrial (December 2023) Gastric (May 2024) Non-Small-Cell Lung (November 2023) MK-3475 *Keytruda* Hepatocellular (May 2016) (EU) Ovarian (December 2018) Small-Cell Lung (May 2017) MK-3475A (pembrolizumab+hyaluronidase subcutaneous) Non-Small-Cell Lung (February 2023) MK-3543 (bomedemstat) Myeloproliferative Disorders (December 2023) MK-4280A (favezelimab+pembrolizumab) Hematological Malignancies (October 2022) MK-5684 (opevesostat)[(1)] Prostate (December 2023) MK-7339 Lynparza[(1)(2)] Non-Small-Cell Lung (June 2019) Small-Cell Lung (December 2020) MK-7684A (vibostolimab+pembrolizumab) Non-Small-Cell Lung (April 2021) MK-7902 Lenvima[(1)(2)] Esophageal (July 2021) Gastric (December 2020) V940[(1)(2)] Melanoma (July 2023) Non-Small-Cell Lung (December 2023) **Diabetic Macular Edema** MK-3000 *Restoret*[(7)] **HIV-1 Infection** MK-8591A (doravirine+islatravir) (February 2020)[(5)] MK-8591D (islatravir+lenacapavir) (October 2024)[(1)(5)] **Hypercholesterolemia** MK-0616 (enlicitide decanoate) (August 2023) **Respiratory Syncytial Virus** MK-1654 (clesrovimab) (November 2021) **Ulcerative Colitis** MK-7240 (tulisokibart) (October 2023)	**New Molecular Entities** **Cancer** MK-1022 (patritumab deruxtecan)[(1)(8)] Non-Small-Cell Lung (U.S.) MK-6482 *Welireg* Renal Cell (EU) (JPN) Von Hippel-Lindau (VHL) Disease (EU) (JPN) **Pneumococcal Vaccine Adult** V116 *Capvaxive* (EU) (JPN)	**Certain Supplemental Filings** **Cancer** MK-3475 *Keytruda* • First-Line Unresectable Advanced or Metastatic Malignant Pleural Mesothelioma (KEYNOTE-483) (EU) (JPN) • Primary Advanced or Recurrent Endometrial Carcinoma (KEYNOTE-868) (JPN) • High-Risk Locally Advanced Cervical Cancer (KEYNOTE-A18) (JPN)

Footnotes:

[(1)] Being developed in a collaboration.

[(2)] Being developed in combination with *Keytruda*.

[(3)] Being developed as monotherapy and/or in combination with *Keytruda*.

[(4)] On FDA clinical hold.

[(5)] On FDA partial clinical hold for higher doses than those used in current clinical trials.

[(6)] Available in the U.S. under Emergency Use Authorization.

[(7)] Program is in a Phase 2/3 study that commenced in August 2024.

[(8)] In June 2024, the FDA issued a CRL for the BLA for patritumab deruxtecan. Merck is working with Daiichi Sankyo to address FDA feedback.

Analysis of Liquidity and Capital Resources

($ in millions)	September 30, 2024	December 31, 2023
Cash and investments	$ 15,168	$ 7,345
Working capital	10,775	6,474
Total debt to total liabilities and equity	32.4 %	32.9 %

Cash provided by operating activities was $18.0 billion in the first nine months of 2024 compared with $12.8 billion in the first nine months of 2023 reflecting stronger operating performance. Cash provided by operating activities was reduced by milestone and option payments related to certain collaborations of $370 million and $240 million in the first nine months of 2024 and 2023, 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 $6.3 billion in the first nine months of 2024 compared with $14.1 billion in the first nine months of 2023. The lower use of cash in investing activities was primarily due to lower cash used for acquisitions, lower purchases of securities and other investments, as well as lower capital expenditures, partially offset by lower proceeds from sales of securities and other investments.

Cash used in financing activities was $4.0 billion in the first nine months of 2024 compared with $2.6 billion in the first nine months of 2023. The higher use of cash in financing activities was primarily due to lower proceeds from the issuance of debt

and higher dividends paid to shareholders, partially offset by lower payments on long-term debt, lower purchases of treasury stock and higher proceeds from the exercise of stock options.

The Company has accounts receivable factoring agreements with financial institutions in certain countries to sell accounts receivable. The Company factored $3.1 billion and $3.0 billion of accounts receivable at September 30, 2024 and December 31, 2023, 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 2024, MSD Netherlands Capital B.V., a wholly-owned finance subsidiary of Merck, completed a registered public offering of €3.4 billion in aggregate principal amount of euro-dominated senior notes comprised of €850 million of 3.25% senior notes due 2032, €850 million of 3.50% senior notes due 2037, €850 million of 3.70% senior notes due 2044 and €850 million of 3.75% senior notes due 2054. The net cash proceeds from the offering were used for general corporate purposes.

