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 March 31, 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**

2000 Galloping Hill Road, Kenilworth, New Jersey 07033
(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 April 30, 2022: 2,528,805,025

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

	Three Months Ended March 31,	
	2022	2021
Sales	$ 15,901	$ 10,627
Costs, Expenses and Other		
Cost of sales	5,380	3,199
Selling, general and administrative	2,323	2,187
Research and development	2,576	2,412
Restructuring costs	53	297
Other (income) expense, net	708	(455)
	11,040	7,640
Income from Continuing Operations Before Taxes	4,861	2,987
Taxes on Income from Continuing Operations	554	238
Net Income from Continuing Operations	4,307	2,749
Less: Net (Loss) Income Attributable to Noncontrolling Interests	(3)	4
Net Income from Continuing Operations Attributable to Merck & Co., Inc.	4,310	2,745
Income from Discontinued Operations, Net of Taxes and Amounts Attributable to Noncontrolling Interests	—	434
Net Income Attributable to Merck & Co., Inc.	$ 4,310	$ 3,179
Basic Earnings per Common Share Attributable to Merck & Co., Inc. Common Shareholders:		
Income from Continuing Operations	$ 1.70	$ 1.08
Income from Discontinued Operations	—	0.17
Net Income	$ 1.70	$ 1.26
Earnings per Common Share Assuming Dilution Attributable to Merck & Co., Inc. Common Shareholders:		
Income from Continuing Operations	$ 1.70	$ 1.08
Income from Discontinued Operations	—	0.17
Net Income	$ 1.70	$ 1.25

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

	Three Months Ended March 31,	
	2022	2021
Net Income Attributable to Merck & Co., Inc.	$ 4,310	$ 3,179
Other Comprehensive Income Net of Taxes:		
Net unrealized gain on derivatives, net of reclassifications	63	230
Benefit plan net gain and prior service credit, net of amortization	32	81
Cumulative translation adjustment	(35)	(299)
	60	12
Comprehensive Income Attributable to Merck & Co., Inc.	$ 4,370	$ 3,191

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)

	March 31, 2022	December 31, 2021
Assets		
Current Assets		
Cash and cash equivalents	$ 8,556	$ 8,096
Short-term investments	372	—
Accounts receivable (net of allowance for doubtful accounts of $95 in 2022 and $62 in 2021)	9,828	9,230
Inventories (excludes inventories of $2,495 in 2022 and $2,194 in 2021 classified in Other assets - see Note 7)	5,774	5,953
Other current assets	6,654	6,987
Total current assets	31,184	30,266
Investments	316	370
Property, Plant and Equipment, at cost, net of accumulated depreciation of $18,498 in 2022 and $18,192 in 2021	19,747	19,279
Goodwill	21,258	21,264
Other Intangibles, Net	23,022	22,933
Other Assets	11,141	11,582
	$ 106,668	$ 105,694
Liabilities and Equity		
Current Liabilities		
Loans payable and current portion of long-term debt	$ 1,208	$ 2,412
Trade accounts payable	3,715	4,609
Accrued and other current liabilities	14,051	13,859
Income taxes payable	1,571	1,224
Dividends payable	1,771	1,768
Total current liabilities	22,316	23,872
Long-Term Debt	30,586	30,690
Deferred Income Taxes	3,071	3,441
Other Noncurrent Liabilities	9,742	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	44,275	44,238
Retained earnings	56,252	53,696
Accumulated other comprehensive loss	(4,369)	(4,429)
	97,946	95,293
Less treasury stock, at cost: 1,048,727,225 shares in 2022 and 1,049,499,023 shares in 2021	57,063	57,109
Total Merck & Co., Inc. stockholders' equity	40,883	38,184
Noncontrolling Interests	70	73
Total equity	40,953	38,257
	$ 106,668	$ 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)

