UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2022

OR

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

For the transition period from _____ to _____

Commission File No. 1-6571

Merck & Co., Inc.

(Exact name of registrant as specified in its charter)

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

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

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

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

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

Title of each class	*Trading Symbol(s)*	*Name of each exchange on which registered*
Common Stock ($0.50 par value)	MRK	New York Stock Exchange
0.500% Notes due 2024	MRK 24	New York Stock Exchange
1.875% Notes due 2026	MRK/26	New York Stock Exchange
2.500% Notes due 2034	MRK/34	New York Stock Exchange
1.375% Notes due 2036	MRK 36A	New York Stock Exchange

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act. (Check one):

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

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

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

The number of shares of common stock outstanding as of the close of business on October 31, 2022: 2,535,395,974

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Sales	$ 14,959	$ 13,154	$ 45,453	$ 35,183
Costs, Expenses and Other				
Cost of sales	3,934	3,450	13,530	9,752
Selling, general and administrative	2,520	2,336	7,355	6,804
Research and development	4,399	2,445	9,773	9,177
Restructuring costs	94	107	288	487
Other (income) expense, net	429	(450)	1,576	(1,007)
	11,376	7,888	32,522	25,213
Income from Continuing Operations Before Taxes	3,583	5,266	12,931	9,970
Taxes on Income from Continuing Operations	330	695	1,423	1,436
Net Income from Continuing Operations	3,253	4,571	11,508	8,534
Less: Net Income Attributable to Noncontrolling Interests	5	4	6	9
Net Income from Continuing Operations Attributable to Merck & Co., Inc.	3,248	4,567	11,502	8,525
Income from Discontinued Operations, Net of Taxes and Amounts Attributable to Noncontrolling Interests	—	—	—	766
Net Income Attributable to Merck & Co., Inc.	$ 3,248	$ 4,567	$ 11,502	$ 9,291
Basic Earnings per Common Share Attributable to Merck & Co., Inc. Common Shareholders:				
Income from Continuing Operations	$ 1.28	$ 1.81	$ 4.55	$ 3.37
Income from Discontinued Operations	—	—	—	0.30
Net Income	$ 1.28	$ 1.81	$ 4.55	$ 3.67
Earnings per Common Share Assuming Dilution Attributable to Merck & Co., Inc. Common Shareholders:				
Income from Continuing Operations	$ 1.28	$ 1.80	$ 4.53	$ 3.36
Income from Discontinued Operations	—	—	—	0.30
Net Income	$ 1.28	$ 1.80	$ 4.53	$ 3.66

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Net Income Attributable to Merck & Co., Inc.	$ 3,248	$ 4,567	$ 11,502	$ 9,291
Other Comprehensive (Loss) Income Net of Taxes:				
Net unrealized gain on derivatives, net of reclassifications	338	84	584	324
Benefit plan net (loss) gain and prior service (cost) credit, net of amortization	(186)	38	92	1,522
Cumulative translation adjustment	(568)	(84)	(990)	(251)
	(416)	38	(314)	1,595
Comprehensive Income Attributable to Merck & Co., Inc.	$ 2,832	$ 4,605	$ 11,188	$ 10,886

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

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

	September 30, 2022	December 31, 2021
Assets		
Current Assets		
Cash and cash equivalents	$ 11,145	$ 8,096
Short-term investments	103	—
Accounts receivable (net of allowance for doubtful accounts of $77 in 2022 and $62 in 2021)	9,482	9,230
Inventories (excludes inventories of $2,641 in 2022 and $2,194 in 2021 classified in Other assets - see Note 7)	5,614	5,953
Other current assets	7,217	6,987
Total current assets	33,561	30,266
Investments	984	370
Property, Plant and Equipment, at cost, net of accumulated depreciation of $17,921 in 2022 and $18,192 in 2021	20,424	19,279
Goodwill	21,160	21,264
Other Intangibles, Net	21,368	22,933
Other Assets	9,584	11,582
	$ 107,081	$ 105,694
Liabilities and Equity		
Current Liabilities		
Loans payable and current portion of long-term debt	$ 1,936	$ 2,412
Trade accounts payable	3,371	4,609
Accrued and other current liabilities	14,222	13,859
Income taxes payable	1,698	1,224
Dividends payable	1,771	1,768
Total current liabilities	22,998	23,872
Long-Term Debt	28,482	30,690
Deferred Income Taxes	2,417	3,441
Other Noncurrent Liabilities	8,660	9,434
Merck & Co., Inc. Stockholders' Equity		
Common stock, $0.50 par value Authorized - 6,500,000,000 shares Issued - 3,577,103,522 shares in 2022 and 2021	1,788	1,788
Other paid-in capital	44,243	44,238
Retained earnings	59,928	53,696
Accumulated other comprehensive loss	(4,743)	(4,429)
	101,216	95,293
Less treasury stock, at cost: 1,043,697,097 shares in 2022 and 1,049,499,023 shares in 2021	56,758	57,109
Total Merck & Co., Inc. stockholders' equity	44,458	38,184
Noncontrolling Interests	66	73
Total equity	44,524	38,257
	$ 107,081	$ 105,694

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

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

	Nine Months Ended September 30,	
	2022	2021
Cash Flows from Operating Activities of Continuing Operations		
Net income from continuing operations	$ 11,508	$ 8,534
Adjustments to reconcile net income from continuing operations to net cash provided by operating activities of continuing operations:		
Amortization	1,623	1,231
Depreciation	1,394	1,148
Intangible asset impairment charges	910	—
Loss (income) from investments in equity securities, net	1,361	(1,535)
Charge for the acquisition of Pandion Therapeutics, Inc.	—	1,556
Deferred income taxes	(1,261)	28
Share-based compensation	396	360
Other	1,169	499
Net changes in assets and liabilities	(2,435)	(3,794)
Net Cash Provided by Operating Activities of Continuing Operations	14,665	8,027
Cash Flows from Investing Activities of Continuing Operations		
Capital expenditures	(3,239)	(3,240)
Purchases of securities and other investments	(710)	(1)
Proceeds from sales of securities and other investments	709	497
Acquisition of Pandion Therapeutics, Inc., net of cash acquired	—	(1,554)
Other acquisitions, net of cash acquired	(121)	(89)
Other	149	15
Net Cash Used in Investing Activities of Continuing Operations	(3,212)	(4,372)
Cash Flows from Financing Activities of Continuing Operations		
Net change in short-term borrowings	—	(3,983)
Payments on debt	(2,250)	(1,153)
Distribution from Organon & Co.	—	9,000
Purchases of treasury stock	—	(822)
Dividends paid to stockholders	(5,262)	(4,967)
Proceeds from exercise of stock options	119	68
Other	(172)	(253)
Net Cash Used in Financing Activities of Continuing Operations	(7,565)	(2,110)
Cash Flows from Discontinued Operations		
Net cash provided by operating activities	—	1,051
Net cash used in investing activities	—	(134)
Net cash used in financing activities	—	(504)
Net Cash Flows Provided by Discontinued Operations	—	413
Effect of Exchange Rate Changes on Cash, Cash Equivalents and Restricted Cash	(776)	(65)
Net Increase in Cash, Cash Equivalents and Restricted Cash	3,112	1,893
Cash, Cash Equivalents and Restricted Cash at Beginning of Year (includes restricted cash of $71 and $103 at January 1, 2022 and 2021, respectively, included in Other current assets)	8,167	8,153
Cash, Cash Equivalents and Restricted Cash at End of Period (includes restricted cash of $134 and $30 at September 30, 2022 and 2021, respectively, included in Other current assets)	$ 11,279	$ 10,046

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

1. Basis of Presentation

The accompanying unaudited condensed consolidated financial statements of Merck & Co., Inc. (Merck or the Company) have been prepared pursuant to the rules and regulations for reporting on Form 10-Q. Accordingly, certain information and disclosures required by accounting principles generally accepted in the United States (U.S.) (GAAP) for complete consolidated financial statements are not included herein. These interim statements should be read in conjunction with the audited financial statements and notes thereto included in Merck's Form 10-K filed on February 25, 2022.

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.

Spin-Off of Organon & Co.

On June 2, 2021, Merck completed the spin-off of products from its women's health, biosimilars and established brands businesses into a new, independent, publicly traded company named Organon & Co. (Organon) through a distribution of Organon's publicly traded stock to Company shareholders. The distribution is expected to qualify and has been treated as tax-free to the Company and its shareholders for U.S. federal income tax purposes. The established brands included in the transaction consisted of dermatology, non-opioid pain management, respiratory, select cardiovascular products, as well as the rest of Merck's diversified brands franchise. Merck's existing research pipeline programs continue to be owned and developed within Merck as planned. The historical results of the businesses that were contributed to Organon in the spin-off have been reflected as discontinued operations in the Company's consolidated financial statements through the date of the spin-off (see Note 2).

Recently Adopted Accounting Standards

In August 2020, the Financial Accounting Standards Board (FASB) issued amended guidance on the accounting for convertible instruments and contracts in an entity's own equity. The guidance removes the separation model for convertible debt instruments and preferred stock, amends requirements for conversion options to be classified in equity as well as amends diluted earnings per share (EPS) calculations for certain convertible debt instruments. The Company adopted the new guidance on January 1, 2022 using a modified retrospective approach. There was no impact to the Company's consolidated financial statements upon adoption.

In November 2021, the FASB issued new guidance to increase the transparency of transactions with a government that are accounted for by applying a grant or contribution accounting model by analogy. The guidance requires annual disclosures of such transactions to include the nature of the transactions and the significant terms and conditions, the accounting treatment and the impact to a company's financial statements. The Company adopted the new guidance on January 1, 2022 on a prospective basis. There was no material impact to the Company's consolidated financial statements upon adoption.

In March 2020, the FASB issued optional guidance to ease the potential burden in accounting for (or recognizing the effects of) reference rate reform on financial reporting and subsequently issued clarifying amendments. The guidance provides optional expedients and exceptions for accounting for contracts, hedging relationships, and other transactions that reference the London Interbank Offered Rate (LIBOR) or another reference rate expected to be discontinued because of reference rate reform. The Company adopted the optional guidance on July 1, 2022 on a prospective basis. There was no material impact to the Company's consolidated financial statements upon adoption.

Recently Issued Accounting Standards Not Yet Adopted

In October 2021, the FASB issued amended guidance that requires acquiring entities to recognize and measure contract assets and liabilities in a business combination in accordance with existing revenue recognition guidance. The amended guidance is effective for interim and annual periods in 2023 and is to be applied prospectively. Early adoption is permitted on a retrospective basis to the beginning of the fiscal year of adoption. The adoption of this guidance will not have an impact on the Company's consolidated financial statements for prior acquisitions; however, the impact in future periods will be dependent upon the contract assets and contract liabilities acquired in future business combinations.

In June 2022, the FASB issued guidance related to the fair value measurement of an equity security subject to contractual restrictions that prohibit the sale of the equity security. The new guidance also introduces new disclosure requirements for equity securities subject to contractual sale restrictions that are measured at fair value. The amended guidance is effective for interim and annual periods in 2024 and is to be applied prospectively. Early adoption is permitted for both interim and annual periods. The Company is currently evaluating the impact of adoption on its consolidated financial statements.

2. Spin-Off of Organon & Co.

On June 2, 2021, Merck completed the spin-off of Organon through a distribution of Organon's publicly traded stock to Company shareholders. In connection with the spin-off, each Merck shareholder received one tenth of a share of Organon's common stock for each share of Merck common stock held by such shareholder. The distribution is expected to qualify and has been treated as tax free to Merck and its shareholders for U.S. federal income tax purposes. Indebtedness of $9.5 billion principal amount, consisting of term loans and senior notes, was issued in 2021 in connection with the spin-off and assumed by Organon. Merck is no longer the obligor of any Organon debt or financing arrangements. Cash proceeds of $9.0 billion were distributed by Organon to Merck in connection with the spin-off.

Also in connection with the spin-off, Merck and Organon entered into a separation and distribution agreement and also entered into various other agreements to effect the spin-off and provide a framework for the relationship between Merck and Organon after the spin-off, including a transition services agreement (TSA), manufacturing and supply agreements (MSAs), trademark license agreements, intellectual property license agreements, an employee matters agreement, a tax matters agreement and certain other commercial agreements. Under the TSA, Merck is providing Organon various services and, similarly, Organon is providing Merck various services. The provision of services under the TSA generally will terminate within 25 months following the spin-off; however, the provision of certain services has been extended to 31 months. Merck and Organon also entered into a series of interim operating agreements pursuant to which in various jurisdictions where Merck held licenses, permits and other rights in connection with marketing, import and/or distribution of Organon products prior to the separation, Merck is continuing to market, import and distribute such products until such time as the relevant licenses and permits are transferred to Organon. Under such interim operating agreements and in accordance with the separation and distribution agreement, Merck is continuing operations in the affected markets on behalf of Organon, with Organon receiving all of the economic benefits and burdens of such activities. Additionally, Merck and Organon entered into a number of MSAs pursuant to which Merck is (a) manufacturing and supplying certain active pharmaceutical ingredients for Organon, (b) manufacturing and supplying certain formulated pharmaceutical products for Organon, and (c) packaging and labeling certain finished pharmaceutical products for Organon. Similarly, Organon and Merck entered into a number of MSAs pursuant to which Organon is (a) manufacturing and supplying certain formulated pharmaceutical products for Merck, and (b) packaging and labeling certain finished pharmaceutical products for Merck. The terms of the MSAs range in initial duration from four years to ten years.

The amounts included in the condensed consolidated statement of income for the above MSAs include sales of $100 million and $293 million and related cost of sales of $104 million and $312 million for the three and nine months ended September 30, 2022, respectively. The amounts included in the condensed consolidated statement of income for the MSAs in the same periods of 2021 were immaterial. Amounts included in the condensed consolidated statement of income for the TSAs were immaterial for the three and nine months ended September 30, 2022 and September 30, 2021.

The amounts due from Organon under all of the above agreements were $567 million and $964 million at September 30, 2022 and December 31, 2021, respectively, and are reflected in *Other current assets*. The amounts due to Organon under these agreements were $333 million and $400 million at September 30, 2022 and December 31, 2021, respectively, and are included in *Accrued and other current liabilities*.

The results of the women's health, biosimilars and established brands businesses (previously included in the Pharmaceutical segment) that were contributed to Organon in the spin-off, as well as interest expense related to the debt issuance in 2021, have been reflected as discontinued operations in the Company's condensed consolidated statement of income as *Income from Discontinued Operations, Net of Taxes and Amounts Attributable to Noncontrolling Interests* for periods prior to the spin-off on June 2, 2021. Merck incurred separation costs of $556 million for the nine months ended September 30, 2021 related to the spin-off of Organon, which are also included in *Income from Discontinued Operations, Net of Taxes and Amounts Attributable to Noncontrolling Interests*. These costs primarily relate to professional fees for separation activities within finance, tax, legal and information technology functions, as well as investment banking fees.

Details of *Income from Discontinued Operations, Net of Taxes and Amounts Attributable to Noncontrolling Interests* are as follows:

($ in millions)	Nine Months Ended September 30, 2021 [1]
Sales	$ 2,512
Costs, Expenses and Other	
Cost of sales	789
Selling, general and administrative	877
Research and development	103
Restructuring costs	1
Other (income) expense, net	(15)
	1,755
Income from discontinued operations before taxes	757
Income tax benefit	(12)
Income from discontinued operations, net of taxes	769
Less: Income of discontinued operations attributable to noncontrolling interests	3
	$ 766

[1] *Reflects amounts through the June 2, 2021 spin-off date.*

3. Acquisitions, Research Collaborations and License Agreements

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

2022 Transactions

In October 2022, Merck and Royalty Pharma plc (Royalty Pharma) entered into a funding arrangement under which Royalty Pharma paid Merck $50 million to co-fund Merck's development costs for a Phase 2b trial of MK-8189, an investigational oral Phosphodiesterase 10A (PDE10A) inhibitor, which is being evaluated for the treatment of schizophrenia. Under the agreement, Royalty Pharma has no rights to MK-8189 and has no decision-making authority over the program. If Merck elects to advance MK-8189 into a Phase 3 study, Royalty Pharma has the option to provide additional funding of 50% of the development costs up to $375 million for the Phase 3 trial. If such additional funding is provided, Royalty Pharma becomes eligible to receive future regulatory milestone payments contingent upon certain marketing approvals, as well as royalties.

In September 2022, Merck exercised its option to jointly develop and commercialize personalized cancer vaccine mRNA-4157/V940 pursuant to the terms of an existing collaboration and license agreement with Moderna, Inc. (Moderna), which resulted in a $250 million charge in *Research and development* expenses in the third quarter and first nine months of 2022. The payment to Moderna was made in the fourth quarter of 2022. mRNA-4157/V940 is currently being evaluated in combination with *Keytruda* (pembrolizumab), Merck's anti-PD-1 therapy, as adjuvant treatment for patients with high-risk melanoma in a Phase 2 clinical trial being conducted by Moderna. Under the 2016 agreement, as amended in 2018, Merck and Moderna will collaborate on development and commercialization and will share costs and any profits equally under this worldwide collaboration.

In August 2022, Merck and Orna Therapeutics (Orna), a biotechnology company pioneering a new investigational class of engineered circular RNA (oRNA) therapies, entered into a collaboration agreement to discover, develop, and commercialize multiple programs, including vaccines and therapeutics in the areas of infectious disease and oncology. Under the terms of the agreement, Merck made an upfront payment to Orna of $150 million, which was recorded in *Research and development* expenses in the third quarter and first nine months of 2022. In addition, Orna is eligible to receive future contingent development-related payments aggregating up to $440 million, $675 million in regulatory milestones, and $2.4 billion in sales milestones associated with the progress of the multiple vaccine and therapeutic programs, as well as royalties

ranging from a high-single-digit rate to a low-double-digit rate on any approved products derived from the collaboration. Merck also invested $100 million in Orna's Series B preferred shares in the fourth quarter of 2022.

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

Also in July 2022, Merck and Sichuan Kelun-Biotech Biopharmaceutical Co., Ltd. (Kelun-Biotech) closed a license and collaboration agreement in which Merck gained exclusive worldwide rights for the development, manufacture and commercialization of an investigational antibody drug conjugate (ADC) (MK-1200) for the treatment of solid tumors. Under the terms of the agreement, Merck and Kelun-Biotech will collaborate on the early clinical development of the investigational ADC. Merck made an upfront payment of $35 million, which was recorded in *Research and development* expenses in the third quarter and first nine months of 2022. Kelun-Biotech is also eligible to receive future contingent milestone payments aggregating up to $82 million in developmental milestones, $334 million in regulatory milestones, and $485 million in sales-based milestones. The agreement also provides for Merck to pay tiered royalties ranging from a mid-single-digit rate to a low-double-digit rate on future net sales.

In May 2022, in connection with an existing arrangement, Merck exercised its option to obtain an exclusive license outside of China for the development, manufacture and commercialization of Kelun-Biotech's trophoblast antigen 2 (TROP2)-targeting ADC programs, including its lead compound, SKB-264 (MK-2870). SKB-264 is currently being evaluated in Phase 2 trials for non-small-cell lung cancer and advanced solid tumors. Under the terms of the agreement, Merck and Kelun-Biotech will collaborate on certain early clinical development plans, including evaluating the potential of SKB-264 as a monotherapy and in combination with *Keytruda* for advanced solid tumors. Upon option exercise, Merck made a payment of $30 million, which was recorded in *Research and development* expenses in the first nine months of 2022, and agreed to make additional payments of $30 million upon completion of specified project activities and $25 million upon technology transfer. Merck also agreed to make quarterly payments in 2022 and 2023 aggregating up to $101 million to fund Kelun-Biotech's ongoing research and development activities. In addition, Kelun-Biotech is eligible to receive future contingent milestone payments (which includes all program compounds) aggregating up to $90 million in developmental milestones, $290 million in first commercial sale milestones, and $780 million in sales-based milestones. The agreement also provides for Merck to pay tiered royalties ranging from a mid-single-digit rate to a low-double-digit rate on future net sales.

