## **UNITED STATES SECURITIES AND EXCHANGE COMMISSION**

FORM 10-Q  OUARTERLY REPORT PURSUANT TO SECTION 13 OR 18(s) OF THE SECURITIES EXCHANGE ACT OF 1934  For the quarterly period ended June 30, 2024  OR  TRANSITION REPORT PURSUANT TO SECTION 13 OR 18(s) OF THE SECURITIES EXCHANGE ACT OF 1934  For the transition period from to		Washington, D.C. 20549	
For the quarterity period ended June 30, 2024  OR  TRANSITION REPORT PURSUANT TO SECTION 13 OR 18(d) OF THE SECURITIES EXCHANGE ACT OF 1934  For the transition period from to  Commission File No. 1-6871  Merck & Co., Inc.  (Exact name of registrant as specified in its charter)  (State or other jurisdiction of incorporation)  (Registrant selection (Proposal executive officials) (IR.S. Employer Identification No.)  (Response of principal executive officials) (IR.S. Employer Identification No.)  (Registrant selection (Proposal executive officials) (IR.S. Employer Identification No.)  (Registrant selection (Proposal executive officials) (IR.S. Employer Identification No.)  (Registrant selection (Proposal executive officials) (IR.S. Employer Identification No.)  (Registrant selection (Proposal executive officials) (IR.S. Employer Identification No.)  (Registrant selection (Proposal executive officials) (IR.S. Employer Identification No.)  (Registrant selection (Proposal executive officials) (IR.S. Employer Identification No.)  (Registrant selection (Proposal executive officials) (IR.S. Employer Identification No.)  (Registrant selection (Proposal executive officials) (IR.S. Employer Identification No.)  (Registrant selection (Proposal executive Officials) (IR.S. Employer Identification No.)  (Registrant selection (Proposal executive Officials) (IR.S. Employer Identification No.)  (Registrant selection (Proposal executive Officials) (IR.S. Employer Identification No.)  (Registrant selection (Proposal executive Officials) (IR.S. Employer Identification No.)  (Registrant selection (Proposal executive Officials) (IR.S. Employer Identification No.)  (Registrant selection (Proposal executive Officials) (IR.S. Employer Identification No.)  (Registrant selection (Proposal executive Officials) (IR.S. Employer Identification No.)  (Registrant selection (Proposal executive		FORM 10-Q	
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For the transition period from to		For the quarterly period ended June 30, 2024	
For the transition period from to		OR	
Commission File No. 1-5571  Merck & Co., Inc.  (Exact name of registrant as specified in its charter)  New Jersey  (State or other jurisdiction of incorporation)  (State or other jurisdiction of incorporation)  126 East Lincoln Avenue  Rahway  New Jersey  (Ragistrant's telephone number, including sure code) (988) 740-4000  Not Applicable  (Registrant's telephone number, including sure code) (988) 740-4000  Not Applicable  (Former name, former address and former fiscal) year, if changed since last report.  127 Securities Registered pursuant to Security (950) of the Act:  128 Common Stock (60.50 par yalue)  129 MRK Now York Stock Exchange on which registered pursuant to Security (950) of the Act:  128 Common Stock (60.50 par yalue)  128 April North Stock Exchange  128 April North Stock Exchange  128 April North Stock Exchange  129 April North Stock Exchange  120 April North Stock Exc	□ тғ	RANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECU	IRITIES EXCHANGE ACT OF 1934
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(Slate or other jurisdiction of incorporation)    Common Stock (\$0.50 par value)   Securities Registered   Securities Register		·	
Table   Tabl	New Jersey	(	22-1918501
Rahway New Jorsey (Address of principal executive blaces) (Izip code)  (Registrant's telephone number, including area code) (908) 740-4000  *******************************	(State or other jurisdiction of incorpo	oration) (I.R.S. Em	ployer Identification No.)
Not Applicable (Former name, former address and former fiscal year, if changed since last report.)    Tatile of each class   Tatile of each class   Tatile of each exchange on which registered		Rahway New Jersey 07065	
Securities Registered pursuant to Section 12(b) of the Act:   Title of each class   Tading Symbol(s)   MRK   New York Stock Exchange   New York St		(Registrant's telephone number, including area code) (908) 740-4000	
Title of each class Common Stock (\$0.50 per value)  MRK  MRK 24  MRK 24  Mew York Stock Exchange 1.875% Notes due 2026  MRK/26  MRK/26  MRK/34  Mew York Stock Exchange 3.250% Notes due 2032  MRK/34  MRK/34  Mew York Stock Exchange 3.250% Notes due 2034  MRK/34  MRK/34  Mew York Stock Exchange 3.500% Notes due 2036  MRK/36  MRK/36  New York Stock Exchange 3.500% Notes due 2036  MRK/36  MRK/36  New York Stock Exchange 3.500% Notes due 2037  MRK/37  MRK/37  Mew York Stock Exchange 3.750% Notes due 2036  MRK/36  MRK/36  New York Stock Exchange 3.750% Notes due 2037  MRK/37  MRK/37  New York Stock Exchange 3.750% Notes due 2037  MRK/34  MRK/44  MRK/44  New York Stock Exchange 3.750% Notes due 2034  MRK/36  New York Stock Exchange 3.750% Notes due 2034  MRK/36  New York Stock Exchange 3.750% Notes due 2036  MRK/36  New York Stock Exchange 3.750% Notes due 2037  MRK/36  New York Stock Exchange 3.750% Notes due 2037  MRK/36  New York Stock Exchange 3.750% Notes due 2034  MRK/36  New York Stock Exchange 3.750% Notes due 2034  MRK/36  New York Stock Exchange 3.750% Notes due 2037  MRK/36  New York Stock Exchange 3.750% Notes due 2037  MRK/36  New York Stock Exchange 3.750% Notes due 2034  MRK/36  New York Stock Exchange 3.750% Notes due 2034  MRK/36  New York Stock Exchange 3.750% Notes due 2034  MRK/36  New York Stock Exchange 3.750% Notes due 2034  MRK/36  New York Stock Exchange 3.750% Notes due 2034  MRK/36  New York Stock Exchange 3.750% Notes due 2034  MRK/36  New York Stock Exchange 3.750% Notes due 2034  MRK/36  New York Stock Exchange 4.750% Notes due 2034  MRK/36  New York Stock Exchange 4.750% Notes due 2034  MRK/36  New York Stock Exchange 4.750% Notes due 2034  MRK/36  New York Stock Exchange 4.750% Notes due 2034  New York Stock E		··	port.)
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		e registrant has elected not to use the extended transition period for complyi	ng with any new or revised financial accounting standards provide
The number of shares of common stock outstanding as of the close of business on July 31, 2024: 2,534,809,312	Indicate by check mark whether the registrant is a shell comp	any (as defined in Rule 12b-2 of the Exchange Act). Yes $\square$ No $lacktriangle$	
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# MERCK & CO., INC. AND SUBSIDIARIES CONDENSED CONSOLIDATED STATEMENT OF OPERATIONS (Unaudited, \$ in millions except per share amounts)

	Three Mo Jun	nths E e 30,	inded	Six Months Ended June 30,							
	2024		2023		2024		2023				
Sales	\$ 16,112	\$	15,035	\$	31,887	\$	29,522				
Costs, Expenses and Other											
Cost of sales	3,745		4,024		7,285		7,951				
Selling, general and administrative	2,739		2,702		5,221		5,182				
Research and development	3,500		13,321		7,492		17,597				
Restructuring costs	80		151		202		218				
Other (income) expense, net	42		172		12		259				
	10,106		20,370		20,212		31,207				
Income (Loss) Before Taxes	6,006		(5,335)		11,675		(1,685)				
Income Tax Provision	545		637		1,447		1,462				
Net Income (Loss)	5,461		(5,972)		10,228		(3,147)				
Less: Net Income Attributable to Noncontrolling Interests	6		3		11		7				
Net Income (Loss) Attributable to Merck & Co., Inc.	\$ 5,455	\$	(5,975)	\$	10,217	\$	(3,154)				
Basic Earnings (Loss) per Common Share Attributable to Merck & Co., Inc. Common Shareholders	\$ 2.15	\$	(2.35)	\$	4.03	\$	(1.24)				
Earnings (Loss) per Common Share Assuming Dilution Attributable to Merck & Co., Inc. Common Shareholders	\$ 2.14	\$	(2.35)	\$	4.02	\$	(1.24)				

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

		Three Mor June		nded	Six Months Ended June 30,								
	2024 2023		2023		2024		2023						
Net Income (Loss) Attributable to Merck & Co., Inc.	\$	5,455	\$	(5,975)	\$	10,217	\$	(3,154)					
Other Comprehensive Loss Net of Taxes:													
Net unrealized gain on derivatives, net of reclassifications		67		145		197		12					
Benefit plan net (loss) gain and prior service (cost) credit, net of amortization		(10)		(25)		(15)		(75)					
Cumulative translation adjustment		(144)		(137)		(382)		(69)					
		(87)		(17)		(200)		(132)					
Comprehensive Income (Loss) Attributable to Merck & Co., Inc.	\$	5,368	\$	(5,992)	\$	10,017	\$	(3,286)					

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

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

	June		Dece	mber 31, 2023
Assets				
Current Assets				
Cash and cash equivalents	\$	11,304	\$	6,841
Short-term investments		50		252
Accounts receivable (net of allowance for doubtful accounts of \$82 in 2024 and \$88 in 2023)		11,642		10,349
Inventories (excludes inventories of \$3,456 in 2024 and \$3,348 in 2023 classified in Other assets - see Note 6)		6,469		6,358
Other current assets		8,740		8,368
Total current assets		38,205		32,168
Investments		357		252
Property, Plant and Equipment, at cost, net of accumulated depreciation of \$18,960 in 2024 and \$18,266 in 2023		23,221		23.051
Goodwill		21,161		21,197
Other Intangibles, Net		16.984		18.011
Other Assets		12,702		11.996
	\$	112,630	\$	106,675
Liabilities and Equity	<u> </u>	112,000	Ψ	100,070
Current Liabilities				
Loans payable and current portion of long-term debt	\$	3,071	\$	1,372
Trade accounts payable	Ψ	3,519	Ψ	3,922
Accrued and other current liabilities		14.712		15.766
Income taxes payable		2,777		2,649
Dividends payable		1,981		1,985
Total current liabilities		26,060		25,694
Long-Term Debt		34.717		33.683
Deferred Income Taxes		876		871
Other Noncurrent Liabilities		7.329		8,792
Merck & Co., Inc. Stockholders' Equity		.,020		0,. 02
Common stock, \$0.50 par value Authorized - 6,500,000,000 shares		4 700		4 700
Issued - 3,577,103,522 shares in 2024 and 2023		1,788		1,788
Other paid-in capital		44,362 60.187		44,509 53.895
Retained earnings Accumulated other comprehensive loss		, -		,
Accumulated other comprehensive loss		(5,361) 100.976		(5,161) 95.031
Less treasury stock, at cost:		,.		,
1,041,454,052 shares in 2024 and 1,045,470,249 shares in 2023		57,394		57,450
Total Merck & Co., Inc. stockholders' equity		43,582		37,581
Noncontrolling Interests		66		54
Total equity		43,648		37,635
	\$	112,630	\$	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)

Six Months Ended June 30,

		Jun	e 30,	
	·	2024		2023
Cash Flows from Operating Activities				
Net income (loss)	\$	10,228	\$	(3,147)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:				
Amortization		1,087		1,020
Depreciation		1,029		874
Income from investments in equity securities, net		(200)		(274)
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		(232)		(632)
Share-based compensation		379		314
Other		174		5
Net changes in assets and liabilities		(4,394)		(4,526)
Net Cash Provided by Operating Activities		8,727		5,043
Cash Flows from Investing Activities				
Capital expenditures		(1,652)		(1,972)
Purchases of securities and other investments		(64)		(587)
Proceeds from sales of securities and other investments		320		785
Acquisition of Harpoon Therapeutics, Inc., net of cash acquired		(746)		_
Acquisition of Prometheus Biosciences, Inc., net of cash acquired		_		(10,705)
Acquisition of Imago BioSciences, Inc., net of cash acquired		_		(1,327)
Other		(303)		4
Net Cash Used in Investing Activities		(2,445)		(13,802)
Cash Flows from Financing Activities		· · · · ·		
Net change in short-term borrowings		_		1,937
Proceeds from issuance of debt		3,600		5,946
Payments on debt		(751)		(1,751)
Dividends paid to stockholders		(3,936)		(3,738)
Purchases of treasury stock		(373)		(487)
Proceeds from exercise of stock options		160		112
Other		(298)		(315)
Net Cash (Used in) Provided by Financing Activities		(1,598)		1,704
Effect of Exchange Rate Changes on Cash, Cash Equivalents and Restricted Cash		(220)		(6)
Net Increase (Decrease) in Cash, Cash Equivalents and Restricted Cash		4,464		(7,061)
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 <i>Other current assets</i> )		6,909		12,773
Cash, Cash Equivalents and Restricted Cash at End of Period (includes restricted cash of \$69 and \$52 at June 30, 2024 and 2023, respectively, included in <i>Other current assets</i> )	\$	11,373	\$	5,712

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 July 2024, Merck acquired the aqua business of Elanco Animal Health Incorporated (Elanco) for approximately \$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. The Company is in the process of determining the preliminary fair value of assets acquired, liabilities assumed and total consideration transferred in this transaction, which will be accounted for as a business combination.