	Three Months Ended March 31,	
	2022	2021
Cash Flows from Operating Activities of Continuing Operations		
Net income from continuing operations	$ 4,307	$ 2,749
Adjustments to reconcile net income from continuing operations to net cash provided by operating activities of continuing operations:		
Amortization	699	514
Depreciation	421	378
Loss (income) from investments in equity securities, net	708	(574)
Deferred income taxes	(338)	18
Share-based compensation	120	111
Other	143	236
Net changes in assets and liabilities	(1,299)	(2,192)
Net Cash Provided by Operating Activities of Continuing Operations	4,761	1,240
Cash Flows from Investing Activities of Continuing Operations		
Capital expenditures	(984)	(1,082)
Purchases of securities and other investments	(372)	(1)
Proceeds from sales of securities and other investments	1	386
Other	182	11
Net Cash Used in Investing Activities of Continuing Operations	(1,173)	(686)
Cash Flows from Financing Activities of Continuing Operations		
Net change in short-term borrowings	—	788
Payments on debt	(1,250)	(1,153)
Dividends paid to stockholders	(1,745)	(1,645)
Proceeds from exercise of stock options	12	9
Other	(103)	(97)
Net Cash Used in Financing Activities of Continuing Operations	(3,086)	(2,098)
Cash Flows from Discontinued Operations		
Net cash provided by operating activities	—	551
Net cash used in investing activities	—	(52)
Net Cash Flows Provided by Discontinued Operations	—	499
Effect of Exchange Rate Changes on Cash, Cash Equivalents and Restricted Cash	(55)	(97)
Net Increase (Decrease) in Cash, Cash Equivalents and Restricted Cash	447	(1,142)
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	8,165
Less: Cash and cash equivalents related to discontinued operations	—	141
Cash, Cash Equivalents and Restricted Cash at End of Period (includes restricted cash of $58 and $42 at March 31, 2022 and 2021, respectively, included in Other current assets)	$ 8,614	$ 6,882

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.

Reclassifications — Certain reclassifications have been made to prior year amounts to conform to the current year presentation.

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.

Recently Issued Accounting Standards Not Yet Adopted

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 optional guidance is effective upon issuance and can be applied on a prospective basis at any time between January 1, 2020 through December 31, 2022. The Company is currently evaluating the impact of adoption on its consolidated financial statements. The Company is progressing in its evaluation of LIBOR cessation exposures, including the review of debt-related contracts, leases, business development and licensing arrangements, royalty and other agreements. The Company has amended certain agreements and continues to review other agreements for potential impacts. With regard to debt-related exposures in particular, the Company's four remaining interest rate swaps linked to LIBOR will mature in September 2022. The Company will transition its LIBOR-based debt to an alternative reference rate upon LIBOR discontinuance. Based on its evaluation thus far, the Company does not anticipate a material impact to its consolidated financial statements as a result of reference rate reform.

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.

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. 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.

Amounts included in the condensed consolidated statement of income for the above MSAs include sales of $99 million and related cost of sales of $105 million for the first quarter of 2022. Amounts included in the condensed consolidated statement of income for the TSAs were immaterial in the first quarter of 2022.

The amounts due from Organon under all of the above agreements were $719 million and $964 million at March 31, 2022 and December 31, 2021, respectively, and are reflected in *Other current assets*. The amounts due to Organon under these agreements were $344 million and $400 million at March 31, 2022 and December 31, 2021, respectively, and are included in A*ccrued 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 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 $249 million in the first quarter of 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)	Three Months Ended March 31, 2021
Sales	$ 1,453
Costs, Expenses and Other	
Cost of sales	471
Selling, general and administrative	446
Research and development	53
Restructuring costs	1
Other (income) expense, net	7
	978
Income from discontinued operations before taxes	475
Tax provision	38
Income from discontinued operations, net of taxes	437
Less: Income of discontinued operations attributable to noncontrolling interests	3
	$ 434

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.

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 quarter 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 $170 million in the first quarter 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. For further details refer to Note 4 to the consolidated financial statements included in Merck's 2021 Form 10-K.