2021 Transactions

In April 2021, Merck acquired Pandion Therapeutics, Inc. (Pandion), a clinical-stage biotechnology company developing novel therapeutics designed to address the unmet needs of patients living with autoimmune diseases. Pandion is advancing a pipeline of precision immune modulators targeting critical immune control nodes. Total consideration paid of $1.9 billion included $147 million of costs primarily comprised of share-based compensation payments to settle equity awards. The transaction was accounted for as an acquisition of an asset. Merck recorded net assets of $156 million (primarily cash) and *Research and development* expenses of $1.7 billion in the first nine months of 2021 related to the transaction. There are no future contingent payments associated with the acquisition.

In January 2021, Merck entered into an exclusive license and research collaboration agreement with Artiva Biotherapeutics, Inc. (Artiva) to discover, develop and manufacture CAR-NK cells that target certain solid tumors using Artiva's proprietary platform. Merck and Artiva agreed to engage in up to three different research programs, each covering a collaboration target. Merck has sole responsibility for all development and commercialization activities (including regulatory filing and approval). Under the terms of the agreement, Merck made an upfront payment of $30 million, which was included in *Research and development* expenses in the first nine months of 2021, for license and other rights for the first two collaboration targets and agreed to make another upfront payment of $15 million for license and other rights for the third collaboration target when it is selected by Merck and accepted by Artiva. In addition, Artiva is eligible to receive future contingent milestone payments (which span all three collaboration targets), aggregating up to $217.5 million in developmental milestones, $570 million in regulatory milestones, and $1.05 billion in sales-based milestones. The agreement also provides for Merck to pay tiered royalties ranging from 7% to 14% on future sales.

As part of Merck's 2020 acquisition of OncoImmune, Merck obtained MK-7110, a therapeutic candidate that was being evaluated for the treatment of patients hospitalized with COVID-19. In 2021, Merck received feedback from the U.S. Food and Drug Administration (FDA) that additional data would be needed to support a potential Emergency Use Authorization application and therefore the Company did not expect MK-7110 would become available until the first half of 2022. Given this timeline and the technical, clinical and regulatory uncertainties, the availability of a number of medicines for patients hospitalized with COVID-19, and the need to concentrate Merck's resources on accelerating the development and manufacture of the most viable therapeutics and vaccines, Merck decided to discontinue development of MK-7110 for the treatment of COVID-19. Due to the discontinuation, the Company recorded charges of $207 million in the first nine months of 2021, which are reflected in *Cost of sales* and relate to fixed assets and materials written off, as well as the recognition of liabilities for purchase commitments.

4. Collaborative Arrangements

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

AstraZeneca

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

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

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

In the first quarter of 2022, Merck determined it was probable that sales of Lynparza in the future would trigger a $600 million sales-based milestone payment from Merck to AstraZeneca. Accordingly, Merck recorded a $600 million liability and a corresponding increase to the intangible asset related to Lynparza. Merck also recognized $250 million of cumulative amortization catch-up expense related to the recognition of this milestone in the first quarter of 2022. In the first nine months of 2022, Merck made a sales-based milestone payment to AstraZeneca (which had been previously accrued for) of $400 million. As of September 30, 2022, sales-based milestone payments accrued but not yet paid totaled $600 million. Potential future sales-based milestone payments of $2.1 billion have not yet been accrued as they are not deemed by the Company to be probable at this time. In the first nine months of 2022, Lynparza received regulatory approvals triggering capitalized milestone payments of $250 million from Merck to AstraZeneca. Potential future regulatory milestone payments of $1.2 billion remain under the agreement.

The intangible asset balance related to Lynparza (which includes capitalized sales-based and regulatory milestone payments) was $1.5 billion at September 30, 2022 and is included in *Other Intangibles, Net*. The amount is being amortized over its estimated useful life through 2028 as supported by projected future cash flows, subject to impairment testing.

Summarized financial information related to this collaboration is as follows:

($ in millions)	Three Months Ended September 30, 2022	Three Months Ended September 30, 2021	Nine Months Ended September 30, 2022	Nine Months Ended September 30, 2021
Alliance revenue - Lynparza	$ 284	$ 246	$ 825	$ 721
Alliance revenue - Koselugo	10	6	43	20
Total alliance revenue	$ 294	$ 252	$ 868	$ 741
Cost of sales [1]	64	42	425	125
Selling, general and administrative	45	44	135	127
Research and development	28	27	79	87

($ in millions)	September 30, 2022	December 31, 2021
Receivables from AstraZeneca included in *Other current assets*	$ 290	$ 271
Payables to AstraZeneca included in *Trade accounts payable* and *Accrued and other current liabilities* [2]	12	415
Payables to AstraZeneca included in *Other Noncurrent Liabilities* [2]	600	—

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

[2] Includes accrued milestone payments.

Eisai

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

Under the agreement, Merck made an upfront payment to Eisai and also made payments over a multi-year period for certain option rights (of which the final $125 million option payment was made in March 2021). 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 nine months of 2022, Merck made sales-based milestone payments to Eisai (which had been previously accrued for) aggregating $600 million. Potential future sales-based milestone payments of $2.6 billion have not yet been accrued as they are not deemed by the Company to be probable at this time. In the first nine months of 2022, Lenvima received regulatory approvals triggering capitalized milestone payments of $50 million from Merck to Eisai. 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 $867 million at September 30, 2022 and is included in *Other Intangibles, Net*. The amount is being amortized over its estimated useful life through 2026 as supported by projected future cash flows, subject to impairment testing.

Summarized financial information related to this collaboration is as follows:

($ in millions)	Three Months Ended September 30, 2022	Three Months Ended September 30, 2021	Nine Months Ended September 30, 2022	Nine Months Ended September 30, 2021
Alliance revenue - Lenvima	$ 202	$ 188	$ 660	$ 498
Cost of sales [1]	53	49	159	143
Selling, general and administrative	42	34	115	88
Research and development	24	43	128	165

($ in millions)	September 30, 2022	December 31, 2021
Receivables from Eisai included in *Other current assets*	$ 202	$ 200
Payables to Eisai included in *Accrued and other current liabilities* [2]	1	625

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

[2] *Amount as of December 31, 2021 includes accrued milestone payments.*

Bayer AG

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

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

The intangible asset balances related to Adempas (which includes the acquired intangible asset balance, as well as capitalized sales-based milestone payments attributed to Adempas) and Verquvo (which reflects the portion of the final sales-based milestone payment that was attributed to Verquvo) were $597 million and $53 million, respectively, at September 30, 2022 and are included in *Other Intangibles, Net*. The assets are being amortized over their estimated useful lives (through 2027 for Adempas and through 2031 for Verquvo) as supported by projected future cash flows, subject to impairment testing.

Summarized financial information related to this collaboration is as follows:

($ in millions)	Three Months Ended September 30, 2022	Three Months Ended September 30, 2021	Nine Months Ended September 30, 2022	Nine Months Ended September 30, 2021
Alliance revenue - Adempas/Verquvo	$ 88	$ 100	$ 258	$ 248
Net sales of Adempas recorded by Merck	57	59	181	188
Net sales of Verquvo recorded by Merck	6	2	15	3
Total sales	$ 151	$ 161	$ 454	$ 439
Cost of sales [1]	55	53	158	328
Selling, general and administrative	42	31	107	84
Research and development	18	16	52	36

($ in millions)	September 30, 2022	December 31, 2021
Receivables from Bayer included in *Other current assets*	$ 144	$ 114
Payables to Bayer included in *Accrued and other current liabilities* [2]	75	472

[1] *Includes amortization of intangible assets. Amount in the first nine months of 2021 includes $153 million of cumulative amortization catch-up expense. In addition, cost of sales includes Bayer's share of profits from sales in Merck's marketing territories.*

[2] *Amount as of December 31, 2021 includes accrued milestone payment.*

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 orally available antiviral candidate in clinical development for the treatment of patients with COVID-19. Merck gained exclusive worldwide rights to develop and commercialize *Lagevrio* and related molecules.

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.

Lagevrio has received multiple authorizations or approvals worldwide and Merck has entered into advance purchase and supply agreements for *Lagevrio* in more than 40 markets. As of September 30, 2022, the Company has 0.8 million remaining courses to be supplied under these agreements.

Summarized financial information related to this collaboration is as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
($ in millions)	2022	2021	2022	2021
Lagevrio sales	$ 436	$ —	$ 4,859	$ —
Cost of sales [1]	234	4	2,580	56
Selling, general and administrative	41	6	105	13
Research and development	8	58	29	167

($ in millions)	September 30, 2022	December 31, 2021
Payables to Ridgeback included in *Accrued and other current liabilities* [2]	$ 193	$ 283

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

[2] *Includes accrued royalty and milestone payments.*

Bristol Myers Squibb

Reblozyl (luspatercept-aamt) is a first-in-class erythroid maturation recombinant fusion protein obtained as part of Merck's November 2021 acquisition of Acceleron Pharma Inc. that is being developed and commercialized through a global collaboration with Bristol Myers Squibb (BMS). Reblozyl is approved in the U.S., Europe, Canada and Australia for the treatment of anemia in certain rare blood disorders and is also being evaluated for additional indications for hematology therapies. BMS is the principal on sales transactions for Reblozyl; however, Merck co-promotes Reblozyl (and will co-promote all future products approved under this collaboration) in North America, which is reimbursed by BMS. Merck receives a 20% sales royalty from BMS which could increase to a maximum of 24% based on sales levels. This royalty will be reduced by 50% upon the earlier of patent expiry or generic entry on an indication-by-indication basis in each market. Additionally, Merck is eligible to receive future contingent sales-based milestone payments of up to $80 million. Merck recorded alliance revenue of $39 million (consisting of royalties) within *Sales* in the third quarter of 2022 related to this collaboration. Merck recorded alliance revenue of $124 million in the first nine months of 2022, which includes royalties of $104 million, as well as the receipt of a regulatory approval milestone payment of $20 million.

5. Restructuring

In 2019, Merck approved a global restructuring program (Restructuring Program) as part of a worldwide initiative focused on further optimizing the Company's manufacturing and supply network, as well as reducing its global real estate footprint. This program is a continuation of the Company's plant rationalization and builds on prior restructuring programs. The actions currently contemplated under the Restructuring Program are expected to be substantially completed by the end of 2023, with the cumulative pretax costs to be incurred by the Company to implement the program estimated to be approximately $3.5 billion. The Company estimates that approximately 70% of the cumulative pretax costs will result in cash outlays, primarily related to employee separation expense and facility shut-down costs. Approximately 30% of the cumulative pretax costs will be non-cash, relating primarily to the accelerated depreciation of facilities to be closed or divested.

The Company recorded total pretax costs of $175 million and $168 million in the third quarter of 2022 and 2021, respectively, and $559 million and $630 million for the first nine months of 2022 and 2021, respectively, related to

restructuring program activities. Since inception of the Restructuring Program through September 30, 2022, Merck has recorded total pretax accumulated costs of approximately $3.2 billion. For the full year of 2022, the Company expects to record charges of approximately $600 million related to the Restructuring Program. For segment reporting, restructuring charges are unallocated expenses.

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

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

	Three Months Ended September 30, 2021				Nine Months Ended September 30, 2021			
($ in millions)	Separation Costs	Accelerated Depreciation	Other	Total	Separation Costs	Accelerated Depreciation	Other	Total
Cost of sales	$ —	$ 11	$ 37	$ 48	$ —	$ 32	$ 81	$ 113
Selling, general and administrative	—	4	1	5	—	8	1	9
Research and development	—	7	1	8	—	20	1	21
Restructuring costs	17	—	90	107	310	—	177	487
	$ 17	$ 22	$ 129	$ 168	$ 310	$ 60	$ 260	$ 630

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

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

Other activity in 2022 and 2021 includes asset abandonment, facility shut-down and other related costs, as well as pretax gains and losses resulting from the sales of facilities and related assets. Additionally, other activity includes certain employee-related costs associated with pension and other postretirement benefit plans (see Note 11) and share-based compensation.

The following table summarizes the charges and spending relating to restructuring program activities for the nine months ended September 30, 2022:

($ in millions)	Separation Costs	Accelerated Depreciation	Other	Total
Restructuring reserves January 1, 2022	$ 596	$ —	$ 41	$ 637
Expense	197	97	265	559
(Payments) receipts, net	(303)	—	(458)	(761)
Non-cash activity	—	(97)	183	86
Restructuring reserves September 30, 2022 [(1)]	$ 490	$ —	$ 31	$ 521

[(1)] *The remaining cash outlays are expected to be substantially completed by the end of 2023.*

6. Financial Instruments

Derivative Instruments and Hedging Activities

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

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

Foreign Currency Risk Management

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

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

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

The Company manages operating activities and net asset positions at each local subsidiary in order to mitigate the effects of exchange on monetary assets and liabilities. The Company also uses a balance sheet risk management program to mitigate the exposure of net monetary assets that are denominated in a currency other than a subsidiary's functional currency from the effects of volatility in foreign exchange. In these instances, Merck principally utilizes forward exchange contracts to offset the effects of exchange on exposures denominated in developed country currencies, primarily the euro, Japanese yen, British pound, Canadian dollar and Swiss franc. For exposures in developing country currencies, including the Chinese renminbi, the Company will enter into forward contracts to offset the effects of exchange on exposures when it is deemed economical to do so based on a cost-benefit analysis that considers the magnitude of the exposure, the volatility of the exchange rate and the cost of the hedging instrument. The cash flows from these contracts are reported as operating activities in the Condensed Consolidated Statement of Cash Flows.

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 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 one year.

The Company also uses forward exchange contracts to hedge a portion of its net investment in foreign operations against movements in exchange rates. The forward contracts are designated as hedges of the net investment in a foreign operation. The unrealized gains or losses on these contracts are recorded in foreign currency translation adjustment within *OCI* and remain in *AOCL* until either the sale or complete or substantially complete liquidation of the subsidiary. The Company excludes certain portions of the change in fair value of its derivative instruments from the assessment of hedge effectiveness (excluded components). Changes in fair value of the excluded components are recognized in *OCI*. The Company recognizes in earnings the initial value of the excluded components on a straight-line basis over the life of the derivative instrument, rather than using the mark-to-market approach. The cash flows from these contracts are reported as investing activities in the Condensed Consolidated Statement of Cash Flows.

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

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

	Amount of Pretax (Gain) Loss Recognized in Other Comprehensive Income[1]				Amount of Pretax (Gain) Loss Recognized in *Other (income) expense, net* for Amounts Excluded from Effectiveness Testing			
	Three Months Ended September 30,		Nine Months Ended September 30,		Three Months Ended September 30,		Nine Months Ended September 30,	
($ in millions)	2022	2021	2022	2021	2022	2021	2022	2021
Net Investment Hedging Relationships								
Foreign exchange contracts	$ (1)	$ 1	$ (47)	$ (27)	$ —	$ (4)	$ (2)	$ (12)
Euro-denominated notes	(250)	(77)	(431)	(199)	—	—	—	—

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

Interest Rate Risk Management

The Company may use interest rate swap contracts on certain investing and borrowing transactions to manage its net exposure to interest rate changes and to reduce its overall cost of borrowing. The Company does not use leveraged swaps and, in general, does not leverage any of its investment activities that would put principal at risk.

In February 2022, five interest rate swap contracts with a total notional amount of $1.25 billion matured. These swaps effectively converted the Company's $1.25 billion, 2.35% fixed-rate notes due 2022 to variable rate debt. In September 2022, four interest rate swap contracts with a total notional amount of $1.0 billion matured. These swaps effectively converted the Company's $1.0 billion, 2.40% fixed rate notes due 2022 to variable rate debt. The interest rate swap contracts were designated hedges of the fair value changes in the notes attributable to changes in the benchmark LIBOR swap rate. The fair value changes in the notes attributable to changes in the LIBOR swap rate were 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 Company is not currently a party to any interest rate swaps.

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

	Carrying Amount of Hedged Liabilities		Cumulative Amount of Fair Value Hedging Adjustment Increase (Decrease) Included in the Carrying Amount	
($ in millions)	September 30, 2022	December 31, 2021	September 30, 2022	December 31, 2021
Balance Sheet Line Item in which Hedged Item is Included				
Loans payable and current portion of long-term debt	$ —	$ 2,263	$ —	$ 13

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

		September 30, 2022			December 31, 2021		
		Fair Value of Derivative		U.S. Dollar Notional	Fair Value of Derivative		U.S. Dollar Notional
($ in millions)		Asset	Liability		Asset	Liability	
Derivatives Designated as Hedging Instruments	*Balance Sheet Caption*						
Interest rate swap contracts	Other current assets	$ —	$ —	$ —	$ 14	$ —	$ 2,250
Foreign exchange contracts	Other current assets	826	—	7,250	271	—	6,778
Foreign exchange contracts	Other Assets	85	—	1,408	43	—	1,551
Foreign exchange contracts	Accrued and other current liabilities	—	1	37	—	24	1,623
Foreign exchange contracts	Other Noncurrent Liabilities	—	1	93	—	1	43
		$ 911	$ 2	$ 8,788	$ 328	$ 25	$ 12,245
Derivatives Not Designated as Hedging Instruments	*Balance Sheet Caption*						
Foreign exchange contracts	Other current assets	$ 597	$ —	$ 9,523	$ 221	$ —	$ 10,073
Foreign exchange contracts	Accrued and other current liabilities	—	240	7,715	—	96	10,640
		$ 597	$ 240	$ 17,238	$ 221	$ 96	$ 20,713
		$ 1,508	$ 242	$ 26,026	$ 549	$ 121	$ 32,958

As noted above, the Company records its derivatives on a gross basis in the Condensed Consolidated Balance Sheet. The Company has master netting agreements with several of its financial institution counterparties (see *Concentrations of Credit Risk* below). The following table provides information on the Company's derivative positions subject to these master

netting arrangements as if they were presented on a net basis, allowing for the right of offset by counterparty and cash collateral exchanged per the master agreements and related credit support annexes:

	September 30, 2022		December 31, 2021	
($ in millions)	Asset	Liability	Asset	Liability
Gross amounts recognized in the condensed consolidated balance sheet	$ 1,508	$ 242	$ 549	$ 121
Gross amounts subject to offset in master netting arrangements not offset in the condensed consolidated balance sheet	(217)	(217)	(110)	(110)
Cash collateral received	(794)	—	(164)	—
Net amounts	$ 497	$ 25	$ 275	$ 11

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

	Three Months Ended September 30,						Nine Months Ended September 30,					
($ in millions)	2022	2021	2022	2021	2022	2021	2022	2021	2022	2021	2022	2021
Financial Statement Line Items in which Effects of Fair Value or Cash Flow Hedges are Recorded	Sales		Other (income) expense, net [1]		Other comprehensive income (loss)		Sales		Other (income) expense, net [1]		Other comprehensive income (loss)	
	$ 14,959	$ 13,154	$ 429	$ (450)	$ (416)	$ 38	$ 45,453	$ 35,183	$ 1,576	$ (1,007)	$ (314)	$ 1,595
(Gain) loss on fair value hedging relationships												
Interest rate swap contracts												
Hedged items	—	—	1	(9)	—	—	—	—	(13)	(29)	—	—
Derivatives designated as hedging instruments	—	—	—	(1)	—	—	—	—	4	(1)	—	—
Impact of cash flow hedging relationships												
Foreign exchange contracts												
Amount of gain recognized in *OCI* on derivatives	—	—	—	—	682	72	—	—	—	—	1,233	193
Increase (decrease) in *Sales* as a result of *AOCL* reclassifications	253	(36)	—	—	(253)	36	491	(219)	—	—	(491)	219
Interest rate contracts												
Amount of gain recognized in *Other (income) expense, net* on derivatives	—	—	(1)	—	—	—	—	—	(2)	(2)	—	—
Amount of loss recognized in *OCI* on derivatives	—	—	—	—	(1)	—	—	—	—	—	(2)	(2)

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

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

		Amount of Derivative Pretax (Gain) Loss Recognized in Income			
		Three Months Ended September 30,		Nine Months Ended September 30,	
($ in millions)		2022	2021	2022	2021
Derivatives Not Designated as Hedging Instruments	*Income Statement Caption*				
Foreign exchange contracts [1]	Other (income) expense, net	$ (41)	$ 18	$ (77)	$ 234
Foreign exchange contracts [2]	Sales	(4)	(4)	(42)	6

[1] *These derivative contracts primarily mitigate changes in the value of remeasured foreign currency denominated monetary assets and liabilities attributable to changes in foreign currency exchange rates. Amount in the first nine months of 2021 includes a loss on forward exchange contracts entered into in conjunction with the spin-off of Organon.*

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

At September 30, 2022, the Company estimates $864 million of pretax net unrealized gains on derivatives maturing within the next 12 months that hedge foreign currency denominated sales over that same period will be reclassified from *AOCL* to *Sales*. The amount ultimately reclassified to *Sales* may differ as foreign exchange rates change. Realized gains and losses are ultimately determined by actual exchange rates at maturity.