Also in July 2024, Merck acquired Eyebiotech Limited (EyeBio), a privately held ophthalmology-focused biotechnology company for an upfront payment of \$1.3 billion. The acquisition agreement also provides for a further \$1.7 billion in potential 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, trispecific 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

will be accounted for as an asset acquisition since Restoret/MK-3000 accounted for substantially all of the fair value of the gross assets acquired (excluding cash and deferred income taxes). Merck will record a charge of approximately \$1.3 billion to Research and development expenses in the third quarter of 2024.

Additionally in July 2024, Merck and Orion Corporation (Orion) announced the mutual exercise of an option to convert the companies' ongoing codevelopment 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 will assume full responsibility for all past and future development and commercialization expenses associated with the candidates covered by the original agreement. In addition, Orion will become eligible to receive developmental milestone payments up to \$30 million, regulatory milestone payments up to \$625 million and sales-based milestone payments up to \$975 million, as well as annually tiered royalty payments ranging from a low double-digit rate up to a rate in the low twenties on net sales for any commercialized licensed product. Orion will retain responsibility for the manufacture of clinical and commercial supply for Merck. No payment was associated with the exercise of the option. The exclusive global license is expected to become effective in the third quarter of 2024, but is subject to certain conditions, including approval under the Hart-Scott-Rodino Antitrust Improvements Act, and other customary conditions.

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 six months of 2024 related to the transaction. There are no future contingent payments associated with the acquisition.

#### **2023 Transactions**

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 acquisition of an asset 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 second quarter and first six months of 2023 related to the transaction. There are no future contingent payments associated with the acquisition.

In February 2023, Merck and Kelun-Biotech (a holding subsidiary of Sichuan Kelun Pharmaceutical Co., Ltd.) closed a license and collaboration agreement expanding their relationship in which Merck gained exclusive rights for the research, development, manufacture and commercialization of up to seven investigational preclinical antibody drug conjugates (ADCs) for the treatment of cancer. Kelun-Biotech retained the right to research, develop, manufacture and commercialize certain licensed and option ADCs for Chinese mainland, Hong Kong and Macau. Merck made an upfront payment of \$175 million, which was recorded as a charge to *Research and development* expenses in the first six 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 an 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 will pay 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 \$1

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 six 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 June 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 \$93 million and \$96 million and related cost of sales of \$92 million and \$101 million for the second quarter of 2024 and 2023, respectively, and sales of \$201 million and \$191 million and related cost of sales of \$202 million and \$208 million for the first six months of 2024 and 2023, respectively. The amounts due from Organon for all spin-off related agreements were \$557 million and \$632 million at June 30, 2024 and December 31, 2023, respectively, and are reflected in Other current assets. The amounts due to Organon under these agreements were \$102 million and \$598 million at June 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 June 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 six 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 June 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:

				Ended		Six Moni Jun	ths En e 30,	ded
(\$ in millions)		2024		2023		2024		2023
Alliance revenue - Lynparza	\$	317	\$	310	\$	609	\$	585
Alliance revenue - Koselugo		37		25		75		48
Total alliance revenue	\$	354	\$	335	\$	684	\$	633
Cost of sales (1)		82		78		163		148
Selling, general and administrative		43		51		82		98
Research and development		18		22		38		43
(\$ in millions)					Ju	June 30, 2024		ecember 31, 2023
Receivables from AstraZeneca included in Other current assets					\$	349	\$	341
Payables to AstraZeneca included in Accrued and other current liabilities (2)						615		256
Payables to AstraZeneca included in Other Noncurrent Liabilities (2)						_		600

<sup>(1)</sup> Represents amortization of capitalized 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 \$72 million and \$81 million of cumulative amortization catch-up expense related to the recognition of these milestones in the first and third quarters 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 \$563 million at June 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.

<sup>(2)</sup> Includes accrued milestone payments.

Summarized financial information related to this collaboration is as follows:

		Three Mo Jur	nths I e 30,			Six Mon Jur	ths En ie 30,	ded
(\$ in millions)		2024		2023	2024			2023
Alliance revenue - Lenvima	\$	249	\$	242	\$	504	\$	474
Cost of sales (1)		60		57		121		183
Selling, general and administrative		41		48		80		99
Research and development		6		17		13		56
(\$ in millions)					June	e 30, 2024	De	ecember 31, 2023
Receivables from Eisai included in Other current assets					\$	245	\$	226
Payables to Eisai included in Accrued and other current liabilities (2)						_		125

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

#### **Bayer AG**

In 2014, the Company entered into a worldwide clinical development collaboration with Bayer AG (Bayer) to market and develop soluble guanylate cyclase (sGC) modulators including Bayer's Adempas (riociguat) 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 \$445 million and \$47 million, respectively, at June 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:

			Three Months Ended June 30,				Six Months Ended June 30,			
(\$ in millions)		2024		2023		2024		2023		
Alliance revenue - Adempas/Verquvo	\$	106	\$	68	\$	203	\$	167		
Net sales of Adempas recorded by Merck		72		65		142		125		
Net sales of Verquvo recorded by Merck		9		9		16		16		
Total sales	\$	187	\$	142	\$	361	\$	308		
Cost of sales (1)		61		56		123		113		
Selling, general and administrative		26		34		59		67		
Research and development		28		25		55		50		
(\$ in millions)					Jui	ne 30, 2024	De	cember 31, 2023		
Receivables from Bayer included in Other current assets					\$	170	\$	156		
Payables to Bayer included in Accrued and other current liabilities						81		80		

<sup>(1)</sup> 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.

<sup>(2)</sup> Represents an accrued milestone payment.

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

Summarized financial information related to this collaboration is as follows:

		Three Mo Jun	nths E ie 30,	nded	Six Months Ended June 30,			
(\$ in millions)		2024		2023	2024		2023	
Net sales of <i>Lagevrio</i> recorded by Merck	\$	110	\$	203	\$ 460	\$	595	
Cost of sales (1)		96		193	287		414	
Selling, general and administrative		16		24	32		51	
Research and development		7		10	2		26	
(\$ in millions)					June 30, 2024	Dec	ember 31, 2023	
Receivables from Ridgeback included in Other current assets					\$ 8	\$	_	
Payables to Ridgeback included in Accrued and other current liabilities (2)					24		113	

<sup>(1)</sup> Includes cost of products sold by Merck, Ridgeback's share of profits, royalty expense, amortization of capitalized milestone payments and inventory reserves.

## 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 provides for a continuation payment of \$750 million related to patritumab deruxtecan due from Merck in October 2024 and a continuation payment of \$750 million related to raludotatug deruxtecan due from Merck in October 2025. If Merck does not make the continuation payments on the dates noted for either patritumab deruxtecan and/or raludotatug deruxtecan, the rights for the applicable 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.

<sup>(2)</sup> Includes accrued royalties.

Summarized financial information related to this collaboration is as follows:

	Three Mo Jur	nths lie 30,	Ended		hs Ended ∋ 30,		
(\$ in millions)	 2024		2023		2024	2023	
Selling, general and administrative	\$ 14	\$	_	\$	16	\$ -	
Research and development	65		_		133	_	

(\$ in millions)	June	30, 2024	Dec	cember 31, 2023
Payables to Daiichi Sankyo included in Accrued and other current liabilities	\$	801	\$	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 will share costs and 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 \$135 million at June 30, 2024 and will be amortized over the assets' estimated useful lives.

Summarized financial information related to this collaboration is as follows:

		Three M Ju	onths line 30,	Ended		Six Mon Jun	iths En ne 30,	ded
(\$ in millions)	_	2024		2023		2024		2023
Selling, general and administrative	\$	4	\$	1	\$	6	\$	2
Research and development		93		60		162		86
(\$ in millions)					Jur	ne 30, 2024	De	cember 31, 2023
Payables to Moderna included in Accrued and other current liabilities					\$	73	\$	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 will co-promote all 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 \$90 million and \$161 million in the second quarter and first six months of 2024, respectively, compared with \$47 million and \$90 million in the second quarter and first six 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 \$177 million and \$422 million in the second quarter and first six months of 2024, respectively, related to the 2024 Restructuring Program, bringing total cumulative pretax costs incurred through June 30, 2024 to \$613 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 \$236 million and \$333 million in the second quarter and first six 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 now 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:

		Thre	ee Months End	ed Ju	une 30, 2024					Six	Months Ende	d Jur	ne 30, 2024	
(\$ in millions)	celerated preciation	Sep	Separation Costs Other Exit Costs Total						Accelerated Depreciation	Sep	aration Costs		Other	Total
2024 Restructuring Program														
Cost of sales	\$ 66	\$	_	\$	_	\$	66	\$	131	\$	_	\$	51	\$ 182
Selling, general and administrative	_		_		31		31		_		_		36	36
Research and development	_		_		_		_		_		_		2	2
Restructuring costs	_		19		61		80		_		111		91	202
	\$ 66	\$	19	\$	92	\$	177	\$	131	\$	111	\$	180	\$ 422

		Thre	ee Months End	ed Ju	ine 30, 2023				Six	x Months Ended	d Jur	ne 30, 2023	
(\$ in millions)	celerated preciation	Separation Costs Other Exit Costs Total				Total	Accelerated Depreciation	Sep	paration Costs		Other	Total	
2019 Restructuring Program													
Cost of sales	\$ 22	\$	_	\$	10	\$	32	\$ 43	\$	_	\$	18	\$ 61
Selling, general and administrative	_		_		52		52	_		_		53	53
Research and development	_		_		1		1	_		_		1	1
Restructuring costs	_		110		41		151	_		151		67	218
	\$ 22	\$	110	\$	104	\$	236	\$ 43	\$	151	\$	139	\$ 333

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

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

(\$ in millions)	erated ciation	Separation Costs	Othe	er Exit Costs	Total
Restructuring reserves January 1, 2024	\$ 	\$ 681	\$	31	\$ 712
Expenses	131	111		180	422
(Payments) receipts, net	_	(132)		(73)	(205)
Non-cash activity	(131)	_		(111)	(242)
Restructuring reserves June 30, 2024	\$ _	\$ 660	\$	27	\$ 687

## 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		etax (Gain) Comprehens			d in (	Other		Amount of expense, n	Pret et fo	r Amounts	cogn Exclu sting	ized in C ded from	ther	<i>(incor</i> ectiven	ne) iess
	Three Months Ended June 30, Six Months Ended June 30,					Т	hree Months 3		ded June	Si	x Months	Enc	ded Ju	ne 30,			
(\$ in millions)	:	2024 2023				2024		2023		2024		2023		2024		20	023
Net Investment Hedging Relationships																	
Foreign exchange contracts	\$	5	\$	_	\$	3	\$	1	\$	(1)	\$	_	\$	(1	)	\$	1
Euro-denominated notes		(34)		21		(96)		73		_		_		_			_

<sup>(1)</sup> 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 June 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.