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* (pembrolizumab) and Imfinzi. The companies are also jointly developing and commercializing AstraZeneca's Koselugo (selumetinib) for multiple indications. Under the terms of the agreement, AstraZeneca and Merck will share the development and commercialization costs for Lynparza and Koselugo monotherapy and non-PD-L1/PD-1 combination therapy opportunities.

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

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

In the first quarter of 2022, Merck determined it was probable that sales of Lynparza in the future would trigger a $600 million sales-based milestone payment from Merck to AstraZeneca. Accordingly, Merck recorded a $600 million liability 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 addition, Merck made a sales-based milestone payment to AstraZeneca (which had been previously accrued for) of $400 million in the first quarter of 2022. Potential future sales-based milestone payments of $2.1 billion have not yet been accrued as they are not deemed by the Company to be probable at this time. In the first quarter of 2022, Lynparza received a regulatory approval triggering a capitalized milestone payment of $175 million from Merck to AstraZeneca, which was paid in April 2022. Potential future regulatory milestone payments of $1.3 billion remain under the agreement.

The intangible asset balance related to Lynparza (which includes capitalized sales-based and regulatory milestone payments) was $1.6 billion at March 31, 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:

	Three Months Ended March 31,	
($ in millions)	2022	2021
Alliance revenue - Lynparza	$ 266	$ 228
Alliance revenue - Koselugo	9	5
Total alliance revenue	$ 275	$ 233
Cost of sales [(1)]	299	42
Selling, general and administrative	44	40
Research and development	26	29

($ in millions)	March 31, 2022	December 31, 2021
Receivables from AstraZeneca included in *Other current assets*	$ 275	$ 271
Payables to AstraZeneca included in *Trade accounts payable* and *Accrued and other current liabilities* [(2)]	190	415
Payables to AstraZeneca included in *Other Noncurrent Liabilities* [(2)]	600	—

[(1)] *Represents amortization of capitalized milestone payments. Amount in the first quarter 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 quarter of 2022, Merck made sales-based milestone payments to Eisai (which had been previously accrued for) aggregating $300 million. In April 2022, Merck made an additional $300 million sales-based milestone payment, which was accrued for as of March 31, 2022. 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 quarter of 2022, Lenvima received a regulatory approval triggering a capitalized milestone payment of $25 million from Merck to Eisai. As of March 31, 2022, regulatory milestone payments accrued but not yet paid totaled $25 million. There are no potential future regulatory milestone payments remaining under the agreement.

The intangible asset balance related to Lenvima (which includes capitalized sales-based and regulatory milestone payments) was $973 million at March 31, 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:

	Three Months Ended March 31,	
($ in millions)	2022	2021
Alliance revenue - Lenvima	$ 227	$ 130
Cost of sales [(1)]	53	47
Selling, general and administrative	31	23
Research and development	57	64

($ in millions)	March 31, 2022	December 31, 2021
Receivables from Eisai included in *Other current assets*	$ 241	$ 200
Payables to Eisai included in *Accrued and other current liabilities* [(2)]	325	625

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

[(2)] *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 $758 million and $65 million, respectively, at March 31, 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:

	Three Months Ended March 31,	
($ in millions)	2022	2021
Alliance revenue - Adempas/Verquvo	$ 72	$ 74
Net sales of Adempas recorded by Merck	61	55
Net sales of Verquvo recorded by Merck	3	—
Total sales	$ 136	$ 129
Cost of sales [1]	50	208
Selling, general and administrative	23	17
Research and development	17	7

($ in millions)	March 31, 2022	December 31, 2021
Receivables from Bayer included in *Other current assets*	$ 129	$ 114
Payables to Bayer included in *Accrued and other current liabilities* [2]	74	472

[1] *Includes amortization of intangible assets. Amount in the first quarter 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 share 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 30 markets. As of March 31, 2022, the Company has 3.4 million remaining courses to be supplied under these agreements.