Investments in Debt and Equity Securities

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

	September 30, 2022				December 31, 2021			
	Amortized	Gross Unrealized		Fair	Amortized	Gross Unrealized		Fair
($ in millions)	Cost	Gains	Losses	Value	Cost	Gains	Losses	Value
U.S. government and agency securities	$ 67	$ —	$ —	$ 67	$ 80	$ —	$ —	$ 80
Commercial paper	4	—	—	4	—	—	—	—
Corporate notes and bonds	3	—	—	3	4	—	—	4
Foreign government bonds	2	—	—	2	2	—	—	2
Total debt securities	$ 76	$ —	$ —	$ 76	$ 86	$ —	$ —	$ 86
Publicly traded equity securities [(1)]				1,334				1,647
Total debt and publicly traded equity securities				$ 1,410				$ 1,733

[(1)] *Unrealized net losses of $221 million and $415 million were recorded in* Other (income) expense, net *in the third quarter and first nine months of 2022, respectively, on equity securities still held at September 30, 2022. Unrealized net (gains) losses of $(90) million and $109 million were recorded in* Other (income) expense, net *in the third quarter and first nine months of 2021, respectively, on equity securities still held at September 30, 2021.*

At September 30, 2022 and September 30, 2021, the Company also had $705 million and $578 million, respectively, of equity investments without readily determinable fair values included in *Other Assets*. The Company records unrealized gains on these equity investments based on favorable observable price changes from transactions involving similar investments of the same investee and records unrealized losses based on unfavorable observable price changes, which are included in *Other (income) expense, net*. During the first nine months of 2022, the Company recorded unrealized gains of $21 million and unrealized net losses of $12 million related to certain of these equity investments still held at September 30, 2022. During the first nine months of 2021, the Company recorded unrealized gains of $104 million and unrealized losses of $1 million related to certain of these investments still held at September 30, 2021. Cumulative unrealized gains and cumulative unrealized losses based on observable price changes for investments in equity investments without readily determinable fair values still held at September 30, 2022 were $255 million and $19 million, respectively.

At September 30, 2022 and September 30, 2021, the Company also had $655 million and $1.2 billion, respectively, recorded in *Other Assets* for equity securities held through ownership interests in investment funds. Losses (gains) recorded in *Other (income) expense, net* relating to these investment funds were $141 million and $(391) million for the third quarter of 2022 and 2021, respectively, and were $952 million and $(893) million for the first nine months of 2022 and 2021, respectively.

Fair Value Measurements

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

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

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

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

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

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

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

	Fair Value Measurements Using				Fair Value Measurements Using			
	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3	Total
($ in millions)	September 30, 2022				December 31, 2021			
Assets								
Investments								
Commercial paper	$ —	$ 4	$ —	$ 4	$ —	$ —	$ —	$ —
Foreign government bonds	—	2	—	2	—	2	—	2
Publicly traded equity securities	1,081	—	—	1,081	368	—	—	368
	1,081	6	—	1,087	368	2	—	370
Other assets [1]								
U.S. government and agency securities	67	—	—	67	80	—	—	80
Corporate notes and bonds	3	—	—	3	4	—	—	4
Publicly traded equity securities	253	—	—	253	1,279	—	—	1,279
	323	—	—	323	1,363	—	—	1,363
Derivative assets [2]								
Forward exchange contracts	—	945	—	945	—	351	—	351
Purchased currency options	—	563	—	563	—	184	—	184
Interest rate swaps	—	—	—	—	—	14	—	14
	—	1,508	—	1,508	—	549	—	549
Total assets	$ 1,404	$ 1,514	$ —	$ 2,918	$ 1,731	$ 551	$ —	$ 2,282
Liabilities								
Other liabilities								
Contingent consideration	$ —	$ —	$ 499	$ 499	$ —	$ —	$ 777	$ 777
Derivative liabilities [2]								
Forward exchange contracts	—	242	—	242	—	120	—	120
Written currency options	—	—	—	—	—	1	—	1
	—	242	—	242	—	121	—	121
Total liabilities	$ —	$ 242	$ 499	$ 741	$ —	$ 121	$ 777	$ 898

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

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

As of September 30, 2022 and December 31, 2021, *Cash and cash equivalents* included $10.0 billion and $6.8 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)	2022	2021
Fair value January 1	$ 777	$ 841
Changes in estimated fair value [1]	(156)	73
Payments	(119)	—
Other	(3)	(12)
Fair value September 30 [2]	$ 499	$ 902

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

[2] *At September 30, 2022, $358 million of the liabilities relate to the 2016 termination of the Sanofi Pasteur MSD joint venture. As part of the termination, Merck recorded a liability for contingent future royalty payments of 11.5% on net sales of all Merck products that were previously sold by the joint venture through December 31, 2024. The fair value of this liability is determined utilizing the estimated amount and timing of projected cash flows using a risk-adjusted discount rate to present value the cash flows. Balance at September 30, 2022 includes $139 million recorded as a current liability for amounts expected to be paid within the next 12 months.*

The payments of contingent consideration in 2022 relate to the Sanofi Pasteur MSD liabilities described above.

Other Fair Value Measurements

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

The estimated fair value of loans payable and long-term debt (including current portion) at September 30, 2022, was $25.9 billion compared with a carrying value of $30.4 billion and at December 31, 2021, was $35.7 billion compared with a carrying value of $33.1 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 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 $2.3 billion and $2.8 billion of accounts receivable as of September 30, 2022 and December 31, 2021, respectively, under these factoring arrangements, which reduced outstanding accounts receivable. The cash received from the financial institutions is reported within operating activities in the Condensed Consolidated Statement of Cash Flows. In certain of these factoring arrangements, for ease of administration, the Company will collect customer payments related to the factored receivables, which it then remits to the financial institutions. As of September 30, 2022 and December 31, 2021, the Company had collected $55 million and $62 million, respectively, on behalf of the financial institutions, which is reflected as restricted cash in *Other current assets* and the related obligation to remit the cash within *Accrued and other current liabilities*. The Company remitted the cash to the financial institutions in October 2022 and January 2022, respectively. The net cash flows related to these collections are reported as financing activities in the Condensed Consolidated Statement of Cash Flows. The cost of factoring such accounts receivable was *de minimis*.

Derivative financial instruments are executed under International Swaps and Derivatives Association master agreements. The master agreements with several of the Company's financial institution counterparties also include credit support annexes. These annexes contain provisions that require collateral to be exchanged depending on the value of the derivative assets and liabilities, the Company's credit rating, and the credit rating of the counterparty. Cash collateral received by the Company from various counterparties was $794 million and $164 million at September 30, 2022 and December 31, 2021, respectively. The obligation to return such collateral is recorded in *Accrued and other current liabilities*.

7. Inventories

Inventories consisted of:

($ in millions)	September 30, 2022	December 31, 2021
Finished goods	$ 1,683	$ 1,747
Raw materials and work in process	6,532	6,220
Supplies	227	196
Total (approximates current cost)	8,442	8,163
Decrease to LIFO cost	(187)	(16)
	$ 8,255	$ 8,147
Recognized as:		
Inventories	$ 5,614	$ 5,953
Other assets	2,641	2,194

Amounts recognized as *Other Assets* are comprised almost entirely of raw materials and work in process inventories. At September 30, 2022 and December 31, 2021, these amounts included $2.2 billion and $1.9 billion, respectively, of inventories not expected to be sold within one year. In addition, these amounts included $417 million and $256 million at September 30, 2022 and December 31, 2021, respectively, of inventories produced in preparation for product launches.

8. Other Intangibles

In the third quarter of 2022, the Company recorded $887 million of impairment charges within *Research and development* expenses related to intangible assets obtained in connection with the 2020 acquisition of ArQule, Inc. Of this amount, $807 million represents an in-process research and development (IPR&D) impairment charge related to nemtabrutinib (MK-1026), a novel, oral BTK inhibitor currently being evaluated for the treatment of B-cell malignancies. Following discussions with regulatory authorities in the third quarter, the development period for nemtabrutinib was extended, which constituted a triggering event that required the evaluation of the nemtabrutinib intangible asset for impairment. The Company estimated the current fair value of nemtabrutinib utilizing an income approach which calculates the present value of projected future cash flows. The market participant assumptions used to derive the forecasted cash flows were updated to reflect a delay in the anticipated launch date for nemtabrutinib, which resulted in lower cumulative revenue forecasts and a reduction in the estimated fair value. The revised estimated fair value of nemtabrutinib when compared with its related carrying value resulted in the IPR&D impairment charge noted above. The remaining IPR&D intangible asset related to nemtabrutinib is $1.2 billion. If the assumptions used to estimate the fair value of nemtabrutinib prove to be incorrect and the development of nemtabrutinib does not progress as anticipated thereby adversely affecting projected future cash flows, the Company may record an additional impairment charge in the future and such charge could be material.

9. Contingencies

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

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

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

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

Product Liability Litigation

Fosamax

As previously disclosed, Merck is a defendant in product liability lawsuits in the U.S. involving Fosamax (alendronate sodium) (Fosamax Litigation). As of September 30, 2022, approximately 3,450 cases are pending against Merck in either a federal multidistrict litigation (Femur Fracture MDL) or state court. Plaintiffs in the vast majority of these cases generally allege that they sustained femur fractures and/or other bone injuries (Femur Fractures) in association with the use of Fosamax.

In March 2014, the Femur Fracture MDL court dismissed with prejudice approximately 650 cases on preemption grounds. Plaintiffs in approximately 515 of those cases appealed that decision to the U.S. Court of Appeals for the Third Circuit (Third Circuit). In March 2017, the Third Circuit issued a decision reversing the Femur Fracture MDL court's preemption ruling and remanding the appealed cases back to the Femur Fracture MDL court. In May 2019, the U.S. Supreme Court decided that the Third Circuit had incorrectly concluded that the issue of preemption should be resolved by a jury, and accordingly vacated the judgment of the Third Circuit and remanded the proceedings back to the Third Circuit to address the issue in a manner consistent with the Supreme Court's opinion. In November 2019, the Third Circuit remanded the cases back to the District Court in order to allow that court to determine in the first instance whether the plaintiffs' state law claims are preempted by federal law under the standards described by the Supreme Court in its opinion. On March 23, 2022, the District Court granted Merck's motion and ruled that plaintiffs' failure to warn claims are preempted as a matter of law to the extent they

assert that Merck should have added a warning or precaution regarding atypical femur fractures prior to September 2010. Plaintiffs have indicated that they do not intend to move forward with any other claims at this point and intend to appeal the District Court's preemption ruling to the Third Circuit.

Discovery is presently stayed in the Femur Fracture MDL. As part of the spin-off of Organon, Organon is required to indemnify Merck for all liabilities relating to, arising from, or resulting from the Fosamax Litigation.

Januvia/Janumet

As previously disclosed, Merck is a defendant in product liability lawsuits in the U.S. involving *Januvia* (sitagliptin) and/or *Janumet* (sitagliptin and metformin HCl).

Most claims were filed in multidistrict litigation before the U.S. District Court for the Southern District of California (MDL). In March 2021, the MDL court issued an omnibus order granting defendants' summary judgment motions based on preemption and failure to establish general causation, as well as granting defendants' motions to exclude plaintiffs' expert witnesses. The plaintiffs appealed that order. Since that time, more than half of these claims have been dismissed with prejudice as to Merck, and in October 2021, the U.S. Court of Appeals for the Ninth Circuit dismissed the appeal as to Merck and two of its codefendants. The MDL court's judgment is now final and no longer appealable with respect to remaining claims.

Outside of the MDL, the majority of claims were filed in coordinated proceedings before the Superior Court of California, County of Los Angeles (California State Court). On April 6, 2021, the court in California issued an omnibus order granting defendants' summary judgment motions and also granting defendants' motions to exclude plaintiffs' expert witnesses. On May 31, 2022, the court entered judgment in favor of Merck as to all of the claims pending against Merck in that jurisdiction.

In addition to the claims noted above, the Company has agreed to toll the statute of limitations for approximately 50 additional claims. The Company intends to continue defending against any remaining lawsuits.

Gardasil/Gardasil 9

Merck is a defendant in product liability lawsuits in the U.S. involving *Gardasil* (Human Papillomavirus Quadrivalent [Types 6, 11, 16 and 18] Vaccine, Recombinant) and *Gardasil* 9 (Human Papillomavirus 9-valent Vaccine, Recombinant). As of September 30, 2022, approximately 65 cases were filed and pending against Merck in either federal or state court. In these actions, plaintiffs allege, among other things, that they suffered various personal injuries after vaccination with *Gardasil* or *Gardasil* 9, with postural orthostatic tachycardia syndrome as a predominate alleged injury. In August 2022, the Judicial Panel on Multidistrict Litigation ordered that *Gardasil/Gardasil* 9 product liability cases pending in federal courts nationwide be transferred to Judge Robert J. Conrad in the Western District of North Carolina for coordinated pre-trial proceedings. There are fewer than 15 product liability cases pending outside the U.S., including one purported class action in Colombia.

Governmental Proceedings

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

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

Commercial and Other Litigation

Zetia Antitrust Litigation

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

In November 2019, the direct purchaser plaintiffs and the indirect purchaser plaintiffs filed motions for class certification. In August 2020, the district court granted in part the direct purchasers' motion for class certification and certified a class of 35 direct purchasers. In August 2021, the Fourth Circuit vacated the district court's class certification order and remanded for further proceedings consistent with the court's ruling. In September 2021, the direct purchaser plaintiffs filed a renewed motion for class certification. On January 25, 2022, the magistrate judge recommended that the district court deny the motion for class certification. On February 8, 2022, the direct purchaser plaintiffs filed objections to the recommendation. On April 13, 2022, the district court denied the direct purchaser plaintiffs' renewed motion for class certification. In August 2021, the district court granted certification of a class of indirect purchasers.

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

On February 9, 2022, the Insurer Plaintiffs filed amended complaints. On March 2, 2022, the Merck Defendants, jointly with other defendants, moved to dismiss certain aspects of the Insurer Plaintiffs' complaints, including any claims for Vytorin damages. That motion to dismiss the Vytorin-related claims is still pending.

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

On September 2, 2022, the Magistrate Judge issued a Report and Recommendation denying the Merck Defendants' and Glenmark Defendants' motions for summary judgment. Defendants have objected to the Report and Recommendation, and are awaiting a final decision from Judge Smith. The court has scheduled trial for all plaintiffs other than the Insurer Plaintiffs for April 2023.

340B Program Litigation

Merck has filed a complaint in the U.S. District Court for the District of Columbia to challenge the letter Merck received from the Health Resources and Services Administration (HRSA) in May 2022 regarding Merck's 340B Program integrity initiative. HRSA's letter to Merck asserts that Merck is in violation of the 340B statute. HRSA further claims that continued failure to provide the 340B price to covered entities using contract pharmacies may result in civil monetary penalties for each instance of alleged overcharging, in addition to repayment for any instance of overcharging. The letter is very similar to letters HRSA has sent to other manufacturers, which letters have been held to be unlawful by multiple federal courts. Merck disagrees with HRSA's assertion. Merck remains committed to the 340B Program and to providing 340B discounts to eligible covered entities. Merck's 340B Program integrity initiative is consistent with the requirements of the 340B statute and is intended to ensure the integrity and sustainability of the 340B statute by reducing prohibited duplicate discounts and diversion and putting patients back at the center of the program. Merck continues to offer all of the Company's covered outpatient drugs to all 340B covered entities for purchase at or below the 340B ceiling price. On September 13, 2022, the court stayed the case pending the D.C. Circuit's ruling in *Novartis Pharmaceuticals Corp. v. Johnson and United Therapeutics Corp. v. Johnson*.

Patent Litigation

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

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

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

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

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

Prior to the beginning of the scheduled October 2021 trial in the U.S. District Court for the District of Delaware on invalidity issues, the Company settled with all defendants scheduled to participate in that trial. In the Company's case against Mylan, a bench trial was held in December 2021 in the U.S. District Court for the Northern District of West Virginia, and the closing arguments were held on April 13, 2022. On September 21, 2022, the District Court for the Northern District of West Virginia issued a decision in the Company's favor, upholding all asserted patent claims. Mylan (now Viatris) has appealed to the U.S. Court of Appeals for the Federal Circuit.

In total, the Company has settled with 22 generic companies providing that these generic companies can bring their generic versions of *Januvia* and *Janumet* to the market in May 2026 or earlier under certain circumstances, and their generic versions of *Janumet XR* to the market in July 2026 or earlier under certain circumstances.

Additionally, in 2019, Mylan filed a petition for *inter partes* review (IPR) at the U.S. Patent and Trademark Office (USPTO) seeking invalidity of some, but not all, of the claims of the 2027 salt/polymorph patent. The USPTO instituted IPR proceedings in May 2020, finding a reasonable likelihood that the challenged claims are not valid. A trial was held in February 2021 and a final decision was rendered in May 2021, holding that all of the challenged claims were not invalid. Mylan appealed the USPTO's decision to the U.S. Court of Appeals for the Federal Circuit, and a hearing was held on August 2, 2022. On September 29, 2022, the Court of Appeals for the Federal Circuit ruled in the Company's favor, upholding the USPTO's decision.

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 application seeking approval of its sitagliptin tablets. While the U.S. District Court for the District of Delaware originally set a three-day bench trial in this matter beginning on October 31, 2022, the trial date has been moved to January 9, 2023.

Generic companies have sought revocation of the Supplementary Protection Certificate (SPC) for *Janumet* in a number of European countries. In February 2022, a Finnish court referred certain questions to the Court of Justice of the European Union that could determine the validity of the *Janumet* SPCs in Europe. In June 2021, a German court decided that the SPC for *Janumet* is invalid, which decision the Company has appealed. The validity of the *Janumet* SPC was upheld in the Czech Republic in March 2022 in a first instance decision, which has been appealed. In June 2022, a Romanian court decided

that the SPC for *Janumet* was invalid in a first instance decision. In August 2022, the validity of the SPC for *Janumet* was upheld in Sweden in a first instance decision, which decision has been appealed. MSD has filed injunction actions against generic companies in Belgium, Finland, France, Greece, Ireland and Portugal. In September 2022, the following decisions were issued: *ex-parte* preliminary injunctions were granted in Finland; a preliminary injunction was granted in France, and the validity of the SPC and the associated patent were held to be *prima facie* valid in these proceedings; and a temporary restraining order was granted in Greece. In October 2022, requests for *ex parte* preliminary injunctions were refused in Portugal.