		June 30, 2024		
(\$ in millions)	Par Value of Debt	Number of Interest Rate Swaps Held	Total Swa	p 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	of Hedged Liabilities	Ac	Cumulative Amount djustment Increase I Am	of Fair V Included Iount	/alue Hedging in the Carrying
(\$ in millions)	_	June 30, 2024	December 31, 2023		June 30, 2024	Dece	ember 31, 2023
Balance Sheet Caption							
Long-Term Debt	\$	1,521	\$ 1,056	\$	30	\$	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:

			Jı	une 30, 2024			Dece	ember 31, 2023	3	
		 Fair Value	of De	erivative	U.S. Dollar	Fair Value	of De	rivative	-	J.S. Dollar
(\$ in millions)		Asset		Liability	Notional	Asset		Liability		Notional
Derivatives Designated as Hedgin Instruments	ng Balance Sheet Caption									
Interest rate swap contracts	Other Assets	\$ 30	\$	_	\$ 1,500	\$ 57	\$	_	\$	1,000
Foreign exchange contracts	Other current assets	226		_	8,830	106		_		6,138
Foreign exchange contracts	Other Assets	46		_	2,052	26		_		1,929
Foreign exchange contracts	Accrued and other current liabilities	_		4	901	_		76		3,680
Foreign exchange contracts	Other Noncurrent Liabilities	_		1	230	_		1		7
		302		5	13,513	189		77		12,754
Derivatives Not Designated as Hedging Instruments	Balance Sheet Caption									
Foreign exchange contracts	Other current assets	187			8,723	153		_		9,693
Foreign exchange contracts	Other Assets	2		_	22	_		_		_
Foreign exchange contracts	Accrued and other current liabilities	_		135	10,818	_		162		8,104
Foreign exchange contracts	Other Noncurrent Liabilities	_		2	22	_		_		_
		189		137	19,585	153		162		17,797
		\$ 491	\$	142	\$ 33,098	\$ 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:

	June 30,	, 202	24	Decembe	er 31,	2023
(\$ in millions)	Asset		Liability	Asset		Liability
Gross amounts recognized in the condensed consolidated balance sheet	\$ 491	\$	142	\$ 342	\$	239
Gross amounts subject to offset in master netting arrangements not offset in the condensed consolidated balance sheet	(114)		(114)	(215)		(215)
Cash collateral received	(123)		_	(3)		_
Net amounts	\$ 254	\$	28	\$ 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 I	Ende	d June 30	٥,						Six	Mor	nths End	ed Ju	ne 30,		
(\$ in millions)	2024	202	23	2024		2023		2024	2	023	2024		2023	2	2024	2	023	2024	2023
Financial Statement Caption in which Effects of Fair Value or Cash Flow Hedges are Recorded	Sa	les				ome) net <sup>(1)</sup>		Ot compre income			Sa	ales			Other (			Oth compre income	hensive
	\$ 16,112	\$ 15	,035	\$ 42	: \$	172	\$	(87)	\$	(17)	\$ 31,887	\$	29,522	\$	12	\$	259	\$ (200)	\$ (132)
(Gain) loss on fair value hedging relationships:																			
Interest rate swap contracts																			
Hedged items	_		_	2	1	_		_		_	_		_		(26)		_	_	_
Derivatives designated as hedging instruments	_		_	(4	.)	_		_		_	_		_		27		_	_	_
Impact of cash flow hedging relationships:																			
Foreign exchange contracts																			
Amount of gain recognized in <i>OCI</i> on derivatives	_		_	_	-	_		139		194	_		_		_		_	348	128
Increase in Sales as a result of AOCL reclassifications	54		24	_	-	_		(54)		(24)	98		125		_		_	(98)	(125)
Interest rate contracts																			
Amount of gain recognized in Other (income) expense, net on derivatives	_		_	_		_		_		_	_		_		(1)		(1)	_	_
Amount of gain recognized in OCI on derivatives	_		_	_	-	_		_		13	_		_		_		_	(1)	13

<sup>(1)</sup> 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:

		Amou	nt of Deri	ivative	e Pretax (G	ain) i	Loss Recog	nizea i	n income
		Three	Months I	Ended	d June 30,	S	ix Months E	nded .	lune 30,
(\$ in millions)							2024		2023
Derivatives Not Designated as Hedging Instruments	Income Statement Caption								
Foreign exchange contracts (1)	Other (income) expense, net	\$	9	\$	(41)	\$	75	\$	(28)
Foreign exchange contracts (2)	Sales		(10)		(5)		(20)		(3)

<sup>(</sup>f) 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.

At June 30, 2024, the Company estimates \$190 million of pretax net unrealized gains on derivatives maturing within the next 12 months that hedge foreign currency denominated sales over that same period will be reclassified from *AOCL* to *Sales*. The amount ultimately reclassified to *Sales* may differ as foreign exchange rates change. Realized gains and losses are ultimately determined by actual foreign exchange rates at maturity.

<sup>(2)</sup> These derivative contracts serve as economic hedges of forecasted transactions.

## **Investments in Debt and Equity Securities**

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

			June 30	), 202	24			December	r <b>31</b> , :	2023	
	Δm	ortized	Gross U	nrea	lized	Fair	Amortized	Gross U	nreal	lized	Fair
(\$ in millions)		Cost	Gains		Losses	Value	Cost	Gains		Losses	Value
U.S. government and agency securities	\$	77	\$ _	\$	_	\$ 77	\$ 72	\$ _	\$	_	\$ 72
Commercial paper		50	_		_	50	252	_		_	252
Corporate notes and bonds		_	_		_	_	13	_		_	13
Total debt securities	\$	127	\$ _	\$	_	\$ 127	\$ 337	\$ _	\$	_	\$ 337
Publicly traded equity securities (1)						1,026					764
Total debt and publicly traded equity securities						\$ 1,153					\$ 1,101

<sup>(1)</sup> Unrealized net losses (gains) of \$8 million and \$(125) million were recorded in Other (income) expense, net in the second quarter and first six months of 2024, respectively, on equity securities still held at June 30, 2024. Unrealized net losses (gains) of \$71 million and \$(267) million were recorded in Other (income) expense, net in the second quarter and first six months of 2023, respectively, on equity securities still held at June 30, 2023.

At June 30, 2024 and June 30, 2023, the Company also had \$936 million and \$949 million, respectively, of equity investments without readily determinable fair values included in *Other Assets*. The Company records unrealized gains on these equity investments based on favorable observable price changes from transactions involving similar investments of the same investee and records unrealized losses based on unfavorable observable price changes, which are included in *Other (income) expense, net.* During the first six months of 2024, the Company recorded unrealized gains of \$61 million and unrealized losses of \$5 million related to certain of these equity investments still held at June 30, 2024. During the first six months of 2023, the Company recorded unrealized gains of \$3 million and unrealized losses of \$23 million related to certain of these equity investments still held at June 30, 2023. Cumulative unrealized gains and cumulative unrealized losses based on observable price changes for investments in equity investments without readily determinable fair values still held at June 30, 2024 were \$355 million and \$69 million, respectively.

At June 30, 2024 and June 30, 2023, the Company also had \$278 million and \$622 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 \$(7) million and \$105 million for the second quarter of 2024 and 2023, respectively, and were \$(5) million and \$(27) million for the first six 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						
	L	_evel 1		Level 2		Level 3		Total		Level 1		Level 2		Level 3		Total	
(\$ in millions)				June 3	0, 20	24						Decembe	er 31,	2023			
Assets																	
Investments																	
Commercial paper	\$	_	\$	50	\$	_	\$	50	\$	_	\$	252	\$	_	\$	252	
Publicly traded equity securities		357		_		_		357		252		_		_		252	
		357		50		_		407		252		252		_		504	
Other assets (1)																	
U.S. government and agency securities		77		_		_		77		72		_		_		72	
Corporate notes and bonds		_		_		_		_		13		_		_		13	
Publicly traded equity securities (2)		669		_		_		669		512		_		_		512	
		746		_		_		746		597		_				597	
Derivative assets (3)																	
Forward exchange contracts		_		278		_		278		_		202		_		202	
Purchased currency options		_		183		_		183		_		83		_		83	
Interest rate swaps		_		30		_		30		_		57		_		57	
		_		491		_		491		_		342		_		342	
Total assets	\$	1,103	\$	541	\$	_	\$	1,644	\$	849	\$	594	\$	_	\$	1,443	
Liabilities																	
Other liabilities																	
Contingent consideration	\$	_	\$	_	\$	225	\$	225	\$	_	\$	_	\$	354	\$	354	
Derivative liabilities (3)																	
Forward exchange contracts		_		115		_		115		_		239		_		239	
Written currency options		_		27		_		27		_		_		_		_	
		_		142		_		142		_		239		_		239	
Total liabilities	\$	_	\$	142	\$	225	\$	367	\$	_	\$	239	\$	354	\$	593	

<sup>(1)</sup> Investments included in other assets are restricted as to use, including for the payment of benefits under employee benefit plans.

As of June 30, 2024 and December 31, 2023, Cash and cash equivalents included \$10.5 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	\$ 3	54 \$	456
Changes in estimated fair value (1)		(3)	10
Payments	(1)	26)	(117)
Fair value June 30 (2)	\$ 2	25 \$	349

<sup>(</sup>f) Recorded in Cost of sales, Research and development expenses, and Other (income) expense, net. Includes cumulative translation adjustments.

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

## Other Fair Value Measurements

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

The estimated fair value of loans payable and long-term debt (including current portion) at June 30, 2024, was \$33.5 billion compared with a carrying value of \$37.8 billion and at December 31, 2023, was \$32.0 billion compared with a carrying

<sup>(2)</sup> Balance at June 30, 2024 includes securities with a fair value of \$285 million, which were subject to a contractual sale restriction that expired in July 2024.

<sup>(9)</sup> 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.

Balance at June 30, 2024, includes \$131 million of current liabilities, all of which relate to the termination of the Sanofi Pasteur MSD joint venture in 2016. As part of the termination, Merck recorded a liability for contingent future royalty payments of 11.5% on net sales of all Merck products that were previously sold by the joint venture through December 31, 2024. The fair value of this liability is determined utilizing the estimated amount and timing of projected cash flows using a risk-adjusted discount rate to present value the cash flows.

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 \$2.9 billion and \$3.0 billion of accounts receivable as of June 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 June 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 within *Accrued and other current liabilities*. The net cash flows related to these collections are reported as financing activities in the Condensed Consolidated Statement of Cash Flows. The cost of factoring such accounts receivable was *de minimis*.

Derivative financial instruments are executed under International Swaps and Derivatives Association master agreements. The master agreements with several of the Company's financial institution counterparties also include credit support annexes. These annexes contain provisions that require collateral to be exchanged depending on the value of the derivative assets and liabilities, the Company's credit rating, and the credit rating of the counterparty. Cash collateral received by the Company from various counterparties was \$123 million and \$3 million at June 30, 2024 and December 31, 2023, respectively. The obligation to return such collateral is recorded in *Accrued and other current liabilities*.