Summarized financial information related to this collaboration is as follows:

	Three Months Ended March 31,	
($ in millions)	2022	2021
Lagevrio sales	$ 3,247	$ —
Cost of sales [1]	1,724	46
Selling, general and administrative	34	3
Research and development	6	42

($ in millions)	March 31, 2022	December 31, 2021
Payables to Ridgeback included in *Accrued and other current liabilities* [2]	$ 1,568	$ 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 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 $52 million within *Sales* in the first quarter of 2022 related to this collaboration, which includes royalties of $32 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 $127 million and $334 million in the first quarter of 2022 and 2021, respectively, related to restructuring program activities. Since inception of the Restructuring Program through March 31, 2022, Merck has recorded total pretax accumulated costs of approximately $2.8 billion. For the full year of 2022, the Company expects to record charges of approximately $400 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 March 31, 2022			
($ in millions)	Separation Costs	Accelerated Depreciation	Other	Total
Cost of sales	$ —	$ 18	$ 28	$ 46
Selling, general and administrative	—	4	17	21
Research and development	—	7	—	7
Restructuring costs	26	—	27	53
	$ 26	$ 29	$ 72	$ 127

	Three Months Ended March 31, 2021			
($ in millions)	Separation Costs	Accelerated Depreciation	Other	Total
Cost of sales	$ —	$ 10	$ 17	$ 27
Selling, general and administrative	—	3	—	3
Research and development	—	7	—	7
Restructuring costs	229	—	68	297
	$ 229	$ 20	$ 85	$ 334

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 programs. Accelerated depreciation costs represent the difference between the depreciation expense to be recognized over the revised useful life of the asset, based upon the anticipated date the site will be closed or divested or the equipment disposed of, and depreciation expense as determined utilizing the useful life prior to the restructuring actions. All the sites 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 10) and share-based compensation.

The following table summarizes the charges and spending relating to restructuring program activities for the three months ended March 31, 2022:

($ in millions)	Separation Costs	Accelerated Depreciation	Other	Total
Restructuring reserves January 1, 2022	$ 596	$ —	$ 41	$ 637
Expense	26	29	72	127
(Payments) receipts, net	(68)	—	(45)	(113)
Non-cash activity	—	(29)	(39)	(68)
Restructuring reserves March 31, 2022 [(1)]	$ 554	$ —	$ 29	$ 583

[(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 March 31,		Three Months Ended March 31,	
($ in millions)	2022	2021	2022	2021
Net Investment Hedging Relationships				
Foreign exchange contracts	$ (16)	$ (25)	$ (1)	$ (4)
Euro-denominated notes	(53)	(166)	—	—

[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 capital at risk.

In February 2022, five interest rate swaps with a total notional amount of $1.25 billion matured. These swaps effectively converted the Company's $1.25 billion, 2.350% fixed-rate notes due 2022 to variable rate debt. At March 31, 2022, the Company was a party to four pay-floating, receive-fixed interest rate swap contracts designated as fair value hedges of fixed-rate notes in which the notional amounts match the amount of the hedged fixed-rate notes as detailed in the table below.

	March 31, 2022		
($ in millions)	Par Value of Debt	Number of Interest Rate Swaps Held	Total Swap Notional Amount
2.40% notes due 2022	$ 1,000	4	$ 1,000

The interest rate swap contracts are 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 are recorded in interest expense along with the offsetting fair value changes in the swap contracts. See Note 1 for a discussion of the pending discontinuation of LIBOR as part of reference rate reform. The cash flows from these contracts are reported as operating activities in the Condensed Consolidated Statement of Cash Flows.