Other Litigation

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

Legal Defense Reserves

Legal defense costs expected to be incurred in connection with a loss contingency are accrued when probable and reasonably estimable. Some of the significant factors considered in the review of these legal defense reserves are as follows: the actual costs incurred by the Company; the development of the Company's legal defense strategy and structure in light of the scope of its litigation; the number of cases being brought against the Company; the costs and outcomes of completed trials and the most current information regarding anticipated timing, progression, and related costs of pre-trial activities and trials in the associated litigation. The amount of legal defense reserves as of September 30, 2022 and December 31, 2021 of approximately $230 million represents the Company's best estimate of the minimum amount of defense costs to be incurred in connection with its outstanding litigation; however, events such as additional trials and other events that could arise in the course of its litigation could affect the ultimate amount of legal defense costs to be incurred by the Company. The Company will continue to monitor its legal defense costs and review the adequacy of the associated reserves and may determine to increase the reserves at any time in the future if, based upon the factors set forth, it believes it would be appropriate to do so.

10. Equity

	Three Months Ended September 30,								
	Common Stock		Other Paid-In Capital	Retained Earnings	Accumulated Other Comprehensive Loss	Treasury Stock		Non-controlling Interests	Total
($ and shares in millions except per share amounts)	Shares	Par Value				Shares	Cost		
Balance at July 1, 2021	3,577	$ 1,788	$ 44,039	$ 48,777	$ (4,628)	1,044	$ (56,682)	$ 94	$ 33,388
Net income attributable to Merck & Co., Inc.	—	—	—	4,567	—	—	—	—	4,567
Other comprehensive income, net of taxes	—	—	—	—	38	—	—	—	38
Cash dividends declared on common stock ($0.65 per share)	—	—	—	(1,653)	—	—	—	—	(1,653)
Treasury stock shares purchased	—	—	—	—	—	8	(583)	—	(583)
Share-based compensation plans and other	—	—	110	—	—	—	21	—	131
Net income attributable to noncontrolling interests	—	—	—	—	—	—	—	4	4
Distributions attributable to noncontrolling interests	—	—	—	—	—	—	—	(29)	(29)
Balance at September 30, 2021	3,577	$ 1,788	$ 44,149	$ 51,691	$ (4,590)	1,052	$ (57,244)	$ 69	$ 35,863
Balance at July 1, 2022	3,577	$ 1,788	$ 44,115	$ 58,437	$ (4,327)	1,044	$ (56,770)	$ 75	$ 43,318
Net income attributable to Merck & Co., Inc.	—	—	—	3,248	—	—	—	—	3,248
Other comprehensive loss, net of taxes	—	—	—	—	(416)	—	—	—	(416)
Cash dividends declared on common stock ($0.69 per share)	—	—	—	(1,757)	—	—	—	—	(1,757)
Share-based compensation plans and other	—	—	128	—	—	—	12	—	140
Net income attributable to noncontrolling interests	—	—	—	—	—	—	—	5	5
Distributions attributable to noncontrolling interests	—	—	—	—	—	—	—	(14)	(14)
Balance at September 30, 2022	3,577	$ 1,788	$ 44,243	$ 59,928	$ (4,743)	1,044	$ (56,758)	$ 66	$ 44,524

	Nine Months Ended September 30,								
	Common Stock		Other Paid-In Capital	Retained Earnings	Accumulated Other Comprehensive Loss	Treasury Stock		Non-controlling Interests	Total
($ and shares in millions except per share amounts)	Shares	Par Value				Shares	Cost		
Balance at January 1, 2021	3,577	$ 1,788	$ 39,588	$ 47,362	$ (6,634)	1,047	$ (56,787)	$ 87	$ 25,404
Net income attributable to Merck & Co., Inc.	—	—	—	9,291	—	—	—	—	9,291
Other comprehensive income, net of taxes	—	—	—	—	1,595	—	—	—	1,595
Cash dividends declared on common stock ($1.95 per share)	—	—	—	(4,962)	—	—	—	—	(4,962)
Treasury stock shares purchased	—	—	—	—	—	11	(822)	—	(822)
Spin-off of Organon & Co.	—	—	4,643	—	449	—	—	(1)	5,091
Share-based compensation plans and other	—	—	(82)	—	—	(6)	365	—	283
Net income attributable to noncontrolling interests	—	—	—	—	—	—	—	12	12
Distributions attributable to noncontrolling interests	—	—	—	—	—	—	—	(29)	(29)
Balance at September 30, 2021	3,577	$ 1,788	$ 44,149	$ 51,691	$ (4,590)	1,052	$ (57,244)	$ 69	$ 35,863
Balance at January 1, 2022	3,577	$ 1,788	$ 44,238	$ 53,696	$ (4,429)	1,049	$ (57,109)	$ 73	$ 38,257
Net income attributable to Merck & Co., Inc.	—	—	—	11,502	—	—	—	—	11,502
Other comprehensive loss, net of taxes	—	—	—	—	(314)	—	—	—	(314)
Cash dividends declared on common stock ($2.07 per share)	—	—	—	(5,270)	—	—	—	—	(5,270)
Share-based compensation plans and other	—	—	5	—	—	(5)	351	—	356
Net income attributable to noncontrolling interests	—	—	—	—	—	—	—	6	6
Distributions attributable to noncontrolling interests	—	—	—	—	—	—	—	(13)	(13)
Balance at September 30, 2022	3,577	$ 1,788	$ 44,243	$ 59,928	$ (4,743)	1,044	$ (56,758)	$ 66	$ 44,524

11. Pension and Other Postretirement Benefit Plans

The Company has defined benefit pension plans covering eligible employees in the U.S. and in certain of its international subsidiaries. The net periodic benefit cost of such plans (including certain costs reported as part of discontinued operations in the first nine months of 2021) consisted of the following components:

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2022		2021		2022		2021	
($ in millions)	U.S.	International	U.S.	International	U.S.	International	U.S.	International
Service cost	$ 91	$ 66	$ 104	$ 75	$ 289	$ 213	$ 302	$ 254
Interest cost	123	35	102	33	330	110	305	92
Expected return on plan assets	(182)	(93)	(188)	(105)	(576)	(292)	(568)	(313)
Amortization of unrecognized prior service credit	(8)	(3)	(9)	(3)	(24)	(10)	(29)	(12)
Net loss amortization	10	24	75	32	122	73	218	110
Termination benefits	1	—	2	—	2	1	54	3
Curtailments	3	—	(1)	—	11	—	15	(27)
Settlements	79	—	139	—	180	—	139	2
	$ 117	$ 29	$ 224	$ 32	$ 334	$ 95	$ 436	$ 109

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
($ in millions)	2022	2021	2022	2021
Service cost	$ 11	$ 11	$ 36	$ 37
Interest cost	11	12	34	34
Expected return on plan assets	(21)	(20)	(64)	(59)
Amortization of unrecognized prior service credit	(14)	(16)	(42)	(48)
Net gain amortization	(11)	(12)	(32)	(30)
Termination benefits	—	—	—	37
Curtailments	—	(1)	(1)	(29)
	$ (24)	$ (26)	$ (69)	$ (58)

Net periodic benefit cost (credit) for pension and other postretirement benefit plans in the first nine months of 2021 includes expenses for curtailments, settlements and termination benefits provided to certain employees in connection with the spin-off of Organon.

In connection with restructuring actions (see Note 5), termination charges were recorded on pension plans related to expanded eligibility for certain employees exiting Merck. Also, in connection with these restructuring activities, curtailments and settlements were recorded on certain pension plans. In addition, lump sum payments to U.S. pension plan participants triggered partial settlement charges in the third quarter and first nine months of 2022 and 2021. These partial settlements triggered remeasurements of some of the Company's U.S. pension plans. The third quarter 2022 remeasurement, which was calculated using discount rates and asset values as of September 30, 2022, resulted in a net increase of $296 million to net pension liabilities and also resulted in a related adjustment to *AOCL*. Remeasurements during the first nine months of 2022 have resulted in a net increase of $131 million to net pension liabilities with related adjustments to *AOCL*.

The components of net periodic benefit cost (credit) other than the service cost component are included in *Other (income) expense, net* (see Note 12), with the exception of certain amounts for termination benefits, curtailments and settlements, which are recorded in *Restructuring costs* if the event giving rise to the termination benefits, curtailment or settlement is related to restructuring actions or in *Income from Discontinued Operations, Net of Taxes and Amounts Attributable to Noncontrolling Interests* if related to the spin-off of Organon (each as noted above).

12. Other (Income) Expense, Net

Other (income) expense, net, consisted of:

	Three Months Ended September 30,		Nine Months Ended September 30,	
($ in millions)	2022	2021	2022	2021
Interest income	$ (40)	$ (7)	$ (62)	$ (27)
Interest expense	244	196	727	597
Exchange losses	96	46	220	202
Loss (income) from investments in equity securities, net [(1)]	371	(683)	1,361	(1,535)
Net periodic defined benefit plan (credit) cost other than service cost	(60)	40	(208)	(159)
Other, net	(182)	(42)	(462)	(85)
	$ 429	$ (450)	$ 1,576	$ (1,007)

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

Interest paid for the nine months ended September 30, 2022 and 2021 was $660 million and $570 million, respectively.

13. Taxes on Income

The effective income tax rates from continuing operations were 9.2% and 13.2% for the third quarter of 2022 and 2021, respectively, and 11.0% and 14.4% for the first nine months of 2022 and 2021, respectively. The effective income tax rates from continuing operations reflect the beneficial impact of foreign earnings. The effective income tax rates from continuing operations in the third quarter and first nine months of 2022 also include the favorable impact of net unrealized losses from investments in equity securities and intangible asset impairment charges, which were taxed at the U.S. tax rate. The effective income tax rate from continuing operations in the first nine months of 2021 reflects the unfavorable effect of a charge for the acquisition of Pandion for which no tax benefit was recognized, as well as a net tax benefit of $207 million related to the settlement of certain federal income tax matters as discussed below.

In the first quarter of 2021, the Internal Revenue Service (IRS) concluded its examinations of Merck's 2015-2016 U.S. federal income tax returns. As a result, the Company was required to make a payment of $190 million (of which $172 million related to continuing operations and $18 million related to discontinued operations). The Company's reserves for unrecognized tax benefits for the years under examination exceeded the adjustments relating to this examination period and therefore the Company recorded a $236 million net tax benefit in the first nine months of 2021 (of which $207 million related to continuing operations and $29 million related to discontinued operations). This net benefit reflects reductions in reserves for unrecognized tax benefits and other related liabilities for tax positions relating to the years that were under examination.

14. Earnings Per Share

The calculations of earnings per share are as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
($ and shares in millions except per share amounts)	2022	2021	2022	2021
Net Income from Continuing Operations Attributable to Merck & Co., Inc.	$ 3,248	$ 4,567	$ 11,502	$ 8,525
Income from Discontinued Operations, Net of Taxes and Amounts Attributable to Noncontrolling Interests	—	—	—	766
Net Income Attributable to Merck & Co., Inc.	$ 3,248	$ 4,567	$ 11,502	$ 9,291
Average common shares outstanding	2,533	2,530	2,531	2,531
Common shares issuable [(1)]	9	6	9	8
Average common shares outstanding assuming dilution	2,542	2,536	2,540	2,539
Basic Earnings per Common Share Attributable to Merck & Co., Inc. Common Shareholders:				
Income from Continuing Operations	$ 1.28	$ 1.81	$ 4.55	$ 3.37
Income from Discontinued Operations	—	—	—	0.30
Net Income	$ 1.28	$ 1.81	$ 4.55	$ 3.67
Earnings per Common Share Assuming Dilution Attributable to Merck & Co., Inc. Common Shareholders:				
Income from Continuing Operations	$ 1.28	$ 1.80	$ 4.53	$ 3.36
Income from Discontinued Operations	—	—	—	0.30
Net Income	$ 1.28	$ 1.80	$ 4.53	$ 3.66

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

For the third quarter of 2022 and 2021, 2 million and 8 million, respectively, and for the first nine months of 2022 and 2021, 5 million and 10 million, respectively, of common shares issuable under share-based compensation plans were excluded from the computation of earnings per common share assuming dilution because the effect would have been antidilutive.

15. Other Comprehensive Income (Loss)

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

	Three Months Ended September 30,			
($ in millions)	Derivatives	Employee Benefit Plans	Foreign Currency Translation Adjustment	Accumulated Other Comprehensive Loss
Balance July 1, 2021, net of taxes	$ (26)	$ (3,028)	$ (1,574)	$ (4,628)
Other comprehensive income (loss) before reclassification adjustments, pretax	72	(24)	(96)	(48)
Tax	(16)	16	12	12
Other comprehensive income (loss) before reclassification adjustments, net of taxes	56	(8)	(84)	(36)
Reclassification adjustments, pretax	36 [(1)]	68 [(2)]	—	104
Tax	(8)	(22)	—	(30)
Reclassification adjustments, net of taxes	28	46	—	74
Other comprehensive income (loss), net of taxes	84	38	(84)	38
Balance September 30, 2021, net of taxes	$ 58	$ (2,990)	$ (1,658)	$ (4,590)
Balance July 1, 2022, net of taxes	$ 390	$ (2,465)	$ (2,252)	$ (4,327)
Other comprehensive income (loss) before reclassification adjustments, pretax	682	(294)	(618)	(230)
Tax	(143)	62	50	(31)
Other comprehensive income (loss) before reclassification adjustments, net of taxes	539	(232)	(568)	(261)
Reclassification adjustments, pretax	(254) [(1)]	77 [(2)]	—	(177)
Tax	53	(31)	—	22
Reclassification adjustments, net of taxes	(201)	46	—	(155)
Other comprehensive income (loss), net of taxes	338	(186)	(568)	(416)
Balance September 30, 2022, net of taxes	$ 728	$ (2,651)	$ (2,820)	$ (4,743)

	Nine Months Ended September 30,			
($ in millions)	Derivatives	Employee Benefit Plans	Foreign Currency Translation Adjustment	Accumulated Other Comprehensive Loss
Balance January 1, 2021, net of taxes	$ (266)	$ (4,540)	$ (1,828)	$ (6,634)
Other comprehensive income (loss) before reclassification adjustments, pretax	193	1,739	(167)	1,765
Tax	(41)	(385)	(84)	(510)
Other comprehensive income (loss) before reclassification adjustments, net of taxes	152	1,354	(251)	1,255
Reclassification adjustments, pretax	218 [(1)]	210 [(2)]	—	428
Tax	(46)	(42)	—	(88)
Reclassification adjustments, net of taxes	172	168	—	340
Other comprehensive income (loss), net of taxes	324	1,522	(251)	1,595
Spin-off of Organon (see Note 2)	—	28	421	449
Balance September 30, 2021, net of taxes	$ 58	$ (2,990)	$ (1,658)	$ (4,590)
Balance January 1, 2022, net of taxes	$ 144	$ (2,743)	$ (1,830)	$ (4,429)
Other comprehensive income (loss) before reclassification adjustments, pretax	1,233	(125)	(1,001)	107
Tax	(259)	25	11	(223)
Other comprehensive income (loss) before reclassification adjustments, net of taxes	974	(100)	(990)	(116)
Reclassification adjustments, pretax	(493) [(1)]	266 [(2)]	—	(227)
Tax	103	(74)	—	29
Reclassification adjustments, net of taxes	(390)	192	—	(198)
Other comprehensive income (loss), net of taxes	584	92	(990)	(314)
Balance September 30, 2022, net of taxes	$ 728	$ (2,651)	$ (2,820)	$ (4,743)

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

[(2)] *Includes net amortization of prior service cost and actuarial gains and losses included in net periodic benefit cost (see Note 11).*

16. Segment Reporting

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

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

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

Sales of the Company's products were as follows:

	Three Months Ended September 30,						Nine Months Ended September 30,					
	2022			2021			2022			2021		
($ 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	$ 3,331	$ 2,095	$ 5,426	$ 2,580	$ 1,954	$ 4,534	$ 9,307	$ 6,180	$ 15,487	$ 7,108	$ 5,501	$ 12,609
Alliance revenue-Lynparza [(1)]	144	140	284	129	117	246	427	397	825	371	350	721
Alliance revenue-Lenvima [(1)]	142	60	202	114	74	188	426	235	660	287	211	498
Alliance revenue-Reblozyl [(2)]	32	7	39	—	—	—	87	37	124	—	—	—
Vaccines												
Gardasil/Gardasil 9	957	1,337	2,294	839	1,154	1,993	1,803	3,624	5,428	1,605	2,539	4,144
ProQuad/M-M-R II*/Varivax*	532	136	668	537	125	661	1,337	379	1,716	1,255	371	1,626
RotaTeq	154	102	256	135	92	227	427	218	644	364	229	593
Pneumovax 23	68	63	131	181	97	277	280	177	457	354	247	600
Vaqta	27	36	64	32	16	48	72	62	134	80	58	138
Hospital Acute Care												
Bridion	233	190	423	181	188	369	665	579	1,244	545	551	1,096
Prevymis	49	64	114	39	57	96	136	174	310	111	159	270
Dificid	72	6	77	52	2	54	184	12	196	108	7	115
Primaxin	—	63	63	—	69	70	1	185	185	—	194	194
Noxafil	13	49	62	19	45	64	39	141	180	48	149	197
Invanz	2	48	50	(2)	55	53	4	144	148	(2)	159	157
Cancidas	1	42	43	1	56	56	5	133	138	4	164	168
Zerbaxa	24	19	43	(1)	(1)	(2)	64	55	120	(5)	(6)	(11)
Cardiovascular												
Alliance revenue-Adempas/Verquvo [(3)]	85	3	88	73	27	100	244	14	258	222	26	248
Adempas	—	57	57	—	59	59	—	181	181	—	188	188
Virology												
Lagevrio	—	436	436	—	—	—	1,523	3,336	4,859	—	—	—
Isentress/Isentress HD	68	93	161	77	112	189	196	270	466	222	368	590
Neuroscience												
Belsomra	20	42	62	23	58	81	60	139	199	56	183	238
Immunology												
Simponi	—	173	173	—	203	203	—	540	540	—	619	619
Remicade	—	49	49	—	73	73	—	163	163	—	233	233
Diabetes												
Januvia	332	385	717	365	487	852	958	1,294	2,252	997	1,448	2,445
Janumet	90	327	417	86	401	487	258	1,089	1,347	244	1,205	1,449
Other pharmaceutical [(4)]	244	321	564	210	306	518	616	949	1,565	637	950	1,589
Total Pharmaceutical segment sales	6,620	6,343	12,963	5,670	5,826	11,496	19,119	20,707	39,826	14,611	16,103	30,714
Animal Health:												
Livestock	186	643	829	190	675	864	521	1,965	2,486	508	1,996	2,503
Companion Animals	289	253	542	277	276	553	904	929	1,834	855	948	1,804
Total Animal Health segment sales	475	896	1,371	467	951	1,417	1,425	2,894	4,320	1,363	2,944	4,307
Total segment sales	7,095	7,239	14,334	6,137	6,777	12,913	20,544	23,601	44,146	15,974	19,047	35,021
Other [(5)]	227	398	625	139	101	241	383	925	1,307	192	(30)	162
	$ 7,322	$ 7,637	$ 14,959	$ 6,276	$ 6,878	$ 13,154	$ 20,927	$ 24,526	$ 45,453	$ 16,166	$ 19,017	$ 35,183

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

(1) Alliance revenue for Lynparza and Lenvima represents Merck's share of profits, which are product sales net of cost of sales and commercialization costs (see Note 4).

(2) Alliance revenue for Reblozyl represents royalties and, for the year-to-date period, a payment received related to the achievement of a regulatory milestone (see Note 4).