In March 2024, the Company's $750 million, 2.90% notes matured in accordance with their terms and were repaid.

Dividends paid to stockholders were $5.9 billion and $5.6 billion for the first nine months of 2024 and 2023, respectively. In May 2024, Merck's Board of Directors declared a quarterly dividend of $0.77 per share on the Company's outstanding common stock for the third quarter that was paid in July 2024. In July 2024, Merck's Board of Directors declared a quarterly dividend of $0.77 per share on the Company's outstanding common stock for the fourth quarter that was paid in October 2024.

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. During the first nine months of 2024, the Company purchased $817 million (7 million shares) of its common stock for its treasury under this program. As of September 30, 2024, the Company's remaining share repurchase authorization was $2.9 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, 2023 included in Merck's Form 10-K filed on February 26, 2024. See Note 1 to the condensed consolidated financial statements for information on the adoption of a new accounting standard during 2024. 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 is included 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, 2023.

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 2023 Form 10-K filed on February 26, 2024.

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, 2024, the Company's disclosure controls and procedures are effective. For the third quarter of 2024, 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. 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, 2023, filed on February 26, 2024, the Company discusses in more detail various important risk factors that could cause actual results to differ from expected or historic results. The Company notes these factors for investors as permitted by the Private Securities Litigation Reform Act of 1995. One should understand that it is not possible to predict or identify all such factors. Consequently, the reader should not consider any such list to be a complete statement of all potential risks or uncertainties.

PART II - Other Information

Item 1. Legal Proceedings

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

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

Issuer purchases of equity securities for the three months ended September 30, 2024 were as follows:

ISSUER PURCHASES OF EQUITY SECURITIES

				($ in millions)
Period	Total Number of Shares Purchased [1]	Average Price Paid Per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Approximate Dollar Value of Shares That May Yet Be Purchased Under the Plans or Programs [1]
July 1 - July 31	880,451	$126.08	880,451	$3,217
August 1 - August 31	1,391,425	$114.53	1,391,425	$3,058
September 1 - September 30	1,496,936	$116.19	1,496,936	$2,884
Total	3,768,812	$117.89	3,768,812	

[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, 2024, 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

Number		Description
3.1	—	Restated Certificate of Incorporation of Merck & Co., Inc. (November 3, 2009) – Incorporated by reference to Merck & Co., Inc.'s Current Report on Form 8-K filed on November 4, 2009 (No. 1-6571)
3.2	—	By-Laws of Merck & Co., Inc. (effective March 22, 2022) – Incorporated by reference to Merck & Co., Inc.'s Current Report on Form 8-K filed on March 25, 2022 (No. 1-6571)
31.1	—	Rule 13a – 14(a)/15d – 14(a) Certification of Chief Executive Officer
31.2	—	Rule 13a – 14(a)/15d – 14(a) Certification of Chief Financial Officer
32.1	—	Section 1350 Certification of Chief Executive Officer
32.2	—	Section 1350 Certification of Chief Financial Officer
101.INS	—	XBRL Instance Document - The instance document does not appear in the interactive data file because its XBRL tags are embedded within the Inline XBRL document.
101.SCH	—	XBRL Taxonomy Extension Schema Document.
101.CAL	—	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	—	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	—	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	—	XBRL Taxonomy Extension Presentation Linkbase Document.
104	—	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

Signatures

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

MERCK & CO., INC.

Date: November 6, 2024

/s/ Jennifer Zachary

JENNIFER ZACHARY

Executive Vice President and General Counsel

Date: November 6, 2024

/s/ Dalton Smart

DALTON SMART

Senior Vice President Finance - Global Controller

Exhibit 31.1

CERTIFICATION

I, Robert M. Davis, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 6, 2024

By: /s/ Robert M. Davis

ROBERT M. DAVIS
Chairman, Chief Executive Officer and President

Exhibit 31.2

CERTIFICATION

I, Caroline Litchfield, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 6, 2024

By: /s/ Caroline Litchfield

CAROLINE LITCHFIELD
Executive Vice President, Chief Financial Officer

Exhibit 32.1

Section 1350
Certification of Chief Executive Officer

Pursuant to 18 U.S.C. Section 1350, the undersigned officer of Merck & Co., Inc. (the “Company”), hereby certifies that the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2024 (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 6, 2024

/s/ Robert M. Davis

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

Exhibit 32.2

Section 1350
Certification of Chief Financial Officer

Pursuant to 18 U.S.C. Section 1350, the undersigned officer of Merck & Co., Inc. (the “Company”), hereby certifies that the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2024 (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 6, 2024

/s/ Caroline Litchfield

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