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

	Carrying Amount of Hedged Liabilities		Cumulative Amount of Fair Value Hedging Adjustment Increase (Decrease) Included in the Carrying Amount	
($ in millions)	March 31, 2022	December 31, 2021	March 31, 2022	December 31, 2021
Balance Sheet Line Item in which Hedged Item is Included				
Loans payable and current portion of long-term debt	$ 1,003	$ 2,263	$ 4	$ 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:

		March 31, 2022			December 31, 2021		
		Fair Value of Derivative		U.S. Dollar	Fair Value of Derivative		U.S. Dollar
($ in millions)		Asset	Liability	Notional	Asset	Liability	Notional
Derivatives Designated as Hedging Instruments	*Balance Sheet Caption*						
Interest rate swap contracts	Other current assets	$ 4	$ —	$ 1,000	$ 14	$ —	$ 2,250
Foreign exchange contracts	Other current assets	341	—	7,429	271	—	6,778
Foreign exchange contracts	Other Assets	46	—	1,595	43	—	1,551
Foreign exchange contracts	Accrued and other current liabilities	—	21	1,060	—	24	1,623
Foreign exchange contracts	Other Noncurrent Liabilities	—	1	9	—	1	43
		$ 391	$ 22	$ 11,093	$ 328	$ 25	$ 12,245
Derivatives Not Designated as Hedging Instruments	*Balance Sheet Caption*						
Foreign exchange contracts	Other current assets	$ 288	$ —	$ 12,466	$ 221	$ —	$ 10,073
Foreign exchange contracts	Accrued and other current liabilities	—	219	7,700	—	96	10,640
		$ 288	$ 219	$ 20,166	$ 221	$ 96	$ 20,713
		$ 679	$ 241	$ 31,259	$ 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:

	March 31, 2022		December 31, 2021	
($ in millions)	Asset	Liability	Asset	Liability
Gross amounts recognized in the condensed consolidated balance sheet	$ 679	$ 241	$ 549	$ 121
Gross amounts subject to offset in master netting arrangements not offset in the condensed consolidated balance sheet	(191)	(191)	(110)	(110)
Cash collateral received	(220)	—	(164)	—
Net amounts	$ 268	$ 50	$ 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 March 31,					
($ in millions)	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)	
	$15,901	$10,627	$ 708	$ (455)	$ 60	$ 12
(Gain) loss on fair value hedging relationships						
Interest rate swap contracts						
Hedged items	—	—	(10)	(11)	—	—
Derivatives designated as hedging instruments	—	—	4	1	—	—
Impact of cash flow hedging relationships						
Foreign exchange contracts						
Amount of gain recognized in *OCI* on derivatives	—	—	—	—	148	180
Increase (decrease) in *Sales* as a result of *AOCL* reclassifications	67	(112)	—	—	(67)	112
Interest rate contracts						
Amount of gain recognized in *Other (income) expense, net* on derivatives	—	—	(1)	(1)	—	—
Amount of loss recognized in *OCI* on derivatives	—	—	—	—	(1)	(1)

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

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

		Amount of Derivative Pretax (Gain) Loss Recognized in Income	
		Three Months Ended March 31,	
($ in millions)		2022	2021
Derivatives Not Designated as Hedging Instruments	*Income Statement Caption*		
Foreign exchange contracts [1]	Other (income) expense, net	$ 28	$ 50
Foreign exchange contracts [2]	Sales	(2)	(4)

[1] *These derivative contracts primarily mitigate changes in the value of remeasured foreign currency denominated monetary assets and liabilities attributable to changes in foreign currency exchange rates.*

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

At March 31, 2022, the Company estimates $248 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:

	March 31, 2022				December 31, 2021			
	Amortized Cost	Gross Unrealized		Fair Value	Amortized Cost	Gross Unrealized		Fair Value
($ in millions)		Gains	Losses			Gains	Losses	
Commercial paper	$ 372	$ —	$ —	$ 372	$ —	$ —	$ —	$ —
U.S. government and agency securities	75	—	—	75	80	—	—	80
Corporate notes and bonds	4	—	—	4	4	—	—	4
Foreign government bonds	3	—	—	3	2	—	—	2
Total debt securities	$ 454	$ —	$ —	$ 454	$ 86	$ —	$ —	$ 86
Publicly traded equity securities [(1)]				1,397				1,647
Total debt and publicly traded equity securities				$ 1,851				$ 1,733