(3) Alliance revenue for Adempas/Verquvo represents Merck's share of profits from sales in Bayer's marketing territories, which are product sales net of cost of sales and commercialization costs (see Note 4).

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

(5) Other is primarily comprised of miscellaneous corporate revenue, including revenue hedging activities, as well as revenue from third-party manufacturing arrangements (including sales to Organon). Other for the nine months ended September 30, 2022 and 2021 also includes $156 million and $191 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 $3.1 billion for the three months ended September 30, 2022 and 2021, respectively, and $9.1 billion for both the nine months ended September 30, 2022 and 2021.

Consolidated sales by geographic area where derived are as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
($ in millions)	2022	2021	2022	2021
United States	$ 7,322	$ 6,276	$ 20,927	$ 16,166
Europe, Middle East and Africa	3,286	3,342	11,228	9,912
China	1,442	1,307	3,957	3,004
Japan	673	638	2,776	1,929
Asia Pacific (other than China and Japan)	854	613	2,792	1,782
Latin America	684	599	1,933	1,631
Other	698	379	1,840	759
	$ 14,959	$ 13,154	$ 45,453	$ 35,183

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
($ in millions)	2022	2021	2022	2021
Segment profits:				
Pharmaceutical segment	$ 9,590	$ 8,606	$ 28,263	$ 22,450
Animal Health segment	515	505	1,672	1,629
Total segment profits	10,105	9,111	29,935	24,079
Other profits	377	141	831	29
Unallocated:				
Interest income	40	7	62	27
Interest expense	(244)	(196)	(727)	(597)
Amortization	(460)	(360)	(1,623)	(1,231)
Depreciation	(448)	(358)	(1,257)	(1,031)
Research and development	(4,277)	(2,312)	(9,374)	(8,775)
Restructuring costs	(94)	(107)	(288)	(487)
Other unallocated, net	(1,416)	(660)	(4,628)	(2,044)
	$ 3,583	$ 5,266	$ 12,931	$ 9,970

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

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

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

Management

In October 2022, Merck announced that its board of directors unanimously elected Robert M. Davis, currently Chief Executive Officer and President, to serve as chairman of the board, effective December 1, 2022. He will succeed Kenneth C. Frazier, who will retire on November 30, 2022.

Business Developments

Below is a summary of significant business development activity thus far in 2022. See Note 3 to the condensed consolidated financial statements for additional information.

In September 2022, Merck exercised its option to jointly develop and commercialize personalized cancer vaccine mRNA-4157/V940 pursuant to the terms of an existing collaboration and license agreement with Moderna, Inc. (Moderna), which resulted in a $250 million charge in *Research and development* expenses in the third quarter and first nine months of 2022. The payment to Moderna was made in the fourth quarter of 2022. mRNA-4157/V940 is currently being evaluated in combination with *Keytruda* (pembrolizumab), Merck's anti-PD-1 therapy, as adjuvant treatment for patients with high-risk melanoma in a Phase 2 clinical trial being conducted by Moderna. Under the 2016 agreement, as amended in 2018, Merck and Moderna will collaborate on development and commercialization and will share costs and any profits equally under this worldwide collaboration.

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

In July 2022, Merck and Orion Corporation (Orion) announced a global co-development and co-commercialization agreement for Orion's investigational candidate ODM-208 (MK-5684) and other drugs targeting cytochrome P450 11A1 (CYP11A1), an enzyme important in steroid production. ODM-208 is an oral, non-steroidal inhibitor of CYP11A1 currently being evaluated in a Phase 2 clinical trial for the treatment of patients with metastatic castration-resistant prostate cancer. Merck made an upfront payment to Orion of $290 million, which was recorded in *Research and development* expenses in the third quarter and first nine months of 2022.

Also in July 2022, Merck and Sichuan Kelun-Biotech Biopharmaceutical Co., Ltd. (Kelun-Biotech) closed a license and collaboration agreement in which Merck gained exclusive worldwide rights for the development, manufacture and commercialization of an investigational antibody drug conjugate (ADC) (MK-1200) for the treatment of solid tumors. Under the terms of the agreement, Merck and Kelun-Biotech will collaborate on the early clinical development of the investigational ADC. Merck made an upfront payment of $35 million, which was recorded in *Research and development* expenses in the third quarter and first nine months of 2022. Kelun-Biotech is also eligible to receive future contingent developmental, regulatory and sales-based milestone payments, as well as tiered royalties on future net sales.

In May 2022, in connection with an existing arrangement, Merck exercised its option to obtain an exclusive license outside of China for the development, manufacture and commercialization of Kelun-Biotech's trophoblast antigen 2 (TROP2)-targeting ADC programs, including its lead compound, SKB-264 (MK-2870). SKB-264 is currently being evaluated in Phase 2 trials for non-small-cell lung cancer (NSCLC) and advanced solid tumors. Under the terms of the agreement, Merck and Kelun-Biotech will collaborate on certain early clinical development plans, including evaluating the potential of SKB-264 as a monotherapy and in combination with *Keytruda* for advanced solid tumors. Upon option exercise, Merck made a payment of $30 million, which was recorded in *Research and development* expenses in the first nine months of 2022, and agreed to make additional payments upon completion of specified project activities, technology transfer, as well as payments to fund Kelun-Biotech's ongoing research and development activities. In addition, Kelun-Biotech is eligible to receive future contingent developmental and sales-based milestone payments and royalties on future net sales.

Spin-Off of Organon & Co.

On June 2, 2021, Merck completed the spin-off of products from its women's health, biosimilars and established brands businesses into a new, independent, publicly traded company named Organon & Co. (Organon) through a distribution of Organon's publicly traded stock to Company shareholders. The distribution is expected to qualify and has been treated as tax-free to the Company and its shareholders for U.S. federal income tax purposes. The established brands included in the transaction consisted of dermatology, non-opioid pain management, respiratory, select cardiovascular products, as well as the rest of Merck's diversified brands franchise. Merck's existing research pipeline programs continue to be owned and developed

within Merck as planned. The historical results of the businesses that were contributed to Organon in the spin-off have been reflected as discontinued operations in the Company's consolidated financial statements through the date of the spin-off (see Note 2 to the condensed consolidated financial statements).

Other Developments

War in Ukraine

In February 2022, Russia invaded Ukraine. The Company's primary concerns are the safety and well-being of its employees and ensuring patients and customers have continued access to medicines and vaccines needed for patient and public health. The Company is working cross-functionally across the globe to monitor and mitigate interruptions to business continuity resulting from the war, including its impact on Merck's supply chain, operations and clinical trials. For humanitarian reasons, the Company is continuing to supply essential medicines and vaccines in Russia while working to maintain compliance with evolving international sanctions. Merck is donating profits resulting from its operations in Russia to humanitarian causes. The Company does not have research or manufacturing facilities in Russia, currently does not plan to make further investments in Russia, and has suspended screening and enrollment in ongoing clinical trials as well as planning for new studies in Russia, although the Company continues to treat patients already enrolled in existing clinical trials and collect data from these studies. The Company is also using its resources to help alleviate the humanitarian crisis in Ukraine, including through donations of funds and products. The financial impacts of the war were immaterial to the Company's consolidated financial statements for the third quarter and first nine months of 2022. Combined sales to Russia and Ukraine were approximately 1% of total Merck consolidated sales for the full year of 2021.

The combination of Russia's invasion of Ukraine, as well as the resultant economic sanctions imposed by the U.S., the European Union (EU) and other governments are having pervasive effects in markets worldwide. The Company is unable to determine at this time the future impacts of this war either directly or indirectly on the Company's business.

COVID-19

Although COVID-19-related disruptions had some negative effects on sales for the third quarter and first nine months of 2022, Merck continues to believe that global health systems and patients have largely adapted to the impacts of the COVID-19 pandemic. Merck's sales of *Lagevrio* (molnupiravir), an investigational oral antiviral COVID-19 medicine, were $436 million and $4.9 billion in the third quarter and first nine months of 2022, respectively. In the third quarter and first nine months of 2021, COVID-19-related disruptions resulted in an estimated negative impact to Pharmaceutical segment sales of approximately $350 million and $1.3 billion, respectively, because a substantial portion of Merck's Pharmaceutical segment revenue is comprised of physician-administered products, which were unfavorably affected by social distancing measures and fewer well visits.

In April 2021, Merck announced it was discontinuing the development of MK-7110 for the treatment of hospitalized patients with COVID-19, which was obtained as part of Merck's acquisition of OncoImmune (see Note 3 to the condensed consolidated financial statements). This decision resulted in charges of $207 million to *Cost of sales* in the first nine months of 2021.

In March 2021, Merck announced it had entered into multiple agreements to support efforts to expand manufacturing capacity and supply of SARS-CoV-2/COVID-19 medicines and vaccines. The Biomedical Advanced Research and Development Authority (BARDA), a division of the Office of the Assistant Secretary for Preparedness and Response within the U.S. Department of Health and Human Services, provided Merck with $102 million of funding in the first quarter of 2022 to adapt and make available a number of existing manufacturing facilities for the production of SARS-CoV-2/COVID-19 vaccines and medicines. The funding was recognized as a reduction to *Cost of sales* over the production period through September 30, 2022, offsetting the depreciation expense related to the amounts that were capitalized in connection with the modification of the manufacturing facilities. Merck and Johnson & Johnson have commenced an arbitration regarding a dispute concerning two agreements pursuant to which Merck was supporting the manufacturing and supply of Johnson & Johnson's SARS-CoV-2/COVID 19 vaccine and vaccine drug product. The amounts included in the condensed consolidated financial statements for these agreements were immaterial for the third quarter and first nine months of 2022. Merck does not believe the outcome of the arbitration will have a material impact on the Company's financial results.

Pricing

Global efforts toward health care cost containment continue to exert pressure on product pricing and market access worldwide. Changes to the U.S. health care system enacted in prior years as part of health care reform, as well as increased purchasing power of entities that negotiate on behalf of Medicare, Medicaid, and private sector beneficiaries, have contributed to pricing pressure. In several international markets, government-mandated pricing actions have reduced prices of generic and patented drugs. In addition, the Company's sales performance in the first nine months of 2022 was negatively affected by other cost-reduction measures taken by governments and other third parties to lower health care costs. In the U.S., Congress recently passed the Inflation Reduction Act, which makes significant changes to how drugs are covered and paid for under the Medicare

program, including the creation of financial penalties for drugs whose prices rise faster than the rate of inflation, redesign of the Medicare Part D program to require manufacturers to bear more of the liability for certain drug benefits, and government price-setting for certain Medicare Part D drugs, starting in 2026, and Medicare Part B drugs starting in 2028. The Company anticipates all of these actions and additional actions in the future will negatively affect sales and profits.

Supply Chain

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

Operating Results

Sales

($ in millions)	Three Months Ended September 30, 2022	2021	% Change	% Change Excluding Foreign Exchange	Nine Months Ended September 30, 2022	2021	% Change	% Change Excluding Foreign Exchange
United States	$ 7,322	$ 6,276	17 %	17 %	$ 20,927	$ 16,166	29 %	29 %
International	7,637	6,878	11 %	19 %	24,526	19,017	29 %	35 %
Total	$ 14,959	$ 13,154	14 %	18 %	$ 45,453	$ 35,183	29 %	32 %

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

Worldwide sales grew 14% to $15.0 billion in the third quarter of 2022 primarily due to higher sales in the oncology franchise, largely driven by strong growth of *Keytruda* (pembrolizumab) and increased alliance revenue from Reblozyl (luspatercept-aamt) and Lynparza (olaparib), as well as higher sales in the virology franchise driven by *Lagevrio* (molnupiravir). Also contributing to revenue growth in the third quarter of 2022 were higher sales in the vaccines franchise, primarily attributable to growth of *Gardasil* (Human Papillomavirus Quadrivalent [Types 6, 11, 16 and 18] Vaccine, Recombinant) and *Gardasil* 9 (Human Papillomavirus 9-valent Vaccine, Recombinant), as well as higher sales of hospital acute care products, including *Bridion* (sugammadex) Injection and *Zerbaxa* (ceftolozane and tazobactam). Higher revenue related to third-party manufacturing arrangements also contributed to revenue growth in the third quarter of 2022.

Worldwide sales rose 29% to $45.5 billion in the first nine months of 2022. Revenue growth was attributable in part to higher sales in the virology franchise driven by *Lagevrio*. Also contributing to revenue growth in the first nine months of 2022 were higher sales in the oncology franchise largely driven by strong growth of *Keytruda* and increased alliance revenue from Lenvima (lenvatinib), Reblozyl and Lynparza, as well as higher sales in the vaccines franchise, primarily attributable to growth of *Gardasil* and *Gardasil* 9. Higher sales of hospital acute care products, including *Bridion* and *Zerbaxa*, as well as higher revenue related to third-party manufacturing arrangements also drove revenue growth in the first nine months of 2022.

As discussed above, COVID-19-related disruptions had some negative effects on sales in the third quarter and first nine months of 2022, but to a lesser extent than in the same periods of 2021 which benefited year-over-year sales growth in both periods.

Revenue growth in the third quarter and first nine months of 2022 was partially offset by lower combined sales of diabetes products *Januvia* (sitagliptin) and *Janumet* (sitagliptin and metformin HCl), lower sales of *Pneumovax* 23 (pneumococcal vaccine polyvalent) and lower sales of virology products *Isentress/Isentress HD* (raltegravir). Lower revenue from the receipt of upfront and milestone payments for out-licensing arrangements also partially offset sales growth in the third quarter and first nine months of 2022.

See Note 16 to the condensed consolidated financial statements for details on sales of the Company's products. A discussion of performance for select products in the franchises follows.

Pharmaceutical Segment

Oncology

($ in millions)	Three Months Ended September 30, 2022	2021	% Change	% Change Excluding Foreign Exchange	Nine Months Ended September 30, 2022	2021	% Change	% Change Excluding Foreign Exchange
Keytruda	$ 5,426	$ 4,534	20 %	26 %	$ 15,487	$ 12,609	23 %	28 %
Alliance Revenue - Lynparza [(1)]	284	246	16 %	23 %	825	721	14 %	20 %
Alliance Revenue - Lenvima [(1)]	202	188	7 %	11 %	660	498	33 %	36 %
Alliance Revenue - Reblozyl	39	—	—	—	124	—	—	—

[(1)] Alliance revenue represents Merck's share of profits, which are product sales net of cost of sales and commercialization costs (see Note 4 to the condensed consolidated financial statements).

Keytruda is an anti-PD-1 (programmed death receptor-1) therapy that has been approved as monotherapy for the treatment of certain patients with cervical cancer, classical Hodgkin lymphoma, cutaneous squamous cell carcinoma, endometrial carcinoma, esophageal or gastroesophageal junction (GEJ) carcinoma, head and neck squamous cell carcinoma (HNSCC), hepatocellular carcinoma (HCC), NSCLC, melanoma, Merkel cell carcinoma, microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) cancer (solid tumors) including MSI-H/dMMR colorectal cancer, primary mediastinal large B-cell lymphoma, tumor mutational burden-high (TMB-H) cancer (solid tumors), and urothelial carcinoma including non-muscle invasive bladder cancer. Additionally, *Keytruda* is approved as monotherapy for the adjuvant treatment of certain patients with renal cell carcinoma (RCC) or stage IIB, IIC or III melanoma. *Keytruda* is also approved for certain patients with high-risk early-stage triple-negative breast cancer (TNBC) in combination with chemotherapy as neoadjuvant treatment, and then continued as a single agent as adjuvant treatment after surgery. In addition, *Keytruda* is approved for the treatment of certain patients in combination with chemotherapy for metastatic squamous and nonsquamous NSCLC, in combination with chemotherapy, with or without bevacizumab for cervical cancer, in combination with chemotherapy for esophageal cancer, in combination with trastuzumab, fluoropyrimidine- and platinum-containing chemotherapy for human epidermal growth factor 2 (HER-2)-positive gastric or GEJ adenocarcinoma, in combination with chemotherapy for HNSCC, in combination with chemotherapy for metastatic TNBC, in combination with axitinib for advanced RCC, and in combination with Lenvima for both endometrial carcinoma and RCC. The *Keytruda* clinical development program includes studies across a broad range of cancer types. See "Research and Development Update" below.

Global sales of *Keytruda* grew 20% and 23% in the third quarter and first nine months of 2022, respectively. Sales growth was primarily driven by higher demand as the Company continues to launch *Keytruda* with multiple new indications globally. Sales in the U.S. continue to build across the multiple approved metastatic indications, in particular for the treatment of certain types of RCC, HNSCC, and MSI-H cancers. *Keytruda* sales growth in the U.S. also benefited from increased uptake across recent launches in earlier-stage indications including in high-risk, early stage TNBC, as well as certain types of RCC and melanoma. *Keytruda* sales growth in international markets reflects continued uptake predominately for the NSCLC, HNSCC and RCC indications, particularly in Europe.

Keytruda received the following regulatory approvals thus far in 2022.

Date	Approval
January 2022	European Commission (EC) approval as monotherapy for the adjuvant treatment of adults with RCC at increased risk of recurrence following nephrectomy, or following nephrectomy and resection of metastatic lesions, based on the KEYNOTE-564 trial.
February 2022	Japan Ministry of Health, Labour and Welfare (MHLW) approval of the combination of *Keytruda* plus Lenvima for radically unresectable or metastatic RCC, based on the CLEAR (Study 307)/KEYNOTE-581 trial.
February 2022	Japan Pharmaceuticals and Medical Devices Agency approval for the treatment of adult patients with advanced or recurrent TMB-H solid tumors that have progressed after chemotherapy (limited to use when difficult to treat with standard of care) based on the KEYNOTE-158 trial.
March 2022	U.S. Food and Drug Administration (FDA) approval as a single agent for the treatment of patients with advanced endometrial carcinoma that is MSI-H or dMMR who have disease progression following prior systemic therapy in any setting and are not candidates for curative surgery or radiation, based on the KEYNOTE-158 trial (Cohorts D & K).
April 2022	EC approval in combination with chemotherapy, with or without bevacizumab, for the treatment of persistent, recurrent or metastatic cervical cancer in certain adults whose tumors express PD-L1, based on the KEYNOTE-826 trial.
April 2022	EC approval as monotherapy for the treatment of certain adult patients with unresectable or metastatic MSI-H/dMMR colorectal, gastric, small intestine or biliary cancer, as well as advanced or recurrent MSI-H/dMMR endometrial cancer, based on the KEYNOTE-164 and KEYNOTE-158 trials.

May 2022	EC approval in combination with chemotherapy as neoadjuvant treatment, and then continued as monotherapy as adjuvant treatment after surgery for adults with locally advanced or early-stage TNBC at high risk of recurrence, based on the KEYNOTE-522 trial.
June 2022	EC approval as monotherapy for the adjuvant treatment of adults and adolescents aged 12 years and older with stage IIB or IIC melanoma and who have undergone complete resection, based on the KEYNOTE-716 trial. Additionally, EC approval expanding the indications in advanced (unresectable or metastatic) melanoma and stage III melanoma with lymph node involvement (as adjuvant treatment following complete resection) to include adolescent patients aged 12 years and older.
September 2022	Japan MHLW approval in combination with chemotherapy as neoadjuvant treatment, and then continued as monotherapy as adjuvant treatment after surgery for patients with hormone receptor-negative and HER2-negative breast cancer at high risk of recurrence, based on the KEYNOTE-522 trial.
September 2022	Japan MHLW approval as monotherapy for the adjuvant treatment of certain patients with RCC at increased risk of recurrence following nephrectomy, or following nephrectomy and resection of metastatic lesions, based on the KEYNOTE-564 trial.
September 2022	Japan MHLW approval in combination with chemotherapy, with or without bevacizumab, for the treatment of patients with advanced or recurrent cervical cancer with no prior chemotherapy who are not amenable to curative treatment, based on the KEYNOTE-826 trial.
September 2022	Japan MHLW approval as monotherapy for the adjuvant treatment of patients with stage IIB or IIC melanoma after complete resection, based on the KEYNOTE-716 trial.