#### 6. Inventories

Inventories consisted of:

(\$ in millions)	Jun	e 30, 2024	Dece	mber 31, 2023
Finished goods	\$	1,889	\$	1,954
Raw materials and work in process		8,456		8,037
Supplies		267		277
Total		10,612		10,268
Decrease to LIFO cost		(687)		(562)
	\$	9,925	\$	9,706
Recognized as:				
Inventories	\$	6,469	\$	6,358
Other Assets		3,456		3,348

Amounts recognized as *Other Assets* are comprised almost entirely of raw materials and work in process inventories. At June 30, 2024 and December 31, 2023, these amounts included \$3.2 billion and \$2.6 billion, respectively, of inventories not expected to be sold within one year. In addition, these amounts included \$250 million and \$790 million at June 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 June 30, 2024, approximately 290 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 June 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 scheduled to commence trial on October 7, 2024. As previously disclosed, there are fewer than 15 product liability cases pending outside the U.S.

#### **Governmental Proceedings**

#### Civil Investigative Demand

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

On 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) has 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.

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 suits 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.

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. On June 13, 2024, the PTAB instituted a review of one of the asserted patents. The additional IPR petitions and institution decisions are all still pending. 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.

Lynparza — In December 2022, AstraZeneca Pharmaceuticals LP received a Paragraph IV Certification Letter under the Hatch-Waxman Act notifying AstraZeneca that Natco Pharma Limited (Natco) has filed an application to the FDA seeking pre-patent expiry approval to sell generic versions of Lynparza (olaparib) tablet. In February 2023, AstraZeneca and the Company filed a patent infringement lawsuit in the U.S. District Court for the District of New Jersey/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 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 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.

## **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 June 30, 2024 and December 31, 2023 of approximately \$215 million and \$210 million, respectively, represents the Company's best estimate of the minimum amount of defense costs to be incurred in connection with its outstanding litigation; however, events such as additional trials and other events that could arise in the course of its litigation could affect the ultimate amount of legal defense costs to be incurred by the Company. The Company will continue to monitor its legal defense costs and review the adequacy of the associated reserves and may determine to increase the reserves at any time in the future if, based upon the factors set forth, it believes it would be appropriate to do so.

## 9. Equity

				Three	Months Ended June	30,			
	Commo	on Stock	Other		Accumulated Other	Treasury	Stock	Non-	
(\$ and shares in millions except per share amounts)	Shares	Par Value	Paid-In Capital	Retained Earnings	Comprehensive Loss	Shares	Cost	controlling Interests	Total
Balance at April 1, 2023	3,577	1,788 \$	44,467 \$	62,039 \$	(4,883)	1,040 \$	(56,577) \$	71 \$	46,905
Net loss attributable to Merck & Co., Inc.	_	_	_	(5,975)	_	_	_	_	(5,975)
Other comprehensive loss, net of taxes	_	_	_	_	(17)	_	_	_	(17)
Cash dividends declared on common stock (\$0.73 per share)	_	_	_	(1,866)	_	_	_	_	(1,866)
Treasury stock shares purchased	_	_	_	_	_	3	(338)	_	(338)
Share-based compensation plans and other	_	_	(248)	_	_	(5)	303	_	55
Net income attributable to noncontrolling interests	_	_	_	_	_	_	_	3	3
Distributions attributable to noncontrolling interests	_	_	_	_	_	_	_	(25)	(25)
Balance at June 30, 2023	3,577	1,788 \$	44,219 \$	54,198 \$	(4,900)	1,038 \$	(56,612) \$	49 \$	38,742
Balance at April 1, 2024	3,577	1,788 \$	44,598 \$	56,697 \$	(5,274)	1,044 \$	(57,445) \$	60 \$	40,424
Net income attributable to Merck & Co., Inc.	_	_	_	5,455		_		_	5,455
Other comprehensive loss, net of taxes	_	_	_	_	(87)	_	_	_	(87)
Cash dividends declared on common stock (\$0.77 per share)	_	_	_	(1,965)	_	_	_	_	(1,965)
Treasury stock shares purchased	_	_	_	_	_	2	(251)	_	(251)
Share-based compensation plans and other	_	_	(236)	_	_	(5)	302	_	66
Net income attributable to noncontrolling interests	_	_	_	_	_	_	_	6	6
Balance at June 30, 2024	3,577	1,788 \$	44,362 \$	60,187 \$	(5,361)	1,041 \$	(57,394) \$	66 \$	43,648

				Six N	Months Ended June 3	0,			
	Commo	on Stock	Other		Accumulated Other	Treasury	Stock	Non-	
(\$ and shares in millions except per share amounts)	Shares	Par Value	Paid-In Capital	Retained Earnings	Comprehensive Loss	Shares	Cost	controlling Interests	Total
Balance at January 1, 2023	3,577	\$ 1,788 \$	44,379	61,081 \$	(4,768)	1,039 \$	(56,489) \$	67 \$	46,058
Net loss attributable to Merck & Co., Inc.	_	_	_	(3,154)	_	_	_	_	(3,154)
Other comprehensive loss, net of taxes	_	_	_	_	(132)	_	_	_	(132)
Cash dividends declared on common stock (\$1.46 per share)	_	_	_	(3,729)	_	_	_	_	(3,729)
Treasury stock shares purchased	_	_	_	_	_	4	(487)	_	(487)
Share-based compensation plans and other	_	_	(160)	_	_	(5)	364	_	204
Net income attributable to noncontrolling interests	_	_	_	_	_	_	_	7	7
Distributions attributable to noncontrolling interests	_	_	_	_	_	_	_	(25)	(25)
Balance at June 30, 2023	3,577	\$ 1,788 \$	44,219	54,198 \$	(4,900)	1,038 \$	(56,612) \$	49 \$	38,742
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.	_	_	_	10,217	_	_	_	_	10,217
Other comprehensive loss, net of taxes	_	_	_	_	(200)	_	_	_	(200)
Cash dividends declared on common stock (\$1.54 per share)	_	_	_	(3,925)	_	_	_	_	(3,925)
Treasury stock shares purchased	_	_	_	_	_	3	(373)	_	(373)
Share-based compensation plans and other	_	_	(147)	_	_	(7)	429	1	283
Net income attributable to noncontrolling interests	_	_	_	_	_	_	_	11	11
Balance at June 30, 2024	3,577	\$ 1,788 \$	44,362	60,187 \$	(5,361)	1,041 \$	(57,394) \$	66 \$	43,648

#### 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:

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	Three Months Ended June 30,									Six Months Ended June 30,								
	2	2024			2	2023			2	2024			2	023				
(\$ in millions)	 U.S.	li	nternational		U.S.		International		U.S.	Inte	rnational		U.S.	Intern	ational			
Service cost	\$ 86	\$	60	\$	76	\$	50	\$	173	\$	122	\$	152	\$	99			
Interest cost	134		73		133		75		269		147		266		149			
Expected return on plan assets	(207)		(137)		(185)		(130)		(417)		(278)		(372)		(257)			
Amortization of unrecognized prior service (credit) cost	_		(3)		_		16		_		(6)		(1)		12			
Net loss (gain) amortization	10		1		_		(1)		20		3		_		(2)			
Termination benefits	_		_		1		_		4		_		1		_			
Curtailments	_		_		2		_		_		_		5		_			
Settlements	_		_		5		_		_		_		26		_			
	\$ 23	\$	(6)	\$	32	\$	10	\$	49	\$	(12)	\$	77	\$	1			

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 Mor Jun	nths E e 30,	inded	Six Mont Jun	ths En e 30,	ded
(\$ in millions)	_	2024		2023	2024		2023
Service cost	\$	8	\$	8	\$ 15	\$	17
Interest cost		14		16	28		31
Expected return on plan assets		(20)		(16)	(40)		(32)
Amortization of unrecognized prior service credit		(11)		(12)	(21)		(25)
Net gain amortization		(12)		(11)	(24)		(21)
	\$	(21)	\$	(15)	\$ (42)	\$	(30)

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 second quarter and first six months of 2023. These partial settlements triggered remeasurements of some of the Company's U.S. pension plans. Remeasurements during the first six months of 2023 resulted in a net increase of \$47 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 Moi Jun	nths E e 30,	inded	Six Months June	
(\$ in millions)	2024		2023	2024	2023
Interest income	\$ (69)	\$	(109)	\$ (141) \$	(221)
Interest expense	310		277	613	519
Exchange losses	60		62	144	122
(Income) loss from investments in equity securities, net (1)	(56)		175	(200)	(274)
Net periodic defined benefit plan (credit) cost other than service cost	(159)		(111)	(319)	(226)
Other, net	(44)		(122)	(85)	339
	\$ 42	\$	172	\$ 12 \$	259

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

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

Interest paid for the six months ended June 30, 2024 and 2023 was \$581 million and \$449 million, respectively.

## 12. Income Taxes

The effective income tax rates were 9.1% and 12.4% for the second quarter and first six months of 2024, respectively. The effective income tax rates in the second quarter and first six months of 2024 reflect a 4.3 percentage point favorable impact and a 2.2 percentage point favorable impact, respectively, 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 for the first six months of 2024 also reflects a 0.7 percentage point unfavorable discrete impact of a charge for the acquisition of Harpoon for which no tax benefit was recognized.

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

The 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 federal tax return year expired in June 2024 as noted above. The statute of limitations for assessments with respect to the 2020 federal tax return year will expire in October of 2024, unless extended.

## 13. Earnings Per Share

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

	Three Mor Jun	nths E e 30,	Ended	Six Mon Jun	ths En e 30,	ded
(\$ and shares in millions except per share amounts)	2024		2023	2024		2023
Net Income (Loss) Attributable to Merck & Co., Inc.	\$ 5,455	\$	(5,975)	\$ 10,217	\$	(3,154)
Average common shares outstanding	2,534		2,539	2,534		2,539
Common shares issuable (1)	10		_	10		_
Average common shares outstanding assuming dilution	2,544		2,539	2,544		2,539
Basic Earnings (Loss) per Common Share Attributable to Merck & Co., Inc. Common Shareholders	\$ 2.15	\$	(2.35)	\$ 4.03	\$	(1.24)
Earnings (Loss) per Common Share Assuming Dilution Attributable to Merck & Co., Inc. Common Shareholders	\$ 2.14	\$	(2.35)	\$ 4.02	\$	(1.24)

<sup>(1)</sup> Issuable primarily under share-based compensation plans.

For the second quarter and first six months of 2024, 7 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. The Company recorded a net loss for the three and six months ended June 30, 2023; therefore, no potential dilutive common shares were used in the computations of loss per common share assuming dilution because the effects would have been antidilutive.