[(1)] *Unrealized net losses of $225 million were recorded in* Other (income) expense, net *on equity securities still held at March 31, 2022 in the first quarter of 2022. Unrealized net losses recorded in* Other (income) expense, net *on equity securities still held at March 31, 2021 were $181 million in the first quarter of 2021.*

At March 31, 2022 and March 31, 2021, the Company also had $643 million and $651 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 quarter of 2022, the Company recorded unrealized gains of $14 million related to certain of these equity investments still held at March 31, 2022. During the first quarter of 2021, the Company recorded unrealized gains of $33 million related to certain of these investments still held at March 31, 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 March 31, 2022 were $248 million and $7 million, respectively.

At March 31, 2022 and 2021, the Company also had $1.2 billion and $884 million, 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 $509 million and $(264) million for the first quarter 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)	March 31, 2022				December 31, 2021			
Assets								
Investments								
Commercial paper	$ —	$ 372	$ —	$ 372	$ —	$ —	$ —	$ —
Foreign government bonds	—	3	—	3	—	2	—	2
Publicly traded equity securities	313	—	—	313	368	—	—	368
	313	375	—	688	368	2	—	370
Other assets [1]								
U.S. government and agency securities	75	—	—	75	80	—	—	80
Corporate notes and bonds	4	—	—	4	4	—	—	4
Publicly traded equity securities	1,084	—	—	1,084	1,279	—	—	1,279
	1,163	—	—	1,163	1,363	—	—	1,363
Derivative assets [2]								
Forward exchange contracts	—	433	—	433	—	351	—	351
Purchased currency options	—	242	—	242	—	184	—	184
Interest rate swaps	—	4	—	4	—	14	—	14
	—	679	—	679	—	549	—	549
Total assets	$ 1,476	$ 1,054	$ —	$ 2,530	$ 1,731	$ 551	$ —	$ 2,282
Liabilities								
Other liabilities								
Contingent consideration	$ —	$ —	$ 572	$ 572	$ —	$ —	$ 777	$ 777
Derivative liabilities [2]								
Forward exchange contracts	—	240	—	240	—	120	—	120
Written currency options	—	1	—	1	—	1	—	1
	—	241	—	241	—	121	—	121
Total liabilities	$ —	$ 241	$ 572	$ 813	$ —	$ 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 March 31, 2022 and December 31, 2021, *Cash and cash equivalents* included $7.4 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]	(84)	(13)
Payments	(119)	—
Other	(2)	(12)
Fair value March 31 [2][3]	$ 572	$ 816

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

[2] *Balance at March 31, 2022 includes $149 million recorded as a current liability for amounts expected to be paid within the next 12 months.*

[3] *At March 31, 2022 and December 31, 2021, $439 million and $620 million, respectively, of the liabilities relate to the termination of the Sanofi Pasteur MSD joint venture in 2016. As part of the termination, Merck recorded a liability for contingent future royalty payments of 11.5% on net sales of all Merck products that were previously sold by the joint venture through December 31, 2024. The fair value of this liability is determined utilizing the estimated amount and timing of projected cash flows using a risk-adjusted discount rate of 8% to present value the cash flows.*

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 March 31, 2022, was $31.7 billion compared with a carrying value of $31.8 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, government agencies, managed health care providers and pharmacy benefit managers. 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 $2.2 billion and $2.8 billion of accounts receivable as of March 31, 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 March 31, 2022 and December 31, 2021, the Company had collected $31 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 April 2022 and January 2022, respectively. The net cash flows relating 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 $220 million and $164 million at March 31, 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)	March 31, 2022	December 31, 2021
Finished goods	$ 1,772	$ 1,747
Raw materials and work in process	6,365	6,220
Supplies	209	196
Total (approximates current cost)	8,346	8,163
Decrease to LIFO cost	(77)	(16)
	$ 8,269	$ 8,147
Recognized as:		
Inventories	$ 5,774	$ 5,953
Other assets	2,495	2,194

Amounts recognized as *Other Assets* are comprised almost entirely of raw materials and work in process inventories. At March 31, 2022 and December 31, 2021, these amounts included $2.1 billion and $1.9 billion, respectively, of inventories

not expected to be sold within one year. In addition, these amounts included $327 million and $256 million at March 31, 2022 and December 31, 2021, respectively, of inventories produced in preparation for product launches.