Lynparza is an oral poly (ADP-ribose) polymerase (PARP) inhibitor being developed as part of a collaboration with AstraZeneca PLC (AstraZeneca) (see Note 4 to the condensed consolidated financial statements). Lynparza is approved for the treatment of certain types of ovarian, breast, pancreatic and prostate cancers. Alliance revenue related to Lynparza increased 16% and 14% in the third quarter and first nine months of 2022, respectively, largely driven by higher demand globally across the multiple approved indications, particularly in the U.S. largely attributable to uptake in the earlier-stage breast cancer indication following recent approval by the FDA. In March 2022, Lynparza was approved by the FDA for the adjuvant treatment of adult patients with deleterious or suspected deleterious germline *BRCA*-mutated, HER2-negative high-risk early breast cancer who have been treated with neoadjuvant or adjuvant chemotherapy, followed by approvals in the EU and Japan in August 2022, based on the OlympiA trial. In September 2022, Lynparza was approved in China as first-line maintenance treatment for adult patients with advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy in combination with bevacizumab and whose cancer is associated with homologous recombination deficiency-positive status. This approval was based on the PAOLA-1 trial.

Lenvima is an oral receptor tyrosine kinase inhibitor being developed as part of a collaboration with Eisai Co., Ltd. (Eisai) (see Note 4 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 RCC, and in combination with *Keytruda* for both endometrial carcinoma and RCC. Alliance revenue related to Lenvima grew 7% and 33% in the third quarter and first nine months of 2022, respectively, reflecting uptake in the advanced RCC and advanced endometrial carcinoma indications, particularly in the U.S. Growth in the third quarter was partially offset by the timing of shipments in China.

Reblozyl is a first-in-class erythroid maturation recombinant fusion protein obtained as part of Merck's November 2021 acquisition of Acceleron Pharma Inc. that is being developed and commercialized through a global collaboration with Bristol Myers Squibb (see Note 4 to the condensed consolidated financial statements). Reblozyl is approved for the treatment of certain types of anemia. Merck recorded alliance revenue of $39 million (consisting of royalties) in the third quarter of 2022 related to this collaboration. Merck recorded alliance revenue of $124 million in the first nine months of 2022, which includes royalties of $104 million, as well as the receipt of a regulatory approval milestone payment of $20 million.

Vaccines

	Three Months Ended September 30,			% Change Excluding Foreign Exchange	Nine Months Ended September 30,			% Change Excluding Foreign Exchange
($ in millions)	2022	2021	% Change		2022	2021	% Change	
Gardasil/Gardasil 9	$ 2,294	$ 1,993	15 %	20 %	$ 5,428	$ 4,144	31 %	35 %
ProQuad	264	244	8 %	10 %	640	598	7 %	9 %
M-M-R II	124	127	(2)%	(1)%	330	295	12 %	14 %
Varivax	280	290	(3)%	(2)%	746	733	2 %	3 %
RotaTeq	256	227	12 %	16 %	644	593	9 %	11 %
Pneumovax 23	131	277	(53)%	(50)%	457	600	(24)%	(21)%

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 15% and 31% in the third quarter and first nine months of 2022, respectively, driven primarily by strong demand outside of the U.S., particularly in China, which also benefited from increased supply. Sales of *Gardasil* 9 in the U.S. increased in the third quarter and first nine months of 2022 due to public sector buying patterns.

China's National Medical Products Administration expanded the use of *Gardasil* 9 for use in girls and women ages 9 to 45. The vaccine was previously approved for use in girls and women ages 16 to 26.

Global sales of *ProQuad* (Measles, Mumps, Rubella and Varicella Virus Vaccine Live), a pediatric combination vaccine to help protect against measles, mumps, rubella and varicella, increased 8% and 7% in the third quarter and first nine months of 2022, respectively, primarily reflecting higher demand in Europe and higher pricing in the U.S.

Worldwide sales of *M-M-R* II (Measles, Mumps and Rubella Virus Vaccine Live), a vaccine to help protect against measles, mumps and rubella, grew 12% in the first nine months of 2022 primarily due to higher pricing and demand in the U.S., as well as higher tenders in Latin America.

Global sales of *Varivax* (Varicella Virus Vaccine Live), a vaccine to help prevent chickenpox (varicella), grew 2% in the first nine months of 2022 primarily attributable to higher pricing in the U.S., partially offset by lower tenders in Latin America.

Global sales of *RotaTeq* (Rotavirus Vaccine, Live Oral, Pentavalent), a vaccine to help protect against rotavirus gastroenteritis in infants and children, grew 12% and 9% in the third quarter and first nine months of 2022, respectively, primarily due to public sector buying patterns and higher pricing in the U.S. Higher volumes in China also contributed to *RotaTeq* sales growth in the third quarter of 2022.

Worldwide sales of *Pneumovax* 23, a vaccine to help prevent pneumococcal disease, declined 53% and 24% in the third quarter and first nine months of 2022, respectively, primarily reflecting lower demand in the U.S. as the market continues to shift toward newer adult pneumococcal conjugate vaccines following changes in the recommendations of the U.S. Centers for Disease Control and Prevention's (CDC's) Advisory Committee on Immunization Practices (ACIP) in 2021. The Company expects the decline in U.S. sales of *Pneumovax* 23 will continue. Lower demand in Europe also contributed to the *Pneumovax* 23 sales declines in the third quarter and first nine months of 2022.

In June 2022, the FDA approved an expanded indication for *Vaxneuvance* (Pneumococcal 15-valent Conjugate Vaccine) to include use in infants and children. *Vaxneuvance* is now indicated for the prevention of invasive disease caused by Streptococcus pneumoniae serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 22F, 23F and 33F in individuals 6 weeks of age and older. The FDA's approval was based on data from seven randomized, double-blind clinical studies assessing safety, tolerability and immunogenicity of *Vaxneuvance* in infants and children. *Vaxneuvance* was previously approved by the FDA in 2021 for use in adults 18 years of age and older. Also in June 2022, the CDC's ACIP unanimously voted to include *Vaxneuvance* as a recommended option for vaccination in infants and children, including routine use in children under 2 years of age. These recommendations subsequently were adopted by the director of the CDC and the U.S. Department of Health and Human Services, and published in the CDC's *Morbidity and Mortality Weekly Report* (*MMWR*). The ACIP also unanimously voted to include *Vaxneuvance* in the Vaccines for Children program. In October 2022, the EC approved an expanded indication for *Vaxneuvance* to include active immunization for the prevention of invasive disease, pneumonia and acute otitis media caused by *Streptococcus pneumoniae (S. pneumoniae)* in infants, children and adolescents from 6 weeks to less than 18 years of age. *Vaxneuvance* was previously approved for use in the EU for individuals 18 years of age and older. In September 2022, *Vaxneuvance* was approved in Japan for use in adult patients. *Vaxneuvance* remains under review in Japan for use in pediatric patients.

Hospital Acute Care

	Three Months Ended September 30,				Nine Months Ended September 30,			
($ in millions)	2022	2021	% Change	% Change Excluding Foreign Exchange	2022	2021	% Change	% Change Excluding Foreign Exchange
Bridion	$ 423	$ 369	15 %	22 %	$ 1,244	$ 1,096	13 %	19 %
Zerbaxa	43	(2)	*	*	120	(11)	*	*

**Calculation not meaningful.*

Worldwide sales of *Bridion*, for the reversal of two types of neuromuscular blocking agents used during surgery, grew 15% and 13% in the third quarter and first nine months of 2022, respectively, due to higher demand globally, particularly in the U.S., largely attributable to *Bridion*'s growing share among neuromuscular blockade reversal agents and an increase in surgical procedures.

In December 2020, the Company temporarily suspended sales of *Zerbaxa*, a combination antibacterial and beta-lactamase inhibitor for the treatment of certain bacterial infections, and subsequently issued a product recall, following the identification of product sterility issues. The phased resupply for *Zerbaxa* that was initiated in the fourth quarter of 2021 has been completed during 2022.

Cardiovascular

($ in millions)	Three Months Ended September 30, 2022	2021	% Change	% Change Excluding Foreign Exchange	Nine Months Ended September 30, 2022	2021	% Change	% Change Excluding Foreign Exchange
Alliance Revenue - Adempas/Verquvo [(1)]	$ 88	$ 100	(12)%	12 %	$ 258	$ 248	4 %	4 %
Adempas	57	59	(5)%	12 %	181	188	(4)%	8 %

[(1)] *Alliance revenue represents Merck's share of profits from sales in Bayer's marketing territories, which are product sales net of cost of sales and commercialization costs (see Note 4 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 4 to the condensed consolidated financial statements). Adempas is approved for the treatment of certain types of pulmonary arterial hypertension. Verquvo was approved in the U.S. in January 2021 to reduce the risk of cardiovascular death and heart failure hospitalization following a hospitalization for heart failure or need for outpatient intravenous diuretics in adults with symptomatic chronic heart failure and reduced ejection fraction. Verquvo was also approved in Japan in June 2021 and in the EU in July 2021. Alliance revenue from the collaboration declined 12% and grew 4% in the third quarter and first nine months of 2022, respectively. Revenue also includes sales of Adempas and Verquvo in Merck's marketing territories.

Virology

($ in millions)	Three Months Ended September 30, 2022	2021	% Change	% Change Excluding Foreign Exchange	Nine Months Ended September 30, 2022	2021	% Change	% Change Excluding Foreign Exchange
Lagevrio	$ 436	$ —	—	—	$ 4,859	$ —	—	—
Isentress/Isentress HD	161	189	(15)%	(11)%	466	590	(21)%	(17)%

Lagevrio is an investigational oral antiviral COVID-19 medicine being developed in a collaboration with Ridgeback (see Note 4 to the condensed consolidated financial statements). *Lagevrio* has received multiple authorizations or approvals worldwide. Sales of *Lagevrio* were $436 million in the third quarter of 2022 primarily consisting of sales in Australia, South Korea, Japan and the United Kingdom (UK). Merck's initial supply commitment of *Lagevrio* to the U.S. was fulfilled in the first quarter of 2022; therefore, there were no sales of *Lagevrio* in the U.S. in the second or third quarters of 2022. Sales of *Lagevrio* were $4.9 billion in the first nine months of 2022 primarily consisting of sales in the U.S., the UK, Japan and Australia. Merck has entered into advance purchase and supply agreements for *Lagevrio* in more than 40 markets. The Company expects full-year 2022 *Lagevrio* sales to be between $5.2 billion and $5.4 billion.

Global combined sales of *Isentress/Isentress HD*, an HIV integrase inhibitor for use in combination with other antiretroviral agents for the treatment of HIV-1 infection, declined 15% and 21% in the third quarter and first nine months of 2022, respectively, primarily due to lower global demand, reflecting in part competitive pressure in Europe and the U.S. The Company expects competitive pressure for *Isentress/Isentress HD* to continue.

Diabetes

($ in millions)	Three Months Ended September 30, 2022	2021	% Change	% Change Excluding Foreign Exchange	Nine Months Ended September 30, 2022	2021	% Change	% Change Excluding Foreign Exchange
Januvia/Janumet	$ 1,133	$ 1,339	(15)%	(9)%	$ 3,599	$ 3,895	(8)%	(2)%

Worldwide combined sales of *Januvia* and *Janumet*, medicines that help lower blood sugar levels in adults with type 2 diabetes, declined 15% and 8% in the third quarter and first nine months of 2022, respectively, primarily reflecting the loss of exclusivity in several markets in Europe and the Asia Pacific region, as well as lower demand in the U.S. The sales decline in the first nine months of 2022 was partially offset by higher demand in China, increased demand in Latin America reflecting in part higher government tenders, as well as the impact of a prior year unfavorable adjustment to rebate reserves in the U.S. The Company anticipates U.S. pricing pressure will unfavorably affect sales of *Januvia* and *Janumet* in future periods. *Januvia* and *Janumet* lost patent exclusivity with respect to the sitagliptin compound patent in China in July 2022, although not with respect to the patent claiming the specific sitagliptin salt form, which expires in June 2024. In addition, the Company lost market

exclusivity with respect to *Januvia* in the EU in September 2022, and additional exclusivity afforded *Janumet* that expires in April 2023 is being challenged. The Company anticipates sales of *Januvia* and *Janumet* in these markets will decline substantially in future periods following the loss of exclusivity.

The Company will lose sitagliptin compound patent protection for *Januvia* and *Janumet* in the U.S. in January 2023. However, in September 2022, the U.S. Court of Appeals for the Federal Circuit ruled in favor of Merck in a patent challenge related to the specific sitagliptin salt form that is the active ingredient in *Januvia* and *Janumet*, affirming the May 2021 decision in Merck's favor by the U.S. Patent Office in an *inter partes* review. Also in September 2022, the U.S. District Court for the Northern District of West Virginia ruled in favor of the Company in an infringement suit related to the same sitagliptin salt patent, as well as a *Janumet* formulation patent, finding both Merck patents valid and infringed. The rulings from the U.S. Court of Appeals and the U.S District Court in West Virginia provide *Januvia* and *Janumet* patent protection through May 2027; although Merck has settled with multiple generic companies, providing that these generic companies can bring their products to the market in May 2026 or earlier under certain circumstances. The decision from the U.S. District Court in West Virginia is under appeal to the U.S. Court of Appeals for the Federal Circuit. (See Note 9 to the condensed consolidated financial statements.)

Combined sales of *Januvia* and *Janumet* in China, Europe and the U.S. represented 10%, 21% and 34%, respectively, of total combined *Januvia* and *Janumet* sales for the first nine months of 2022.

In response to a request from a regulatory authority, Merck evaluated its sitagliptin-containing products for the presence of nitrosamines. Nitrosamines are organic compounds found at trace levels in water and food. Nitrosamines can also result from chemical reactions and can form in drugs either due to the drug's manufacturing process, chemical structure, or the conditions in which the drugs are stored or packaged. The Company detected a nitrosamine identified as Nitroso-STG-19 (NTTP) in some batches of its sitagliptin-containing medicines. The Company has engaged with major health authorities around the world and has implemented additional quality controls to ensure its portfolio of sitagliptin-containing products meet health authorities' interim acceptable NTTP limits for continuing distribution of product to the market. The Company does not anticipate any significant impact on supply of these medicines.

Animal Health Segment

	Three Months Ended September 30,			% Change Excluding Foreign	Nine Months Ended September 30,			% Change Excluding Foreign
($ in millions)	2022	2021	% Change	Exchange	2022	2021	% Change	Exchange
Livestock	$ 829	$ 864	(4)%	4 %	$ 2,486	$ 2,503	(1)%	6 %
Companion Animal	542	553	(2)%	4 %	1,834	1,804	2 %	6 %

Sales of livestock products declined 4% and 1% in the third quarter and first nine months of 2022, respectively. Excluding the unfavorable effect of foreign exchange in both periods, livestock sales performance primarily reflects higher pricing, as well as increased demand for poultry and ruminant products. Sales of companion animal products declined 2% in the third quarter of 2022 and grew 2% in first nine months of 2022. Excluding the unfavorable effect of foreign exchange in both periods, sales performance primarily reflects higher pricing and demand in the companion animal portfolio, led by the *Bravecto* (fluralaner) line of products, partially offset by lower sales of vaccines due to supply constraints. Sales of the *Bravecto* line of products represented approximately 20% of animal health sales in the first nine months of 2022.

Costs, Expenses and Other

	Three Months Ended September 30,			Nine Months Ended September 30,		
($ in millions)	2022	2021	% Change	2022	2021	% Change
Cost of sales	$ 3,934	$ 3,450	14 %	$ 13,530	$ 9,752	39 %
Selling, general and administrative	2,520	2,336	8 %	7,355	6,804	8 %
Research and development	4,399	2,445	80 %	9,773	9,177	6 %
Restructuring costs	94	107	(12)%	288	487	(41)%
Other (income) expense, net	429	(450)	*	1,576	(1,007)	*
	$ 11,376	$ 7,888	44 %	$ 32,522	$ 25,213	29 %

**Calculation not meaningful.*

Cost of Sales

Cost of sales increased 14% and 39% in the third quarter and first nine months of 2022, respectively. Cost of sales includes $234 million and $2.6 billion in the third quarter and first nine months of 2022, respectively, related to the collaboration with Ridgeback for *Lagevrio* (see Note 4 to the condensed consolidated financial statements). Cost of sales also

includes the amortization of intangible assets recorded in connection with acquisitions, collaborations and licensing arrangements, which totaled $445 million and $346 million in the third quarter of 2022 and 2021, respectively, and $1.6 billion and $1.2 billion in the first nine months of 2022 and 2021, respectively. Amortization expense in the first nine months of 2022 and 2021 includes $250 million and $153 million, respectively, of cumulative catch-up amortization related to Merck's collaborations with AstraZeneca and Bayer, respectively, (see Note 4 to the condensed consolidated financial statements). Additionally, costs in the first nine months of 2021 include charges of $225 million related to the discontinuation of COVID-19 development programs. Also included in cost of sales are expenses associated with restructuring activities which amounted to $54 million and $48 million in the third quarter of 2022 and 2021, respectively, and $167 million and $113 million in the first nine months of 2022 and 2021, respectively, including accelerated depreciation and asset write-offs related to the planned sale or closure of manufacturing facilities. Separation costs associated with manufacturing-related headcount reductions have been incurred and are reflected in *Restructuring costs* as discussed below.

Gross margin was 73.7% in the third quarter of 2022 compared with 73.8% in the third quarter of 2021. Gross margin was 70.2% in the first nine months of 2022 compared with 72.3% in the first nine months of 2021. The gross margin declines primarily reflect the impacts of higher revenue from third-party manufacturing arrangements and sales of *Lagevrio*, both of which have lower gross margins, as well as higher amortization of intangible assets (noted above). The gross margin declines were partially offset by the favorable effects of product mix and foreign exchange. The gross margin decline in the first nine months of 2022 was also partially offset by charges in 2021 related to the discontinuation of COVID-19 development programs.

Selling, General and Administrative

Selling, general and administrative (SG&A) expenses increased 8% in both the third quarter and first nine months of 2022 primarily due to higher administrative costs, including compensation and benefits, as well as higher promotional spending and restructuring costs, partially offset by the favorable effect of foreign exchange.

Research and Development

Research and development (R&D) expenses increased to $4.4 billion and $9.8 billion in the third quarter and first nine months of 2022, respectively, from $2.4 billion and $9.2 billion in the third quarter and first nine months of 2021, respectively. The increase in both periods was primarily due to $887 million of intangible asset impairment charges related to ArQule, Inc. (see Note 8 to the condensed consolidated financial statements), higher charges related to collaborations and licensing arrangements, increased clinical development spending, increased investments in technology in support of the digital enablement of Merck's research operations, as well as higher compensation and benefit costs, partially offset by the favorable effect of foreign exchange. In addition, the increase in R&D expenses in the first nine months of 2022 was partially offset by a $1.7 billion charge in the prior year period related to the acquisition of Pandion Therapeutics, Inc. (Pandion).

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 $2.0 billion and $1.8 billion for the third quarter of 2022 and 2021, respectively, and were $5.6 billion and $5.3 billion for the first nine months of 2022 and 2021, respectively. Also included in R&D expenses are Animal Health research costs, licensing costs and costs incurred by other divisions in support of R&D activities, including depreciation, production and general and administrative, which in the aggregate were approximately $1.5 billion and $710 million for the third quarter of 2022 and 2021, respectively, and $3.2 billion and $2.1 billion for the first nine months of 2022 and 2021, respectively. The increase in these expenses in the third quarter and first nine months of 2022 compared with the same periods of 2021 largely reflects $690 million of upfront and option payments in the aggregate for collaborations and licensing agreements with Orion, Moderna and Orna. Additionally, R&D expenses in the first nine months of 2022 include $887 million of intangible assets impairment charges and in the first nine months of 2021 include a $1.7 billion charge for the acquisition of Pandion as noted above. See Note 3 for additional information related to business development activity in the current and prior year.