## 14. Other Comprehensive Income (Loss)

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

			Three Months	Ended	June 30,	
(\$ in millions)	Derivatives		Employee Benefit Plans	1	eign Currency Franslation Adjustment	umulated Other emprehensive Loss
Balance April 1, 2023, net of taxes	\$	(60)	\$ (2,458)	\$	(2,365)	\$ (4,883)
Other comprehensive income (loss) before reclassification adjustments, pretax		194	(6)		(115)	73
Tax		(41)	1		(22)	(62)
Other comprehensive income (loss) before reclassification adjustments, net of taxes		153	(5)		(137)	11
Reclassification adjustments, pretax		(11) <sup>(1)</sup>	(23) <sup>(2)</sup>		_	(34)
Tax		3	3		_	6
Reclassification adjustments, net of taxes		(8)	(20)		_	(28)
Other comprehensive income (loss), net of taxes		145	(25)		(137)	(17)
Balance June 30, 2023, net of taxes	\$	85	\$ (2,483)	\$	(2,502)	\$ (4,900)
Balance April 1, 2024, net of taxes	\$	106	\$ (2,798)	\$	(2,582)	\$ (5,274)
Other comprehensive income (loss) before reclassification adjustments, pretax		139	1		(157)	(17)
Tax		(29)	2		(7)	(34)
Other comprehensive income (loss) before reclassification adjustments, net of taxes		110	3		(164)	(51)
Reclassification adjustments, pretax		(55) <sup>(1)</sup>	(15) <sup>(2)</sup>		20	(50)
Tax		12	2		_	14
Reclassification adjustments, net of taxes		(43)	(13)		20	(36)
Other comprehensive income (loss), net of taxes		67	(10)		(144)	 (87)
Balance June 30, 2024, net of taxes	\$	173	\$ (2,808)	\$	(2,726)	\$ (5,361)

			Six Months E	nded	June 30,	
(\$ in millions)	De	erivatives	Employee Benefit Plans		reign Currency Translation Adjustment	umulated Other omprehensive Loss
Balance January 1, 2023, net of taxes	\$	73	\$ (2,408)	\$	(2,433)	\$ (4,768)
Other comprehensive income (loss) before reclassification adjustments, pretax		128	(53)		(36)	39
Tax		(27)	3		(42)	(66)
Other comprehensive income (loss) before reclassification adjustments, net of taxes		101	(50)		(78)	(27)
Reclassification adjustments, pretax		(113) <sup>(1)</sup>	(30) (2)		9	(134)
Tax		24	5		_	29
Reclassification adjustments, net of taxes		(89)	(25)		9	(105)
Other comprehensive income (loss), net of taxes		12	(75)		(69)	(132)
Balance June 30, 2023, net of taxes	\$	85	\$ (2,483)	\$	(2,502)	\$ (4,900)
Balance January 1, 2024, net of taxes	\$	(24)	\$ (2,793)	\$	(2,344)	\$ (5,161)
Other comprehensive income (loss) before reclassification adjustments, pretax		348	6		(382)	(28)
Tax		(73)	(2)		(20)	(95)
Other comprehensive income (loss) before reclassification adjustments, net of taxes		275	4		(402)	(123)
Reclassification adjustments, pretax		(99) <sup>(1)</sup>	(30) <sup>(2)</sup>		20	(109)
Tax		21	11		_	32
Reclassification adjustments, net of taxes		(78)	(19)		20	(77)
Other comprehensive income (loss), net of taxes		197	(15)		(382)	(200)
Balance June 30, 2024, net of taxes	\$	173	\$ (2,808)	\$	(2,726)	\$ (5,361)

<sup>(1)</sup> Primarily relates to foreign currency cash flow hedges that were reclassified from AOCL to Sales.

<sup>(2)</sup> 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 June 3	30,				Six Months E	Ended June 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	\$ 4,412	\$ 2,858	\$ 7,270	\$ 3,863	\$ 2,408	\$ 6,271	\$ 8,531	\$ 5,686	\$ 14,217	\$ 7,348	\$ 4,718	\$ 12,065
Alliance revenue-Lynparza (1)	153	165	317	144	166	310	288	321	609	286	299	585
Alliance revenue-Lenvima (1)	177	73	249	163	79	242	349		504	316	158	474
Welireg	116	10	126	49	2	50	194		211	90	3	92
Alliance revenue-Reblozyl (2)	75	15	90	36	11	47	133	28	161	66	24	90
Vaccines												
Gardasil/Gardasil 9	536	1,941	2,478	464	1,994	2,458	1,024		4,727	880	3,550	4,430
ProQuad/M-M-R II/Varivax	490	127	617	447	135	582	928		1,187	868	242	1,109
Vaxneuvance	99	90	189	147	20	168	260		408	241	33	274
RotaTeq	107	56	163	93	37	131	257		379	273	155	428
Pneumovax 23	11	48	59	23	69	92	17	103	120	63	125	188
Hospital Acute Care												
Bridion	351	104	455	299	203	502	680		895	576	413	989
Prevymis	90	98	188	61	82	143	165		362	116	157	273
Dificid	79	12	92	68	8	76	147		165	130	11	141
Zerbaxa	33	28	62	30	24	54	67		118	57	47	104
Noxafil	_	44	45	11	45	55	8	92	101	25	91	116
Cardiovascular												
Alliance revenue-Adempas/Verquvo	98	8	106	70	(2)	68	188	16	203	153	14	167
Adempas	_	72	72	_	65	65	_	142	142	_	125	125
Winrevair	70	_	70	_	_	_	70	_	70	_	_	_
Virology												
Lagevrio	15	95	110	2	201	203	60	400	460	_	595	595
Isentress/Isentress HD	43	46	89	56	80	136	93	107	200	108	151	259
Delstrigo	14	45	60	13	37	50	26	89	116	24	70	94
Pifeltro	27	12	39	27	11	38	56	25	81	51	21	72
Neuroscience												
Belsomra	19	34	53	21	42	63	33	66	99	37	82	119
Immunology												
Simponi	_	172	172	_	180	180	_	356	356	_	359	359
Remicade	_	35	35	_	48	48	_	74	74	_	99	99
Diabetes												
Januvia	177	227	405	243	267	511	361	463	824	514	548	1,062
Janumet	17	208	224	82	272	354	55	420	475	138	544	683
Other pharmaceutical (4)	190	386	573	158	403	560	346	807	1,151	328	857	1,187
Total Pharmaceutical segment sales	7,399	7,009	14,408	6,570	6,887	13,457	14,336	14,079	28,415	12,688	13,491	26,179
Animal Health:												
Livestock	168	669	837	165	643	807	334	1,352	1,686	338	1,318	1,656
Companion Animal	287	358	645	310	339	649	595	712	1,307	618	673	1,291
Total Animal Health segment sales	455	1,027	1,482	475	982	1,456	929	2,064	2,993	956	1,991	2,947
Total segment sales	7,854	8,036	15,890	7,045	7,869	14,913	15,265	16,143	31,408	13,644	15,482	29,126
Other (5)	22	200	222	(27)	149	122	89		479	32	364	396
	\$ 7,876	\$ 8,236	\$ 16,112	\$ 7,018	\$ 8,018	\$ 15,035	\$ 15,354	\$ 16,533	\$ 31,887	\$ 13,676	\$ 15,846	\$ 29,522

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

<sup>(</sup>f) 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).

<sup>(2)</sup> Alliance revenue for Reblozyl represents royalties (see Note 3).

<sup>(9)</sup> 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).

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

<sup>(5)</sup> Other is primarily comprised of miscellaneous corporate revenue, including revenue hedging activities which increased sales by \$118 million and \$128 million for the six months ended June 30, 2024 and 2023, respectively, as well as revenue from third-party manufacturing arrangements (including sales to Organon). Other for the six months ended June 30, 2024 and 2023 also includes \$76 million and \$54 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 \$3.3 billion and \$3.2 billion for the three months ended June 30, 2024 and 2023, respectively, and \$6.6 billion and \$6.3 billion for the six months ended June 30, 2024 and June 30, 2023, respectively.

Consolidated sales by geographic area where derived are as follows:

	Three Mo Jur	onths E ne 30,	nded	Six Mont Jun	ths En e 30,	ded
(\$ in millions)	 2024		2023	 2024		2023
United States	\$ 7,876	\$	7,018	\$ 15,354	\$	13,676
Europe, Middle East and Africa	3,515		3,348	7,078		6,651
China	1,817		1,913	3,589		3,628
Latin America	858		742	1,655		1,403
Japan	686		675	1,507		1,434
Asia Pacific (other than China and Japan)	748		848	1,472		1,694
Other	612		491	1,232		1,036
	\$ 16,112	\$	15,035	\$ 31,887	\$	29,522

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

	Three Mor	nths E e 30,	inded	Six Mon	hs En e 30,	ded
(\$ in millions)	2024		2023	2024		2023
Segment profits:						
Pharmaceutical segment	\$ 11,200	\$	9,854	\$ 22,104	\$	18,993
Animal Health segment	508		467	1,064		1,032
Total segment profits	11,708		10,321	23,168		20,025
Other profits	129		19	274		184
Unallocated:						
Interest income	69		109	141		221
Interest expense	(310)		(277)	(613)		(519)
Amortization	(614)		(477)	(1,087)		(1,020)
Depreciation	(450)		(376)	(902)		(775)
Research and development	(3,360)		(13,194)	(7,209)		(17,341)
Restructuring costs	(80)		(151)	(202)		(218)
Charge for Zetia antitrust litigation settlements	_		_	_		(573)
Other unallocated, net	(1,086)		(1,309)	(1,895)		(1,669)
	\$ 6,006	\$	(5,335)	\$ 11,675	\$	(1,685)

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 July 2024, Merck acquired the aqua business of Elanco Animal Health Incorporated (Elanco) for approximately \$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. The Company is in the process of determining the preliminary fair value of assets acquired, liabilities assumed and total consideration transferred in this transaction, which will be accounted for as a business combination.

Also in July 2024, Merck acquired Eyebiotech Limited (EyeBio), a privately held ophthalmology-focused biotechnology company for an upfront payment of \$1.3 billion. The acquisition agreement also provides for a further \$1.7 billion in potential 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, trispecific 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 will be accounted for as an asset acquisition. Merck will record a charge of approximately \$1.3 billion to *Research and development* expenses, or approximately \$0.51 per share, in the third quarter of 2024.

Additionally in July 2024, Merck and Orion Corporation (Orion) announced the mutual exercise of an option to convert the companies' ongoing codevelopment 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 will assume full responsibility for all past and future development and commercialization expenses associated with the candidates covered by the original agreement. In addition, Orion will become eligible to receive developmental, regulatory and sales-based milestone payments, as well as annually tiered royalty payments ranging from a low double-digit rate up to a rate in the low twenties on net sales for any commercialized licensed product. Orion will retain responsibility for the manufacture of clinical and commercial supply for Merck. No payment was associated with the exercise of the option. The exclusive global license is expected to become effective in the third quarter of 2024, but is subject to certain conditions, including approval under the Hart-Scott-Rodino Antitrust Improvements Act, and other customary conditions.

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 six months of 2024 related to the transaction. There are no future contingent payments associated with the acquisition.

## **Pricing**

Global efforts toward health care cost containment continue to exert pressure on product pricing and market access worldwide. Changes to the U.S. health care system enacted in prior years as part of health care reform, as well as increased purchasing power of entities that negotiate on behalf of Medicare, Medicaid, and private sector beneficiaries, have contributed to pricing pressure. In 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 HCI) in the first six months of 2024. In 2022, the U.S. Congress passed the Inflation Reduction Act (IRA), which makes significant changes to how drugs are covered and paid for under the Medicare program, including the creation of financial penalties for drugs whose prices rise faster than the rate of inflation, redesign of the Medicare Part D program to require manufacturers to bear more of the liability for certain drug benefits, and government price-setting for certain Medicare Part D drugs (starting in 2026) and Medicare Part B drugs (starting in 2028). In August 2023, the U.S. Department of Health and Human Services (HHS), through the Centers for Medicare & Medicaid Services (CMS), announced that *Januvia* 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. Furthermore, the Biden Administration and Congress continue to discuss legislation designed to control health care costs, including the cost o

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 Mo Jun	nths I e 30,	Ended		% Change Excluding Foreign	Six Moni Jun	ths E e 30,	nded		% Change Excluding Foreign
(\$ in millions)	2024		2023	% Change	Exchange	2024		2023	% Change	Exchange
United States	\$ 7,876	\$	7,018	12 %	12 %	\$ 15,354	\$	13,676	12 %	12 %
International	8,236		8,018	3 %	9 %	16,533		15,846	4 %	11 %
Total	\$ 16,112	\$	15,035	7 %	11 %	\$ 31,887	\$	29,522	8 %	11 %

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

Worldwide sales were \$16.1 billion in the second quarter of 2024, representing growth of 7% compared with the second quarter of 2023, or 11% excluding the unfavorable effect of foreign exchange. Global sales were \$31.9 billion in the first six months of 2024, an increase of 8% compared with the same period of 2023, or 11% excluding the unfavorable effect of foreign exchange. Approximately 2 percentage points of the negative impact of foreign exchange in both periods 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 both periods was primarily due to higher sales in the oncology franchise, largely due to strong growth of *Keytruda* (pembrolizumab) and *Welireg* (belzutifan). Higher sales in the vaccines franchise also contributed to revenue growth in the second quarter and first six months of 2024, reflecting increased combined sales of *Gardasil* (Human Papillomavirus Quadrivalent [Types 6, 11, 16 and 18] Vaccine, Recombinant)/*Gardasil* 9 (Human Papillomavirus 9-valent Vaccine, Recombinant) and continued uptake of *Vaxneuvance* (Pneumococcal 15-valent Conjugate Vaccine) for pediatric use. Revenue growth in the second quarter and first six months of 2024 also benefited from higher sales in the cardiovascular franchise largely attributable to the launch of *Winrevair* (sotatercept-csrk). Revenue growth in the second quarter and first six 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* (molnupiravir).