Restructuring Costs

In 2019, Merck approved a global restructuring program (Restructuring Program) as part of a worldwide initiative focused on further optimizing the Company's manufacturing and supply network, as well as reducing its global real estate footprint. This program is a continuation of the Company's plant rationalization and builds on prior restructuring programs. The actions currently contemplated under the Restructuring Program are expected to be substantially completed by the end of 2023, with the cumulative pretax costs to be incurred by the Company to implement the program estimated to be approximately $3.5 billion. Merck expects to record charges of approximately $600 million for the full year of 2022 related to the Restructuring Program. The Company anticipates the actions under the Restructuring Program will result in annual net cost savings of approximately $900 million by the end of 2023.

Restructuring costs, primarily representing separation and other related costs associated with these restructuring activities, were $94 million and $107 million for the third quarter of 2022 and 2021, respectively, and $288 million and $487 million for the first nine months of 2022 and 2021, respectively. Separation costs incurred were associated with actual headcount reductions, as well as estimated expenses under existing severance programs for headcount reductions that were probable and could be reasonably estimated. Also included in restructuring costs are asset abandonment, facility shut-down and other related costs, as well as employee-related costs such as curtailment, settlement and termination charges associated with pension and other postretirement benefit plans and share-based compensation plan costs. For segment reporting, restructuring costs are unallocated expenses.

Additional costs associated with the Company's restructuring activities are included in *Cost of sales*, *Selling, general and administrative* expenses and *Research and development* costs. The Company recorded aggregate pretax costs of $175 million and $168 million in the third quarter of 2022 and 2021, respectively, and $559 million and $630 million for the first nine months of 2022 and 2021, respectively, related to restructuring program activities (see Note 5 to the condensed consolidated financial statements).

Other (Income) Expense, Net

Other (income) expense, net, was $429 million of expense in the third quarter of 2022 compared with $450 million of income in the third quarter of 2021. Other (income) expense, net, was $1.6 billion of expense for the first nine months of 2022 compared with $1.0 billion of income for the first nine months of 2021. The change in both periods is primarily due to net unrealized losses from investments in equity securities recorded in the third quarter and first nine months of 2022 compared with net realized and unrealized gains from investments in equity securities recorded in the third quarter and first nine months of 2021. The unfavorability in both periods was partially offset by lower pension costs.

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

Segment Profits

	Three Months Ended September 30,		Nine Months Ended September 30,	
($ in millions)	2022	2021	2022	2021
Pharmaceutical segment profits	$ 9,590	$ 8,606	$ 28,263	$ 22,450
Animal Health segment profits	515	505	1,672	1,629
Other	(6,522)	(3,845)	(17,004)	(14,109)
Income from Continuing Operations Before Taxes	$ 3,583	$ 5,266	$ 12,931	$ 9,970

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

Pharmaceutical segment profits increased 11% and 26% in the third quarter and first nine months of 2022, respectively, reflecting higher sales, partially offset by higher administrative and promotional costs, as well as the unfavorable effect of foreign exchange. Animal Health segment profits grew 2% in the third quarter of 2022 reflecting favorable product mix, partially offset by the unfavorable effect of foreign exchange. Animal Health segment profits grew 3% in the first nine months of 2022 reflecting higher sales, partially offset by higher selling and administrative costs and the unfavorable effect of foreign exchange.

Taxes on Income

The effective income tax rates from continuing operations were 9.2% and 13.2% for the third quarter of 2022 and 2021, respectively, and 11.0% and 14.4% for the first nine months of 2022 and 2021, respectively. The effective income tax rates from continuing operations reflect the beneficial impact of foreign earnings. The effective income tax rates from continuing operations in the third quarter and first nine months of 2022 also include the favorable impact of net unrealized losses from investments in equity securities and intangible asset impairment charges, which were taxed at the U.S. tax rate. The effective income tax rate from continuing operations in the first nine months of 2021 reflects the unfavorable effect of a charge for the acquisition of Pandion for which no tax benefit was recognized, as well as a net tax benefit of $207 million related to the settlement of certain federal income tax matters as discussed below.

In the first quarter of 2021, the Internal Revenue Service (IRS) concluded its examinations of Merck's 2015-2016 U.S. federal income tax returns. As a result, the Company was required to make a payment of $190 million (of which $172 million related to continuing operations and $18 million related to discontinued operations). The Company's reserves for unrecognized tax benefits for the years under examination exceeded the adjustments relating to this examination period and therefore the Company recorded a $236 million net tax benefit in the first nine months of 2021 (of which $207 million related to continuing operations and $29 million related to discontinued operations). This net benefit reflects reductions in reserves for unrecognized tax benefits and other related liabilities for tax positions relating to the years that were under examination.

Non-GAAP Income and Non-GAAP EPS from Continuing Operations

Non-GAAP income and non-GAAP EPS are alternative views of the Company's performance that Merck is providing because management believes this information enhances investors' understanding of the Company's results since management uses non-GAAP measures to assess performance. Non-GAAP income and non-GAAP EPS exclude certain items because of the nature of these items and the impact that they have on the analysis of underlying business performance and trends. The excluded items (which should not be considered non-recurring) consist of acquisition and divestiture-related costs, restructuring costs, income and losses from investments in equity securities, and certain other items. These excluded items are significant components in understanding and assessing financial performance. Non-GAAP income and non-GAAP EPS are important internal measures for the Company. Senior management receives a monthly analysis of operating results that includes a non-GAAP EPS metric. Management uses non-GAAP measures internally for planning and forecasting purposes and to measure the performance of the Company along with other metrics. In addition, senior management's annual compensation is derived in part using a non-GAAP pretax income metric. Since non-GAAP income and non-GAAP EPS are not measures determined in accordance with GAAP, they have no standardized meaning prescribed by GAAP and, therefore, may not be comparable to the calculation of similar measures of other companies. The information on non-GAAP income and non-GAAP EPS should be considered in addition to, but not as a substitute for or superior to, net income and EPS prepared in accordance with generally accepted accounting principles in the U.S. (GAAP).

In 2022, the Company changed the treatment of certain items for purposes of its non-GAAP reporting. Historically, Merck's non-GAAP results excluded expenses for upfront and milestone payments related to collaborations and licensing agreements, as well as charges related to pre-approval assets obtained in transactions accounted for as asset acquisitions, to the extent the charges were considered by the Company to be significant to the results of a particular period (as well as any related adjustments recorded in a subsequent period). Beginning in 2022, Merck's non-GAAP results no longer exclude charges related to these items. Prior periods have been recast to conform to the current presentation.

A reconciliation between GAAP financial measures and non-GAAP financial measures (from continuing operations) is as follows:

($ in millions except per share amounts)	Three Months Ended September 30, 2022	Three Months Ended September 30, 2021	Nine Months Ended September 30, 2022	Nine Months Ended September 30, 2021
Income from continuing operations before taxes as reported under GAAP	$ 3,583	$ 5,266	$ 12,931	$ 9,970
Increase (decrease) for excluded items:				
Acquisition and divestiture-related costs	1,344	445	2,512	1,445
Restructuring costs	175	168	559	630
Loss (income) from investments in equity securities, net	350	(684)	1,268	(1,503)
Other items:				
Charges for the discontinuation of COVID-19 development programs	—	—	—	225
Non-GAAP income from continuing operations before taxes	5,452	5,195	17,270	10,767
Taxes on income from continuing operations as reported under GAAP	330	695	1,423	1,436
Estimated tax benefit (provision) on excluded items [(1)]	414	(29)	965	84
Net tax benefit from the settlement of certain federal income tax matters	—	—	—	207
Non-GAAP taxes on income from continuing operations	744	666	2,388	1,727
Non-GAAP net income from continuing operations	4,708	4,529	14,882	9,040
Less: Net income attributable to noncontrolling interests as reported under GAAP	5	4	6	9
Non-GAAP net income from continuing operations attributable to Merck & Co., Inc.	$ 4,703	$ 4,525	$ 14,876	$ 9,031
EPS assuming dilution from continuing operations as reported under GAAP	$ 1.28	$ 1.80	$ 4.53	$ 3.36
EPS difference	0.57	(0.02)	1.33	0.20
Non-GAAP EPS assuming dilution from continuing operations	$ 1.85	$ 1.78	$ 5.86	$ 3.56

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

Acquisition and Divestiture-Related Costs

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

Restructuring Costs

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

Income and Losses from Investments in Equity Securities

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

Certain Other Items

Non-GAAP income and non-GAAP EPS exclude certain other items. These items are adjusted for after evaluating them on an individual basis, considering their quantitative and qualitative aspects. Typically, these consist of items that are unusual in nature, significant to the results of a particular period or not indicative of future operating results. Excluded from non-GAAP income and non-GAAP EPS in 2021 are charges related to the discontinuation of COVID-19 development programs (see Note 3 to the condensed consolidated financial statements) and a net tax benefit related to the settlement of certain federal income tax matters (see Note 13 to the condensed consolidated financial statements).

Research and Development Update

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

MK-4482, *Lagevrio*, is an investigational oral antiviral medicine for the treatment of mild to moderate COVID-19 in adults who are at risk for progressing to severe disease. Merck is developing *Lagevrio* in collaboration with Ridgeback. The FDA granted Emergency Use Authorization for *Lagevrio* in December 2021; last reissued in October 2022, to authorize *Lagevrio* for the treatment of mild to moderate COVID-19 in adults with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death, and for whom alternative COVID-19 treatment options approved or authorized by the FDA are not accessible or clinically appropriate. The authorization is based on the Phase 3 MOVe-OUT trial. *Lagevrio* is not approved for any use in the U.S. and is authorized only for the duration of the declaration that circumstances exist justifying the authorization of its emergency use under the Food, Drug and Cosmetic Act, unless the authorization is terminated or revoked sooner. *Lagevrio* has also received Conditional Marketing Authorization in the UK and Special Approval for Emergency in Japan. In November 2021, the European Medicines Agency (EMA) issued a positive scientific opinion for *Lagevrio*, which is intended to support national decision-making on the possible use of *Lagevrio* prior to marketing authorization. In October 2021, the EMA initiated a rolling review for *Lagevrio* for the treatment of COVID-19 in adults. Merck plans to work with the Committee for Medicinal Products for Human Use of the EMA to complete the rolling review process to facilitate initiating the formal review of the Marketing Authorization Application. Applications to other regulatory bodies are underway. *Lagevrio* is also being evaluated for post-exposure prophylaxis in the Phase 3 MOVe-AHEAD trial, which is evaluating the efficacy and safety of *Lagevrio* for the prevention of COVID-19 in adults who reside with a person with COVID-19.

In October 2022, Merck provided an update on new clinical and non-clinical studies of *Lagevrio*. A preliminary analysis of the University of Oxford's PANORAMIC study, conducted in the UK in highly-vaccinated adults mostly over 65 years of age, showed no evidence of a difference between *Lagevrio* added to usual care compared to usual care alone for the reduction of hospitalizations and deaths through Day 28 (primary endpoint was not met); the incidence of hospitalizations and death through Day 28 was very low overall. The main secondary endpoint (time to first self-reported recovery) in the PANORAMIC study was 6 days shorter with the *Lagevrio* group compared to the usual care group; in addition, the use of *Lagevrio* also was associated with earlier recovery across a wide range of other symptom measures, as compared to the usual care group. Additionally, an analysis of real-world data from a separate study conducted by investigators in Israel (known as the Clalit study) showed that in a cohort of non-hospitalized, high-risk patients, *Lagevrio* reduced hospitalizations and mortality due to COVID-19 in patients 65 years and above; no evidence of benefit was found in younger adults ages 40 to 64 years. Also, Merck reported results from a separate, non-clinical 6-month carcinogenicity study in transgenic mice, which demonstrated that *Lagevrio* was not carcinogenic at any dose tested.

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

MK-3475, *Keytruda*, is an anti-PD-1 therapy approved for the treatment of many cancers that is in clinical development for expanded indications. These approvals were the result of a broad clinical development program that currently consists of more than 1,650 clinical trials, including more than 1,200 trials that combine *Keytruda* with other cancer treatments. 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 review by the FDA for the treatment of patients with previously treated advanced HCC. This submission is based on data from the Phase 3 KEYNOTE-394 trial along with supportive data from the KEYNOTE-240 and KEYNOTE-224 trials. *Keytruda* is approved for this indication in the U.S. under the FDA's accelerated approval process. This submission is to convert the accelerated approval to full (regular) approval.

Keytruda is also under review by the FDA for the adjuvant treatment of patients with stage IB (≥4 centimeters), II or IIIA NSCLC following complete surgical resection. The supplemental Biologics License Application is based on data from the pivotal Phase 3 KEYNOTE-091 trial, also known as EORTC-1416-LCG/ETOP-8-15 – PEARLS. The FDA set a Prescription

Drug User Fee Act (PDUFA) date of January 29, 2023, however, further data may be provided during the review process that may delay this date. *Keytruda* is also under review for this indication in the EU.

In July 2022, Merck announced that the Phase 3 KEYNOTE-412 trial evaluating *Keytruda* with concurrent chemoradiation therapy (CRT) followed by *Keytruda* as maintenance therapy (the *Keytruda* regimen) did not meet its primary endpoint of event-free survival for the treatment of patients with unresected locally advanced HNSCC. At the final analysis of the study, there was an improvement in event-free survival for patients who received the *Keytruda* regimen compared to placebo plus CRT; however, these results did not meet statistical significance per the pre-specified statistical plan. Results were presented at the 2022 European Society for Medical Oncology (ESMO) congress.

In August 2022, Merck announced that the Phase 3 KEYNOTE-921 trial evaluating *Keytruda* in combination with chemotherapy (docetaxel) compared to chemotherapy alone did not meet its dual primary endpoints of overall survival and radiographic progression-free survival for the treatment of patients with metastatic castration-resistant prostate cancer. In the study, there were modest trends toward an improvement in both overall survival and radiographic progression-free survival for patients who received *Keytruda* plus chemotherapy compared with chemotherapy alone; however, these results did not meet statistical significance per the pre-specified statistical plan. Results will be presented at an upcoming medical meeting.

MK-7339, Lynparza, is an oral PARP inhibitor currently approved for certain types of ovarian, breast, pancreatic and prostate cancers being co-developed for multiple cancer types as part of a collaboration with AstraZeneca.

In August 2022, the FDA granted priority review for a supplemental NDA for Lynparza in combination with abiraterone and prednisone or prednisolone for the treatment of adult patients with metastatic castration-resistant prostate cancer. The supplemental NDA was based on results from the Phase 3 PROpel trial, which were presented at the 2022 American Society of Clinical Oncology (ASCO) Genitourinary Cancers Symposium and later published in *NEJM Evidence*. The FDA set a PDUFA date in the fourth quarter of 2022. Lynparza is also under review in the EU and Japan for the treatment of certain patients with metastatic castration-resistant prostate cancer based on the PROpel clinical trial.

In March 2022, Merck announced that it would stop the Phase 3 KEYLYNK-010 trial investigating *Keytruda* in combination with Lynparza for the treatment of patients with metastatic castration-resistant prostate cancer who progressed after treatment with chemotherapy and either abiraterone acetate or enzalutamide. Merck has discontinued the study following the recommendation of an independent Data Monitoring Committee (DMC) after the DMC reviewed data from a planned interim analysis. At the interim analysis, the combination of *Keytruda* and Lynparza did not demonstrate a benefit in overall survival, one of the study's dual primary endpoints, compared to the control arm of either abiraterone acetate or enzalutamide. The trial's other dual primary endpoint, radiographic progression free survival, was evaluated at an earlier interim analysis and did not demonstrate improvement compared to the control arm. Results from the study were presented at the 2022 ESMO congress.

In July 2022, Merck announced it will stop the Phase 3 LYNK-003 trial investigating Lynparza with or without bevacizumab for the treatment of patients with unresectable or metastatic colorectal cancer who have not progressed following first-line induction. This action follows the recommendation of an independent DMC, after the DMC reviewed the data from a planned interim analysis. At the pre-specified interim analysis for progression-free survival, the efficacy of Lynparza as a monotherapy and in combination with bevacizumab relative to control met the criteria for futility by the DMC and accordingly, both experimental arms were discontinued. Data from this study will be shared in a future scientific forum.

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

In August 2022, Merck and Eisai announced that the Phase 3 LEAP-002 trial investigating *Keytruda* plus Lenvima versus Lenvima monotherapy did not meet its dual primary endpoints of overall survival and progression-free survival as a first-line treatment for patients with unresectable hepatocellular carcinoma (uHCC). There were trends toward improvement in overall survival and progression-free survival for patients who received *Keytruda* plus Lenvima versus Lenvima monotherapy; however, these results did not meet statistical significance per the pre-specified statistical plan. Results were presented at the 2022 ESMO congress.

In July 2020, Merck and Eisai announced that the FDA issued a CRL regarding Merck's and Eisai's applications seeking accelerated approval of *Keytruda* plus Lenvima for the first-line treatment of patients with uHCC based on data from the Phase 1b KEYNOTE-524/Study 116 trial. Given the results of the LEAP-002 trial noted above, Merck no longer intends to pursue the application.

In October 2022, Merck announced positive top-line results from the pivotal Phase 3 STELLAR trial evaluating the safety and efficacy of sotatercept, an investigational activin receptor type IIA-Fc (ActRIIA-Fc) fusion protein being evaluated as an add-on to stable background therapy for the treatment of pulmonary arterial hypertension (PAH) (World Health Organization [WHO] Group 1). The trial met its primary efficacy outcome measure, demonstrating a statistically significant and

clinically meaningful improvement in 6-minute walk distance (6MWD, which measures how far patients can walk in 6 minutes). Eight of nine secondary efficacy outcome measures achieved statistical significance, including the outcome measure of proportion of participants achieving multicomponent improvement (defined as improvement in 6MWD, improvement in N-terminal pro-B-type natriuretic peptide level, and either improvement in WHO Functional Class [FC] or maintenance of WHO FC II), and the outcome measure of time to death or the first occurrence of a clinical worsening event. The Cognitive/Emotional Impacts domain score of PAH-SYMPACT®, which was assessed as the ninth and final secondary outcome measure, did not achieve statistical significance. Results from the study will be presented at an upcoming scientific congress.

In September 2022, Merck announced it will initiate a new Phase 3 clinical program with once-daily islatravir for the treatment of people with HIV-1 infection. These new Phase 3 studies will evaluate a once-daily oral combination of doravirine 100 mg and a lower dose of islatravir (DOR/ISL). One study will evaluate DOR/ISL in previously untreated adults with HIV-1 infection and two studies will evaluate DOR/ISL as a switch in antiretroviral therapy in adults with HIV-1 infection who are virologically suppressed. The investigational new drug application for the once-daily oral DOR/ISL treatment program remains under a partial clinical hold for any studies that would use doses higher than the dose to be studied in the new Phase 3 program. The Phase 2 clinical trial evaluating an investigational oral once-weekly combination treatment regimen of islatravir and Gilead Sciences' lenacapavir in adults with HIV-1 infection who are virologically suppressed will resume under an amended protocol with a lower dose of islatravir. The investigational new drug application under which the islatravir + lenacapavir once-weekly treatment regimen is being investigated remains under a partial clinical hold for any studies that would use weekly oral islatravir doses higher than the doses considered for the revised clinical program. Additionally, Merck announced it will discontinue the development of once-monthly oral islatravir for pre-exposure prophylaxis (PrEP).