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 services marks are those of their respective owners.

### **Pharmaceutical Segment**

## Oncology

	 Three Mo Jun	nths l e 30,			% Change Excluding Foreign	Six Mont Jun	hs Er e 30,	nded		% Change Excluding Foreign
(\$ in millions)	 2024		2023	% Change	Exchange	2024		2023	% Change	Exchange
Keytruda	\$ 7,270	\$	6,271	16 %	21 %	\$ 14,217	\$	12,065	18 %	22 %
Alliance Revenue - Lynparza (1)	317		310	2 %	4 %	609		585	4 %	6 %
Alliance Revenue - Lenvima (1)	249		242	3 %	4 %	504		474	6 %	7 %
Welireg	126		50	*	*	211		92	*	*
Alliance Revenue - Reblozyl (2)	90		47	92 %	92 %	161		90	80 %	80 %

<sup>\* &</sup>gt; 100%

Keytruda is an anti-PD-1 (programmed death receptor-1) therapy that has been approved in 40 indications in the U.S., including 17 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 16% in the second quarter of 2024 and rose 18% in the first six months of 2024, or 21% and 22%, respectively, excluding the unfavorable effect of foreign exchange. Approximately 4 percentage points of the negative impact of foreign exchange in both periods 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, microsatellite instability-high (MSI-H) and renal cell cancers, as well as 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, renal and gastric cancer metastatic indications, particularly in Europe and Latin America.

<sup>(1)</sup> 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)

<sup>(2)</sup> Alliance revenue for Reblozyl represents royalties (see Note 3 to the condensed consolidated financial statements).

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, 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 <i>Keytruda</i> as a single agent, for the treatment of adult patients with primary advanced or recurrent endometrial carcinoma, based on the NRG-GY018 trial, also known as KEYNOTE-868.
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.

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 will expire in the U.S. in September 2024 and 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 2% in the second quarter of 2024 primarily driven by higher demand in the U.S. and certain international markets, particularly in China and Europe. Alliance revenue related to Lynparza grew 4% in the first six months of 2024 primarily due to higher demand in certain international markets, particularly in Latin America, China and Europe.

Lenvima (lenvatinib) is an oral receptor tyrosine kinase inhibitor being developed as part of a collaboration with Eisai Co., Ltd. (Eisai) (see Note 3 to the condensed consolidated financial statements). Lenvima is approved for the treatment of certain types of thyroid cancer, RCC, HCC, in combination with everolimus for certain patients with advanced RCC, and in combination with *Keytruda* for certain patients with advanced endometrial carcinoma or advanced RCC. Alliance revenue related to Lenvima grew 3% and 6% in the second quarter and first six months of 2024, respectively, primarily reflecting higher demand in the U.S.

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 second quarter and first six months of 2024. Sales growth in both periods was primarily due to higher demand in the U.S. largely attributable to the launch 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 for the treatment of previously treated advanced RCC based on the LITESPARK-005 clinical trial and in the EU 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 92% and 80% in the second quarter and first six months of 2024, respectively, due to strong underlying sales performance.

#### Vaccines

	Three Mo Jun	nths E e 30,	Ended		% Change Excluding Foreign	Six Mont Jun	hs Eı e 30,	nded		% Change Excluding Foreign
(\$ in millions)	 2024		2023	% Change	Exchange	2024		2023	% Change	Exchange
Gardasil/Gardasil 9	\$ 2,478	\$	2,458	1 %	4 %	\$ 4,727	\$	4,430	7 %	10 %
ProQuad	239		222	7 %	8 %	443		412	8 %	8 %
M-M-R II	113		104	8 %	9 %	217		207	5 %	6 %
Varivax	266		255	4 %	5 %	527		491	7 %	8 %
Vaxneuvance	189		168	13 %	16 %	408		274	49 %	51 %
RotaTeq	163		131	25 %	26 %	379		428	(11)%	(10)%
Pneumovax 23	59		92	(36)%	(32)%	120		188	(36)%	(32)%

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), grew 1% in the second quarter of 2024 primarily driven by higher sales in the U.S. due to higher pricing, demand and public sector buying patterns, as well as higher demand in several ex-U.S. markets. Sales growth of *Gardasil/Gardasil* 9 in the second quarter of 2024 was largely offset by lower sales in China due to the timing of shipments compared with prior year. Combined worldwide sales of *Gardasil* and *Gardasil* 9 grew 7% in the first six months of 2024 primarily due to higher global demand, as well as public sector buying patterns in the U.S., and higher pricing. 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), into the points of vaccination compared with prior quarters, resulting in above normal inventory levels at Zhifei. If shipments from Zhifei into the points of vaccination do not increase, it is likely that the Company will ship less than its full year 2024 contracted doses by the end of 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 7% and 8% in the second quarter and first six months of 2024, respectively, primarily reflecting higher pricing and demand 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 8% and 5% in the second quarter and first six months of 2024, respectively, largely reflecting higher demand in several ex-U.S. markets.

Global sales of *Varivax* (Varicella Virus Vaccine Live), a vaccine to help prevent chickenpox (varicella), increased 4% and 7% in the second quarter and first six months of 2024, respectively, primarily attributable to higher pricing in the U.S. Sales growth in the second quarter of 2024 was partially offset by the timing of sales in Latin America.

Worldwide sales of *Vaxneuvance*, a vaccine to help protect against invasive pneumococcal disease, grew 13% in the second quarter of 2024 primarily reflecting continued uptake following launches in the pediatric indication in Japan and Europe, partially offset by lower sales in the U.S. due to lower demand and public sector buying patterns. Worldwide sales of *Vaxneuvance* grew 49% in the first six months of 2024 primarily reflecting higher demand in Europe and Japan, as well as the beneficial impact of public sector buying patterns in the U.S.

Global sales of *RotaTeq* (Rotavirus Vaccine, Live Oral, Pentavalent), a vaccine to help protect against rotavirus gastroenteritis in infants and children, grew 25% in the second quarter of 2024 largely due to the timing of sales in China, as well as higher sales in the U.S. reflecting a benefit from public sector buying patterns that was partially offset by lower demand. Worldwide sales of *RotaTeq* declined 11% first six months of 2024 primarily due to lower sales in China reflecting first quarter 2023 inventory stocking, as well as lower sales in the U.S. due to lower demand and public sector buying patterns, partially offset by higher pricing.

Worldwide sales of *Pneumovax* 23 (pneumococcal vaccine polyvalent), a vaccine to help prevent pneumococcal disease, declined 36% in both the second quarter and first six months of 2024 driven by lower demand in most markets, 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 unanimously voted to recommend *Capvaxive* as an option for certain adults for pneumococcal vaccination. 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 will pay royalties on sales of *Capvaxive*. Under the more significant of these agreements, Merck will pay 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 Mo Jun	nths l e 30,	Ended		% Change Excluding Foreign	 Six Mon Jun	ths E e 30			% Change Excluding Foreign
(\$ in millions)	 2024		2023	% Change	Exchange	2024		2023	% Change	Exchange
Bridion	\$ 455	\$	502	(9)%	(8)%	\$ 895	\$	989	(9)%	(8)%
Prevymis	188		143	31 %	35 %	362		273	33 %	37 %

Worldwide sales of *Bridion* (sugammadex), for the reversal of two types of neuromuscular blocking agents used during surgery, declined 9% in both the second quarter and first six months of 2024 primarily driven by lower demand in certain ex-U.S. markets due to generic competition, particularly in the EU and the Asia Pacific region, partially offset by higher demand in the U.S. The patent that provided market exclusivity for *Bridion* in the EU expired in July 2023. Accordingly, the Company is experiencing sales declines of *Bridion* in these markets and expects the declines to continue. The patent that provided market exclusivity for *Bridion* in Japan expired in January 2024; the Company anticipates sales of *Bridion* in Japan will decline in future periods.

Worldwide sales of *Prevymis* (letermovir), a medicine for prophylaxis (prevention) of cytomegalovirus (CMV) infection and disease in certain high risk adult recipients of an allogenic hematopoietic stem cell transplant and for prophylaxis of CMV disease in certain high risk adult recipients of a kidney transplant, grew 31% and 33% in the second quarter and first six months of 2024, respectively, largely due to higher global demand, particularly in the U.S., China and Europe.

#### Cardiovascular

	 Three Mo Jun	nths E e 30,	Ended		% Change Excluding Foreign	 Six Mon	ths E e 30,	nded		% Change Excluding Foreign
(\$ in millions)	2024		2023	% Change	Exchange	2024		2023	% Change	Exchange
Alliance Revenue - Adempas/ Verquvo <sup>(1)</sup>	\$ 106	\$	68	56 %	56 %	\$ 203	\$	167	22 %	22 %
Adempas	72		65	11 %	15 %	142		125	14 %	17 %
Winrevair	70		_	_	_	70		_	_	_

<sup>(1)</sup> 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 56% and 22% in the second quarter and first six months of 2024, respectively, 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 14% in the second quarter and first six 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, and reduce the risk of clinical worsening events. The approval is based on the STELLAR trial. 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. Merck estimates approximately 40% of *Winrevair* sales in the second quarter 2024 were attributable to doses administered to patients, with the remainder due to distributors building inventory in support of increasing demand.

## Virology

	 Three Mo Jun	nths l e 30,			% Change Excluding Foreign	Six Moni Jun	ths E e 30,	nded		% Change Excluding Foreign
(\$ in millions)	2024		2023	% Change	Exchange	2024		2023	% Change	Exchange
Lagevrio	\$ 110	\$	203	(46)%	(42)%	\$ 460	\$	595	(23)%	(18)%

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 46% and 23% in the second quarter and first six months of 2024, respectively, primarily due to lower demand and pricing in certain markets in the Asia Pacific region, partially offset by uptake from commercial distribution in the U.S. and higher demand in Japan.

## *Immunology*

	Three Mo	nths E e 30,	Ended		% Change Excluding Foreign	Six Mon Jur	ths E ie 30,			% Change Excluding Foreign
(\$ in millions)	2024		2023	% Change	Exchange	2024		2023	% Change	Exchange
Simponi	\$ 172	\$	180	(4)%	(2)%	\$ 356	\$	359	(1)%	(1)%
Remicade	35		48	(27)%	(20)%	74		99	(25)%	(21)%

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

#### **Diabetes**

	Three Mor Jun	nths l e 30,	Ended		% Change Excluding Foreign	 Six Mon Jun	ths E e 30,	nded		% Change Excluding Foreign
(\$ in millions)	2024		2023	% Change	Exchange	2024		2023	% Change	Exchange
Januvia/Janumet	\$ 629	\$	864	(27)%	(23)%	\$ 1,299	\$	1,744	(26)%	(22)%

Worldwide combined sales of *Januvia* and *Janumet*, medicines that help lower blood sugar levels in adults with type 2 diabetes, declined 27% and 26% in the second quarter and first six 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 six 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**

	Three Mo Jun	nths I e 30,	Ended		% Change Excluding Foreign	Six Mont Jun	ths Er e 30,	nded		% Change Excluding Foreign
(\$ in millions)	 2024		2023	% Change	Exchange	2024		2023	% Change	Exchange
Livestock	\$ 837	\$	807	4 %	11 %	\$ 1,686	\$	1,656	2 %	7 %
Companion Animal	645		649	(1)%	1 %	1,307		1,291	1 %	3 %
	\$ 1,482	\$	1,456	2 %	6 %	\$ 2,993	\$	2,947	2 %	5 %

Animal Health sales grew 2% in the second quarter of 2024, or 6% excluding the unfavorable effect of foreign exchange, and increased 2% in the first six months of 2024, or 5% excluding the unfavorable effect of foreign exchange. Approximately 3 percentage points of the negative impact of foreign exchange in both periods 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 4% and 2% in the second quarter and first six months of 2024, respectively, primarily due to higher pricing, as well as increased demand for poultry products. Higher demand for ruminant products also contributed to sales growth in the second quarter of 2024. Sales of companion animal products were relatively flat in the second quarter of 2024. Sales of companion animal products grew 1% in the first six months of 2024 due to higher pricing, largely offset by lower volumes reflecting a reduction in distributor inventory. Sales of *Bravecto* (fluralaner), a line of oral, topical and injectable parasitic control products, were \$331 million for the second quarter of 2024, representing growth of 2% compared with the second quarter of 2023, or 3% excluding the unfavorable effect of foreign exchange. Sales of *Bravecto* were \$663 million for the first six months of 2024, representing growth of 4% compared with the corresponding prior year period, or 5% excluding the unfavorable effect of foreign exchange.

In July 2024, Merck acquired the aqua business of Elanco for \$1.3 billion. See "Business Development Transactions" above for additional information related to this transaction.

#### Costs, Expenses and Other

	Three Months Ended June 30,				Six Months Ended June 30,					
(\$ in millions)		2024		2023	% Change		2024		2023	% Change
Cost of sales	\$	3,745	\$	4,024	(7)%	\$	7,285	\$	7,951	(8)%
Selling, general and administrative		2,739		2,702	1 %		5,221		5,182	1 %
Research and development		3,500		13,321	(74)%		7,492		17,597	(57)%
Restructuring costs		80		151	(47)%		202		218	(7)%
Other (income) expense, net		42		172	(76)%		12		259	(95)%
	\$	10,106	\$	20,370	(50)%	\$	20,212	\$	31,207	(35)%

#### Cost of Sales

Cost of sales declined 7% and 8% in the second quarter and first six months of 2024, respectively. Cost of sales includes the amortization of intangible assets recorded in connection with acquisitions, collaborations, and licensing arrangements, which totaled \$603 million and \$468 million in the second quarter of 2024 and 2023, respectively, and \$1.1 billion and \$1.0 billion in the first six months of 2024 and 2023, respectively. Amortization expense in the first six months of 2023 includes \$72 million 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 \$66 million and \$32 million in the second quarter of 2024 and 2023, respectively, and \$182 million and \$61 million in the first six months of 2024 and 2023, respectively, primarily reflecting accelerated depreciation and asset write-offs related to the planned sale or closure of manufacturing facilities. Separation costs associated with manufacturing-related headcount reductions have been incurred and are reflected in Restructuring costs as discussed below.

Gross margin was 76.8% in the second quarter of 2024 compared with 73.2% in the second quarter of 2023. Gross margin was 77.2% in the first six months of 2024 compared with 73.1% in the first six 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 and amortization of intangible assets.

#### Selling, General and Administrative

Selling, general and administrative (SG&A) expenses increased 1% in the second quarter of 2024 primarily due to higher administrative and promotional costs, largely offset by the favorable effect of foreign exchange and lower restructuring costs. SG&A expenses rose 1% in the first six months of 2024 primarily due to higher administrative costs, largely offset by the favorable effect of foreign exchange, lower promotional spending, reflecting the prioritization of spending on key growth products, as well as lower restructuring costs.

### Research and Development

Research and development (R&D) expenses were \$3.5 billion in the second quarter of 2024 compared with \$13.3 billion in the second quarter of 2023. The decline was primarily due to a \$10.2 billion charge in the second quarter of 2023 for the acquisition of Prometheus. R&D expenses were \$7.5 billion in the first six months 2024 compared with \$17.6 billion in the first six months of 2023. The decline was primarily due to lower charges for business development transactions, which included a \$656 million charge for the acquisition of Harpoon in the first six months of 2024, compared with charges of \$10.2 billion for the acquisition of Prometheus, \$1.2 billion for the acquisition of Imago and \$175 million for a license and collaboration agreement with Kelun-Biotech in the first six months of 2023. The declines in R&D expenses for both the second quarter and first six months of 2024 were partially offset by increased clinical development spending, as well as higher compensation and benefit costs in 2024.

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 second quarter of 2024 and 2023, respectively, and \$4.9 billion and \$4.3 billion for the first six 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 the charges for the Harpoon, Prometheus and Imago acquisitions 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 approximately \$955 million and \$11.1 billion for the second quarter of 2024 and 2023, respectively, and \$2.5 billion and \$13.3 billion for the first six 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 \$800 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 now being accounted for as part of the 2024 Restructuring Program.

Restructuring costs, primarily representing separation and other costs associated with these restructuring activities, were \$80 million and \$151 million for the second quarter of 2024 and 2023, respectively, and \$202 million and \$218 million for the first six 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 \$177 million and \$236 million in the second quarter of 2024 and 2023, respectively, and \$422 million and \$333 million for the first six 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 \$42 million of expense in the second quarter of 2024 compared with \$172 million of expense in the second quarter of 2023 primarily due to net income from investments in equity securities in 2024 compared with net losses in 2023, partially offset by higher net interest expense in 2024. Other (income) expense, net was \$12 million of expense in the first six months of 2024 compared with \$259 million of expense in the first six 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, partially offset by higher net interest expense and lower income from investments in equity securities 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 June 30,			Six Months Ended June 30,			ded				
(\$ in millions)	2024			2023		2023		2024		2023	
Pharmaceutical segment profits	\$	11,200	\$	9,854	\$	22,104	\$	18,993			
Animal Health segment profits		508		467		1,064		1,032			
Other		(5,702)		(15,656)		(11,493)		(21,710)			
Income (Loss) Before Taxes	\$	6,006	\$	(5,335)	\$	11,675	\$	(1,685)			

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 14% and 16% in the second quarter and first six 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 9% and 3% in the second quarter and first six months of 2024, respectively, primarily due to higher sales, partially offset by increased promotional costs, as well as the unfavorable effect of foreign exchange.

#### **Taxes on Income**

The effective income tax rates were 9.1% and 12.4% for the second quarter and first six months of 2024, respectively. The effective income tax rates in the second quarter and first six months of 2024 reflect a 4.3 percentage point favorable impact and a 2.2 percentage point favorable impact, respectively, 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 for the first six months of 2024 also reflects a 0.7 percentage point unfavorable discrete impact of a charge for the acquisition of Harpoon for which no tax benefit was recognized.

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

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 (Loss) and Non-GAAP EPS

Non-GAAP income (loss) and non-GAAP earnings (loss) 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 (loss) 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 (loss) 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 (loss) metric. Since non-GAAP income (loss) 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 (loss) and non-GAAP EPS should be considered in addition to, but not as a substitute for or superior to, net income (loss) and EPS prepared in accordance with generally accepted accounting principles in the U.S. (GAAP).

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

		Three Mo Jun	nths I e 30,	Ended	Six Mont Jun	hs Er e 30,	nded
(\$ in millions except per share amounts)		2024		2023	2024		2023
Income (loss) before taxes as reported under GAAP	\$	6,006	\$	(5,335)	\$ 11,675	\$	(1,685)
Increase (decrease) for excluded items:							
Acquisition- and divestiture-related costs		633		498	1,129		1,088
Restructuring costs		177		236	422		333
(Income) loss from investments in equity securities, net		(49)		194	(165)		(235)
Other items:							
Charge for Zetia antitrust litigation settlements		_		_	_		573
Non-GAAP income (loss) before taxes		6,767		(4,407)	13,061		74
Income tax provision as reported under GAAP		545		637	1,447		1,462
Estimated tax benefit on excluded items (1)		148		173	257		261
Tax benefit resulting from the expiration of the statute of limitations for assessments related to the 2019 federal tax return year		259		_	259		_
Non-GAAP income tax provision		952		810	1,963		1,723
Non-GAAP net income (loss)		5,815		(5,217)	11,098		(1,649)
Less: Net income attributable to noncontrolling interests as reported under GAAP		6		3	11		7
Non-GAAP net income (loss) attributable to Merck & Co., Inc.	\$	5,809	\$	(5,220)	\$ 11,087	\$	(1,656)
EPS assuming dilution as reported under GAAP (2)(3)	\$	2.14	\$	(2.35)	\$ 4.02	\$	(1.24)
EPS difference		0.14		0.29	0.34		0.59
Non-GAAP EPS assuming dilution (2)(3)	\$	2.28	\$	(2.06)	\$ 4.36	\$	(0.65)

<sup>(</sup>f) The estimated tax impact on the excluded items is determined by applying the statutory rate of the originating territory of the non-GAAP adjustments.

### Acquisition- and Divestiture-Related Costs

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

#### Restructuring Costs

Non-GAAP income (loss) 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 abandonment, facility shut-down and other related costs, as well as employee-related costs such as curtailment, settlement and termination charges associated with pension and other postretirement benefit plans and share-based compensation costs.

## Income and Losses from Investments in Equity Securities

Non-GAAP income (loss) 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 (loss) and non-GAAP EPS exclude certain other items. These items are adjusted for after evaluating them on an individual basis, considering their quantitative and qualitative aspects. Typically, these consist of items that are unusual in nature, significant to the results of a particular period or not indicative of future operating results. Excluded from non-GAAP income and non-GAAP EPS in 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 (see Note 12 to the condensed consolidated financial statements). Excluded from non-GAAP income (loss) and non-GAAP EPS in 2023 is a charge related to settlements with certain plaintiffs in the Zetia antitrust litigation.

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

<sup>(3)</sup> GAAP and non-GAAP EPS were negatively affected in the second quarter of 2023 by \$4.02 per share, and for the first six months of 2024 and 2023 by \$0.26 per share and \$4.53 per share, respectively, of charges for certain upfront payments related to collaborations and licensing agreements, as well as charges related to pre-approval assets obtained in transactions accounted for as asset acquisitions.

### **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.

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. The application is 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-7962, Winrevair (sotatercept), Merck's novel activin signaling inhibitor, is under review in the EU for the treatment of adult patients with PAH. In June 2024, the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) recommended the approval of Winrevair, in combination with other PAH therapies, for the treatment of PAH in adult patients with WHO functional class II to III, to improve exercise capacity. The CHMP recommendation is based on data from the Phase 3 STELLAR trial. Winrevair was previously granted Priority Medicines (PRIME) scheme and Orphan Drug designation by the EMA for the treatment of PAH. The EC will now review the CHMP recommendation, and the EC's decision is expected in the third quarter of 2024.