In June 2022, Merck announced the presentation of positive results from a Phase 1/2 study evaluating the safety, tolerability and immunogenicity of V116, the Company's investigational 21-valent pneumococcal conjugate vaccine (PCV), in pneumococcal vaccine-naïve adults 18-49 years of age (Phase 1) and 50 years of age and older (Phase 2). In both populations, V116 met the primary immunogenicity objectives and was well-tolerated with an overall safety profile generally comparable to *Pneumovax* 23 across age groups. In April 2022, Merck announced that V116 received Breakthrough Therapy Designation from the FDA for the prevention of invasive pneumococcal disease and pneumococcal pneumonia caused by Streptococcus pneumoniae serotypes 3, 6A/C, 7F, 8, 9N, 10A, 11A, 12F, 15A, 15B/C, 16F, 17F, 19A, 20, 22F, 23A, 23B, 24F, 31, 33F, 35B in adults 18 years of age and older. The Breakthrough Therapy Designation is an FDA program designed to expedite the development and review of products intended for serious or life-threatening conditions. To qualify for this designation, preliminary clinical evidence must indicate that the product may demonstrate substantial improvement over currently available options on at least one clinically significant endpoint. Enrollment in several Phase 3 trials evaluating V116 is ongoing.

In October 2022, Merck and Royalty Pharma plc (Royalty Pharma) entered into a funding arrangement under which Royalty Pharma paid Merck $50 million to co-fund Merck's development costs for a Phase 2b trial of MK-8189, an investigational oral Phosphodiesterase 10A (PDE10A) inhibitor, which is being evaluated for the treatment of schizophrenia. Under the agreement, Royalty Pharma has no rights to MK-8189 and has no decision-making authority over the program. If Merck elects to advance MK-8189 into a Phase 3 study, Royalty Pharma has the option to provide additional funding of 50% of the development costs up to $375 million for the Phase 3 trial. If such additional funding is provided, Royalty Pharma becomes eligible to receive future regulatory milestone payments contingent upon certain marketing approvals, as well as royalties.

The charts below reflect the Company's research pipeline as of November 3, 2022. Candidates shown in Phase 3 include the date such candidate entered into Phase 3 development. Candidates shown in Phase 2 include the most advanced compound with a specific mechanism or, if listed compounds have the same mechanism, they are each currently intended for commercialization in a given therapeutic area. Small molecules and biologics are given MK-number designations and vaccine candidates are given V-number designations. Except as otherwise noted, candidates in Phase 1, additional indications in the same therapeutic area (other than with respect to cancer) and additional claims, line extensions or formulations for in-line products are not shown.

Phase 2

Cancer
- MK-0482[2]
  - Non-Small-Cell Lung
- MK-1026 (nemtabrutinib)
  - Hematological Malignancies
- MK-1308 (quavonlimab)[2]
  - Non-Small-Cell Lung
- MK-1308A (quavonlimab+pembrolizumab)
  - Colorectal
  - Hepatocellular
  - Melanoma
  - Small-Cell Lung
- MK-2140 (zilovertamab vedotin)
  - Breast
  - Gastric
  - Hematological Malignancies
  - Non-Small-Cell Lung
  - Ovarian
  - Pancreatic
- MK-2870[1][3]
  - Neoplasm Malignant
- MK-3475 *Keytruda*
  - Advanced Solid Tumors
- MK-4280 (favezelimab)[2]
  - Non-Small-Cell Lung
- MK-4280A (favezelimab+pembrolizumab)
  - Esophageal
  - Renal Cell
  - Small-Cell Lung
- MK-4830[2]
  - Colorectal
  - Esophageal
  - Melanoma
  - Non-Small-Cell Lung
  - Ovarian
  - Renal Cell
  - Small-Cell Lung
- MK-5684[1]
  - Prostate
- MK-5890 (boserolimab)[2]
  - Non-Small-Cell Lung
  - Small-Cell Lung

Cancer
- MK-6440 (ladiratuzumab vedotin)[1][3]
  - Breast
  - Esophageal
  - Gastric
  - Head and Neck
  - Melanoma
  - Non-Small-Cell Lung
  - Prostate
  - Small-Cell Lung
- MK-6482 *Welireg*[3]
  - Biliary
  - Colorectal
  - Endometrial
  - Esophageal
  - Hepatocellular
  - Pancreatic
  - Rare cancers
  - Von Hippel-Lindau Disease-Associated Tumors (EU)
- MK-7119 Tukysa[1]
  - Advanced Solid Tumors
  - Biliary
  - Bladder
  - Cervical
  - Endometrial
  - Gastric
  - Non-Small-Cell Lung
- MK-7339 Lynparza[1][3]
  - Advanced Solid Tumors
- MK-7684 (vibostolimab)[2]
  - Melanoma
- MK-7684A (vibostolimab+pembrolizumab)
  - Biliary
  - Breast
  - Cervical
  - Colorectal
  - Endometrial
  - Esophageal
  - Head and Neck
  - Hematological Malignancies
  - Hepatocellular
  - Prostate

Cancer
- MK-7902 Lenvima[1][2]
  - Biliary
  - Glioblastoma
  - Pancreatic
  - Prostate
  - Small-Cell Lung
- V940[1]
  - Melanoma

Chikungunya Virus Vaccine
- V184

Dengue Fever Virus Vaccine
- V181

HIV-1 Infection
- MK-8591B (islatravir+MK-8507)[4]
- MK-8591D (islatravir+lenacapavir)[1][5]

Hypercholesterolemia
- MK-0616

Nonalcoholic Steatohepatitis (NASH)
- MK-3655
- MK-6024

Overgrowth Syndrome
- MK-7075 (miransertib)

Pulmonary Arterial Hypertension
- MK-5475

Pulmonary Hypertension Due To Left Heart Disease
- MK-7962 (sotatercept)

Schizophrenia
- MK-8189[6]

Thrombosis
- MK-2060

Treatment Resistant Depression
- MK-1942

<table>
<tr><th>Phase 3 (Phase 3 entry date)</th><th colspan="2">Under Review</th></tr>
<tr>
<td rowspan="2">
Antiviral COVID-19
MK-4482 Lagevrio (U.S.) (May 2021)[1][7]
Cancer
MK-1308A (quavonlimab+pembrolizumab)
Renal Cell (April 2021)
MK-3475 Keytruda
Biliary (September 2019)
Cutaneous Squamous Cell (August 2019) (EU)
Gastric (May 2015) (EU)
Hepatocellular (May 2016) (EU)
Mesothelioma (May 2018)
Ovarian (December 2018)
Prostate (May 2019)
Small-Cell Lung (May 2017)
MK-3475 (pembrolizumab subcutaneous)
Non-Small-Cell Lung (August 2021)
MK-4280A (favezelimab+pembrolizumab)
Colorectal (November 2021)
Hematological Malignancies (October 2022)
MK-6482 Welireg[3]
Renal Cell (February 2020)
MK-7119 Tukysa[1]
Breast (October 2019)
Colorectal (August 2022)
MK-7339 Lynparza[1][3]
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[1][2]
Colorectal (April 2021)
Esophageal (July 2021)
Gastric (December 2020)
Head and Neck (February 2020)
Melanoma (March 2019)
Non-Small-Cell Lung (March 2019)
HIV-1 Infection
MK-8591A (doravirine+islatravir) (February 2020)[5]
Pneumococcal Vaccine Adult
V116 (July 2022)
Pulmonary Arterial Hypertension
MK-7962 (sotatercept) (January 2021)
Respiratory Syncytial Virus
MK-1654 (clesrovimab) (November 2021)
</td>
<td>
New Molecular Entities/Vaccines
Antiviral COVID-19
MK-4482 Lagevrio (EU)[1]
Cough
MK-7264 (gefapixant) (U.S.)[8] (EU)
</td>
<td>
Certain Supplemental Filings
Cancer
MK-3475 Keytruda
• Second-Line Hepatocellular Cancer (KEYNOTE-394) (U.S.)
• Adjuvent Non-Small-Cell Lung Cancer (KEYNOTE-091) (U.S.) (EU)

MK-7339 Lynparza[1]
• First-Line Metastatic Prostate Cancer (PROpel) (U.S.) (EU) (JPN)
</td>
</tr>
<tr>
<td colspan="2">
Footnotes:
[1] Being developed in a collaboration.
[2] Being developed in combination with Keytruda.
[3] Being developed as monotherapy and/or in combination with Keytruda.
[4] On FDA clinical hold.
[5] On FDA partial clinical hold.
[6] Phase 2b development costs are being co-funded.
[7] Available in the U.S. under Emergency Use Authorization.
[8] In response to the CRL received from the FDA for this application in January 2022, Merck is performing additional analyses and anticipates submitting this information to the FDA in the first half of 2023.
</td>
</tr>
</table>

Liquidity and Capital Resources

($ in millions)	September 30, 2022	December 31, 2021
Cash and investments	$ 12,232	$ 8,466
Working capital	10,563	6,394
Total debt to total liabilities and equity	28.4 %	31.3 %

Cash provided by operating activities of continuing operations was $14.7 billion in the first nine months of 2022 compared with $8.0 billion in the first nine months of 2021 reflecting stronger operating performance, including the impact of *Lagevrio* (see Note 4 to the condensed consolidated financial statements). Cash provided by operating activities of continuing operations in the first nine months of 2022 was reduced by $1.8 billion of milestone payments related to collaborations compared with $432 million of milestone and option payments related to collaborations in the first nine months of 2021. Cash provided by operating activities of continuing operations continues to be the Company's primary source of funds to finance operating needs, with excess cash serving as the primary source of funds to finance capital expenditures, dividends paid to shareholders and treasury stock purchases. As a result of the mandatory change in R&D capitalization rules that are effective for tax years beginning after December 31, 2021 (related to the Tax Cuts and Jobs Act of 2017), the Company has paid higher taxes in the U.S. in the first nine months of 2022 compared with the same prior year period.

Cash used in investing activities of continuing operations was $3.2 billion in the first nine months of 2022 compared with $4.4 billion in the first nine months of 2021. The lower use of cash in investing activities of continuing operations was primarily due to lower cash used for acquisitions and higher proceeds from the sale of securities and other investments, partially offset by higher purchases of securities and other investments.

Cash used in financing activities of continuing operations was $7.6 billion in the first nine months of 2022 compared with $2.1 billion in the first nine months of 2021. The increase in cash used in financing activities of continuing operations was primarily due to the cash distribution in 2021 received from Organon in connection with the spin-off (see Note 2 to the condensed consolidated financial statements) coupled with higher payments on long-term debt and higher dividends paid to shareholders in the current period. The increase in cash used in financing activities was partially offset by net repayments of short-term borrowings and treasury stock purchases in the prior year period that did not occur in the current period.

Capital expenditures totaled $3.2 billion in both the first nine months of 2022 and the first nine months of 2021.

The Company has accounts receivable factoring agreements with financial institutions in certain countries to sell accounts receivable. The Company factored $2.3 billion and $2.8 billion of accounts receivable at September 30, 2022 and December 31, 2021, respectively, under these factoring arrangements, which reduced outstanding accounts receivable. The cash received from the financial institutions is reported within operating activities in the Condensed Consolidated Statement of Cash Flows. In certain of these factoring arrangements, for ease of administration, the Company will collect customer payments related to the factored receivables, which it then remits to the financial institutions. The net cash flows relating to these collections are reported as financing activities in the Condensed Consolidated Statement of Cash Flows.

Dividends paid to stockholders were $5.3 billion and $5.0 billion for the first nine months of 2022 and 2021, respectively. In May 2022, the Board of Directors declared a quarterly dividend of $0.69 per share on the Company's stock for the third quarter that was paid in July 2022. In July 2022, the Board of Directors declared a quarterly dividend of $0.69 per share on the Company's stock for the fourth quarter that was paid in October 2022.

In February 2022, the Company's $1.25 billion, 2.35% notes matured in accordance with their terms and were repaid. In September 2022, the Company's $1.0 billion, 2.40% notes matured in accordance with their terms and were repaid. In January 2021, the Company's $1.15 billion, 3.875% notes matured in accordance with their terms and were repaid.

In 2018, Merck's Board of Directors authorized purchases of up to $10 billion of Merck's common stock for its treasury. The treasury stock purchase authorization has no time limit and will be made over time in open-market transactions, block transactions on or off an exchange, or in privately negotiated transactions. The Company did not purchase any shares of its common stock during the first nine months of 2022. As of September 30, 2022, the Company's remaining share repurchase authorization was $5.0 billion.

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

Critical Accounting Estimates

The Company's significant accounting policies, which include management's best estimates and judgments, are included in Note 2 to the consolidated financial statements for the year ended December 31, 2021 included in Merck's Form 10-K filed on February 25, 2022. See Note 1 to the condensed consolidated financial statements for information on the adoption of new accounting standards during 2022. 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, 2021.

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 2021 Form 10-K filed on February 25, 2022.

The economy of Turkey was recently determined to be hyperinflationary. Consequently, in accordance with U.S. GAAP, the Company's monetary assets and liabilities that are subject to remeasurement as a result of the changes in the Turkish lira changed beginning in the second quarter of 2022. This change had an immaterial impact to Merck's condensed consolidated financial statements.

Item 4. Controls and Procedures

Management of the Company, with the participation of its Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of the Company's disclosure controls and procedures over financial reporting. Based on their evaluation, the Company's Chief Executive Officer and Chief Financial Officer have concluded that as of September 30, 2022, the Company's disclosure controls and procedures are effective. For the third quarter of 2022, there were no changes in internal control over financial reporting that materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

CAUTIONARY FACTORS THAT MAY AFFECT FUTURE RESULTS

This report and other written reports and oral statements made from time to time by the Company may contain so-called "forward-looking statements," all of which are based on management's current expectations and are subject to risks and uncertainties which may cause results to differ materially from those set forth in the statements. One can identify these forward-looking statements by their use of words such as "anticipates," "expects," "plans," "will," "estimates," "forecasts," "projects" and other words of similar meaning, or negative variations of any of the foregoing. One can also identify them by the fact that they do not relate strictly to historical or current facts. These statements are likely to address the Company's growth strategy, financial results, product approvals, product potential, development programs, environmental or other sustainability initiatives, and may include statements related to the expected impact of the COVID-19 pandemic. One must carefully consider any such statement and should understand that many factors could cause actual results to differ materially from the Company's forward-looking statements. These factors include inaccurate assumptions and a broad variety of other risks and uncertainties, including some that are known and some that are not. No forward-looking statement can be guaranteed and actual future results may vary materially.

The Company does not assume the obligation to update any forward-looking statement. One should carefully evaluate such statements in light of factors, including risk factors, described in the Company's filings with the Securities and Exchange Commission, especially on Forms 10-K, 10-Q and 8-K. In Item 1A. "Risk Factors" of the Company's Annual Report on Form 10-K for the year ended December 31, 2021, filed on February 25, 2022, in the Company's Form 10-Q for the quarterly period ended March 31, 2022, filed on May 5, 2022, the Company's Form 10-Q for the quarterly period ended June 30, 2022, filed on August 5, 2022, and in this Form 10-Q, the Company discusses in more detail various important risk factors that could cause actual results to differ from expected or historic results. The Company notes these factors for investors as permitted by the Private Securities Litigation Reform Act of 1995. One should understand that it is not possible to predict or identify all such factors. Consequently, the reader should not consider any such list to be a complete statement of all potential risks or uncertainties.

PART II - Other Information

Item 1. Legal Proceedings

The information called for by this Item is incorporated herein by reference to Note 9 included in Part I, Item 1, Financial Statements (unaudited) — Notes to Condensed Consolidated Financial Statements.

Item 1A. Risk Factors

For a discussion of risks that affect the Company's business, please refer to Part I, Item IA, "Risk Factors" in the Company's Annual Report on Form 10-K for the year ended December 31, 2021. There have been no material changes to the risk factors as previously disclosed in the Company's Annual Report on Form 10-K, except as follows:

The ongoing war between Russia and Ukraine and related global disruptions could adversely affect the Company's business, results of operations and financial condition.

The ongoing war between Russia and Ukraine, and the financial and economic sanctions imposed by the U.S., the European Union and other countries in response, are having pervasive direct and indirect effects on the global economy, and may adversely affect the Company's business, results of operations and financial condition. The Company is working cross-functionally across the globe to monitor and mitigate interruptions to business continuity resulting from the war, including its impact on Merck's supply chain, operations and clinical trials.

For humanitarian reasons, the Company is continuing to supply essential medicines and vaccines in Russia while working to maintain compliance with evolving international sanctions. Merck is donating profits resulting from its operations in Russia to humanitarian causes. The Company does not have research or manufacturing facilities in Russia, currently does not plan to make further investments in Russia, and has suspended screening and enrollment in ongoing clinical trials as well as

planning for new studies in Russia, although the Company continues to treat patients already enrolled in existing clinical trials and collect data from these studies. The Company is also using its resources to help alleviate the humanitarian crisis in Ukraine, including through donations of funds and products.

The financial impacts of the war between Russia and Ukraine were immaterial to the Company's consolidated financial statements for the third quarter and first nine months of 2022. However, the degree to which the war and related disruptions will impact the Company's results for the remainder of 2022 or beyond is difficult to predict and will depend on developments outside of the Company's control, including, but not limited to, the duration and severity of the war, ongoing and additional financial and economic sanctions imposed by governments in response, restrictions on travel, regional instability, geopolitical shifts, and adverse effects on fuel and energy costs, supply chains, macroeconomic conditions, currency exchange rates and financial markets. Such developments may negatively impact the Company directly or indirectly as well as the parties with which the Company conducts business. In addition, the effects of the war between Russia and Ukraine could heighten other risks disclosed in the Company's Annual Report on Form 10-K for the year ended December 31, 2021, which could materially adversely affect the Company's business, results of operations and financial condition.

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

Issuer purchases of equity securities for the three months ended September 30, 2022 were as follows:

ISSUER PURCHASES OF EQUITY SECURITIES

				($ in millions)
Period	Total Number of Shares Purchased [(1)]	Average Price Paid Per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Approximate Dollar Value of Shares That May Yet Be Purchased Under the Plans or Programs [(1)]
July 1 - July 31	—	$0.00	—	$5,047
August 1 - August 31	—	$0.00	—	$5,047
September 1 - September 30	—	$0.00	—	$5,047
Total	—	$0.00	—	

[(1)] The Company did not purchase any shares during the three months ended September 30, 2022 under the plan approved by the Board of Directors in October 2018 to purchase up to $10 billion of Merck's common stock for its treasury.

Item 6. Exhibits

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

Signatures

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

MERCK & CO., INC.

Date: November 3, 2022

/s/ Jennifer Zachary

JENNIFER ZACHARY
Executive Vice President and General Counsel

Date: November 3, 2022

/s/ Rita A. Karachun

RITA A. KARACHUN
Senior Vice President Finance - Global Controller

Exhibit 31.1

CERTIFICATION

I, Robert M. Davis, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 3, 2022

By: /s/ Robert M. Davis

ROBERT M. DAVIS
Chief Executive Officer and President

Exhibit 31.2

CERTIFICATION

I, Caroline Litchfield, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 3, 2022

By: /s/ Caroline Litchfield

CAROLINE LITCHFIELD
Executive Vice President, Chief Financial Officer

Exhibit 32.1

Section 1350
Certification of Chief Executive Officer

Pursuant to 18 U.S.C. Section 1350, the undersigned officer of Merck & Co., Inc. (the "Company"), hereby certifies that the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2022 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 3, 2022

/s/ Robert M. Davis

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

Exhibit 32.2

Section 1350
Certification of Chief Financial Officer

Pursuant to 18 U.S.C. Section 1350, the undersigned officer of Merck & Co., Inc. (the "Company"), hereby certifies that the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2022 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: November 3, 2022

/s/ Caroline Litchfield

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