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 chronic cough and unexplained chronic cough. The CRL was not related to the safety of gefapixant. Merck is reviewing the FDA's feedback to determine next steps.

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

Keytruda is under priority review by the FDA in combination with chemotherapy, 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. The FDA set a Prescription Drug User Fee Act (PDUFA) date of September 25, 2024 for the supplemental BLA. KEYNOTE-483 is also under review in the EU and Japan.

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

In addition, *Keytruda* is under review in the EU and Japan in combination with Padcev (enfortumab vedotin-ejfv), an ADC, for the treatment of adult patients with locally advanced or metastatic urothelial carcinoma, based on the KEYNOTE-A39 trial that was conducted in collaboration with Seagen (now Pfizer Inc.) and Astellas. In July 2024, the EMA's CHMP adopted a positive opinion recommending approval of *Keytruda* in combination with Padcev for the first-line treatment of adult patients with unresectable or metastatic urothelial carcinoma. The CHMP's recommendation will now be reviewed by the EC for marketing authorization in the EU, and a final decision is expected in the third quarter of 2024.

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

Keytruda is under review in Japan as part of a perioperative treatment regimen for certain patients with resectable stage II, IIIA or IIIB (T3-4N2) NSCLC based on the KEYNOTE-671 study. A perioperative treatment regimen includes treatment before surgery (neoadjuvant) and continued after surgery (adjuvant).

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

In May 2024, the Company announced that the Phase 3 KEYNOTE-B21 trial evaluating *Keytruda* in combination with chemotherapy as adjuvant treatment, with or without radiotherapy, did not meet its primary endpoint of disease-free survival for the treatment of patients with newly diagnosed, high-risk endometrial cancer after surgery with curative intent. At a pre-specified interim analysis conducted by an independent Data Monitoring Committee (DMC), adjuvant treatment with *Keytruda* plus

chemotherapy, with or without radiotherapy, did not meet the study's pre-specified statistical criteria for disease-free survival compared to placebo plus adjuvant chemotherapy, with or without radiotherapy. The study's other primary endpoint of overall survival was not formally tested since superiority was not reached for disease-free survival. A full evaluation of the data from this study is ongoing. The Company will work with investigators to share the results with the scientific community.

Also In May 2024, the Company announced the discontinuation of the vibostolimab and pembrolizumab coformulation arm of the Phase 3 KeyVibe-010 trial that is evaluating the regimen as adjuvant treatment for patients with resected high-risk melanoma (Stage IIB-IV). At a pre-planned analysis, data showed that the primary endpoint of recurrence-free survival met the pre-specified futility criteria. A higher rate of discontinuation of all adjuvant therapy by patients in the coformulation arm versus the *Keytruda*-only arm, primarily due to immune-mediated adverse experiences, rendered it highly unlikely that the trial could achieve a statistically significant improvement in recurrence-free survival. Based on the recommendation of an independent DMC, the Company is unblinding the study and recommends that patients receiving the vibostolimab and pembrolizumab coformulation be offered the option to be treated with *Keytruda* monotherapy. Data analysis from this study is ongoing. Results will be shared with the scientific community and communicated to regulatory agencies.

The chart below reflects the Company's research pipeline as of August 2, 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	
MK-1022 (patritumab deruxtecan) <sup>(1)</sup> Gastric Head and Neck Melanoma MK-1308 (quavonlimab) <sup>(2)</sup> Non-Small-Cell Lung MK-1308A (quavonlimab+pembrolizumab) Colorectal MK-2140 (zilovertamab vedotin) Hematological Malignancies MK-2400 (ifinatamab deruxtecan) <sup>(1)</sup> Bladder Colorectal Endometrial Head and Neck MK-2870 (sacituzumab tirumotecan) <sup>(1)(3)</sup> Biliary Colorectal Neoplasm Malignant Pancreatic	MK-5909 (raludotatug deruxtecan) <sup>(1)</sup> Ovarian MK-6482 Welireg <sup>(3)</sup> Endometrial Esophageal Hepatocellular Prostate Rare cancers MK-7339 Lynparza <sup>(1/3)</sup> Advanced Solid Tumors MK-7684A (vibostolimab+pembrolizumab) Bladder Colorectal Endometrial Melanoma Ovarian Prostate Renal Cell MK-7902 Lenvima <sup>(1)(2)</sup>	Dengue Fever Virus Vaccine V181  Diabetic Macular Edema MK-3000 Restoret HIV-1 Infection MK-8591B (islatravir+MK-8507) <sup>(4)</sup> MK-8591D (islatravir+lenacapavir) <sup>(1)(5)</sup> HIV-1 Prevention 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 Schizophrenia MK-8189 <sup>(6)</sup> Thrombosis MK-2060 Vitiligo MK-6194

Phase 3 (Phase 3 entry date)		Under Review
Antiviral COVID-19	New Molecular Entities	Certain Supplemental Filings
MK-4482 Lagevrio (U.S.) (May 2021) <sup>(1)(7)</sup> Cancer  MK-1022 (patritumab deruxtecan) <sup>(1)</sup> Non-Small-Cell Lung (May 2022) (EU) MK-1026 (nemtabrutinib) Hematological Malignancies (March 2023) MK-1084 Non-Small-Cell Lung (May 2024) MK-1308A (quavonlimab+pembrolizumab) Renal Cell (April 2021) MK-2400 (ifinatamab deruxtecan) <sup>(1)</sup> Small-Cell Lung (July 2024) MK-2870 (sacituzumab tirumotecan) <sup>(1)(3)</sup> Breast (April 2024) Cervical (July 2024) Gastric (May 2024) Endometrial (December 2023) Non-Small-Cell Lung (November 2023) MK-3475 Keytruda Cutaneous Squamous Cell (August 2019) (EU) 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) Colorectal (November 2021) Hematological Malignancies (October 2022) MK-5684 (opevesostat) <sup>(7)</sup> Prostate (December 2023)	Cancer MK-1022 (patritumab deruxtecan) <sup>(1)(8)</sup> Non-Small-Cell Lung (U.S.) MK-6482 Welireg Von Hippel-Lindau (VHL) Disease (EU)  Cough MK-7264 (gefapixant) (U.S.) <sup>(6)</sup> Pneumococcal Vaccine Adult V116 Capvaxive (EU)  Pulmonary Arterial Hypertension MK-7962 Winrevair (EU)	Cancer MK-3475 Keytruda  • First-Line Unresectable Advanced or Metastatic Malignant Pleural Mesothelioma (KEYNOTE-483) (U.S.) (EU) (JPN)  • Primary Advanced or Recurrent Endometrial Carcinoma (KEYNOTE-868) (EU) (JPN)  • First-Line Locally Advanced or Metastatic Urothelial Carcinoma (KEYNOTE-A39) (EU) (JPN)  • High-Risk Locally Advanced Cervical Cancer (KEYNOTE-A18) (EU) (JPN)  • Resectable Stage II, IIIA or IIIB (T3-4N2) NSCLC (KEYNOTE-671) (JPN)  MK-6482 Welireg  • Previously Treated Advanced Renal Cell Carcinoma (LITESPARK-005) (EU) (JPN)
MK-7339 Lynparza <sup>(1)(2)</sup> Non-Small-Cell Lung (June 2019) Small-Cell Lung (December 2020) MK-7684A (vibostolimab+pembrolizumab) Non-Small-Cell Lung (April 2021) Small-Cell Lung (March 2022) MK-7902 Lenvima <sup>(1)(2)</sup> Esophageal (July 2021) Gastric (December 2020) V940 <sup>(1)(2)</sup> Melanoma (July 2023) Non-Small-Cell Lung (December 2023) HIV-1 Infection MK-8591A (doravirine+islatravir) (February 2020) <sup>(5)</sup> Hypercholesterolemia MK-0616 (August 2023) Respiratory Syncytial Virus MK-1654 (clesrovimab) (November 2021) Ulcerative Colitis MK-7240 (tulisokibart) (October 2023)	address FDA feedback.	ose used in current clinical trials.

## **Analysis of Liquidity and Capital Resources**

(\$ in millions)	June	e 30, 2024	Decer	mber 31, 2023
Cash and investments	\$	11,711	\$	7,345
Working capital		12,145		6,474
Total debt to total liabilities and equity		33.6 %	)	32.9 %

Cash provided by operating activities was \$8.7 billion in the first six months of 2024 compared with \$5.0 billion in the first six 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 six 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 \$2.4 billion in the first six months of 2024 compared with \$13.8 billion in the first six 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 \$1.6 billion in the first six months of 2024 compared with cash provided by financing activities of \$1.7 billion in the first six months of 2023. The change was primarily due to lower proceeds from the

issuance of debt, no proceeds from short-term borrowings 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 \$2.9 billion and \$3.0 billion of accounts receivable at June 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 3.70% 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 \$3.9 billion and \$3.7 billion for the first six months of 2024 and 2023, respectively. In January 2024, Merck's Board of Directors declared a quarterly dividend of \$0.77 per share on the Company's outstanding common stock for the second quarter that was paid in April 2024. 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 of 2024 that was paid in July 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 six months of 2024, the Company purchased \$373 million (3 million shares) of its common stock for its treasury under this program. As of June 30, 2024, the Company's remaining share repurchase authorization was \$3.3 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 are disclosed in the Critical Accounting Estimates section of Management's Discussion and Analysis of Financial Condition and Results of Operations included in Merck's Form 10-K. There have been no significant changes in the Company's critical accounting estimates since December 31, 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 filled 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 June 30, 2024, the Company's disclosure controls and procedures are effective. For the second 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 June 30, 2024 were as follows:

#### ISSUER PURCHASES OF EQUITY SECURITIES

			_	(\$ in millions)
Period	Total Number of Shares Purchased <sup>(1)</sup>	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 <sup>(1)</sup>
April 1 - April 30	408,640	\$126.80	408,640	\$3,527
May 1 - May 31	811,903	\$129.33	811,903	\$3,422
June 1 - June 30	727,448	\$129.80	727,448	\$3,328
Total	1,947,991	\$128.97	1,947,991	

<sup>(1)</sup> Shares purchased during the period were made as part of a plan approved by the Board of Directors in October 2018 to purchase up to \$10 billion of Merck's common stock for its treasury.

## Item 5. Other Information

## **Insider Trading Arrangements**

During the three months ended June 30, 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		<u>Description</u>
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).

# <u>Signatures</u>

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

MERCK & CO., INC.

Date: August 5, 2024 /s/ Jennifer Zachary

JENNIFER ZACHARY

**Executive Vice President and General Counsel** 

Date: August 5, 2024 /s/ Dalton Smart

DALTON SMART

Senior Vice President Finance - Global Controller

### **CERTIFICATION**

- I, Robert M. Davis, certify that:
- 1. I have reviewed this quarterly report on Form 10-Q of Merck & Co., Inc.;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 5, 2024

By: /s/ Robert M. Davis

ROBERT M. DAVIS Chairman, Chief Executive Officer and President

### CERTIFICATION

- I, Caroline Litchfield, certify that:
- 1. I have reviewed this quarterly report on Form 10-Q of Merck & Co., Inc.;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 5, 2024

By: /s/ Caroline Litchfield

CAROLINE LITCHFIELD

Executive Vice President, Chief Financial Officer

## Section 1350 **Certification of Chief Executive Officer**

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

/s/ Robert M. Davis Date: August 5, 2024

Name: Title:

ROBERT M. DAVIS Chairman, Chief Executive Officer and President

## Section 1350 Certification of Chief Financial Officer

Pursuant to 18 U.S.C. Section 1350, the undersigned officer of Merck & Co., Inc. (the "Company"), hereby certifies that the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 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: August 5, 2024 /s/ Caroline Litchfield

Name: CAROLINE LITCHFIELD

Title: Executive Vice President, Chief Financial Officer