8. Contingencies

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

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

The Company records accruals for contingencies when it is probable that a liability has been incurred and the amount can be reasonably estimated. These accruals are adjusted periodically as assessments change or additional information becomes available. 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 March 31, 2022, approximately 3,460 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. Whether the plaintiffs will attempt to move forward on other claims or seek to appeal the District Court's ruling is not yet known.

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). As of March 31, 2022, Merck is aware of approximately 660 product users alleging that *Januvia* and/or *Janumet* caused the development of pancreatic cancer and other injuries.

Most claims have been filed in multidistrict litigation before the U.S. District Court for the Southern District of California (MDL). On March 9, 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 on October 5, 2021, the U.S. Court of Appeals for the Ninth Circuit dismissed the appeal as to Merck and two of its codefendants.

Outside of the MDL, the majority of claims have been 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.

As of March 31, 2022, six product users have claims pending against Merck in state courts other than California, including Illinois. In June 2017, the Illinois trial court denied Merck's motion for summary judgment based on federal preemption. Merck appealed, and the Illinois appellate court affirmed in December 2018. Merck filed a petition for leave to appeal to the Illinois Supreme Court in February 2019. In April 2019, the Illinois Supreme Court stayed consideration of the pending petition to appeal until the U.S. Supreme Court issued its opinion in *Merck Sharp & Dohme Corp. v. Albrecht* (relating to the Fosamax matter discussed above). Merck filed the opinion in *Albrecht* with the Illinois Supreme Court in June 2019. The petition for leave to appeal was decided in September 2019, in which the Illinois Supreme Court directed the intermediate appellate court to reconsider its earlier ruling. The Illinois Appellate Court issued a favorable decision concluding, consistent with *Albrecht*, that preemption presents a legal question to be resolved by the court. In May 2020, the Illinois Appellate Court issued a mandate to the state trial court, which, as of March 31, 2022, had not scheduled a case management conference or otherwise taken action.

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.

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 putative class action and opt-out 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 have been consolidated for pretrial purposes in a federal multidistrict litigation before Judge Rebecca Beach Smith in the Eastern District of Virginia. In December 2018, the court denied the Merck Defendants' motions to dismiss or stay the direct purchaser putative class actions pending bilateral arbitration. In August 2019, the district court adopted in full the report and recommendation of the magistrate judge with respect to the Merck Defendants' motions to dismiss on non-arbitration issues, thereby granting in part and denying in part Merck Defendants' motions to dismiss.

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 overruled the direct purchaser plaintiffs' objections, adopted the magistrate judge's recommendation, and denied the direct purchaser plaintiffs' renewed motion for class certification.

In August 2020, the Merck Defendants filed a motion for summary judgment and other motions, and plaintiffs filed a motion for partial summary judgment, and other motions. Those motions are now fully briefed, and the court has heard

argument on certain of the motions. The court granted partial summary judgment to the plaintiffs on issues of market definition. Defendants Glenmark Pharmaceuticals Ltd. and Glenmark Pharmaceuticals Inc., USA (collectively, the Glenmark Defendants) filed a motion to certify the court's decision for interlocutory appeal on March 28, 2022. This motion is fully briefed and awaiting decision. The court may hold additional hearings on the summary judgment and other motions that remain undecided. Trial in this matter has been adjourned.

Also, in August 2020, the magistrate judge recommended that the court grant the motion for class certification filed by the putative indirect purchaser class. In August 2021, the district court granted certification of a class of indirect purchasers. In September 2021, the Merck Defendants petitioned to appeal the class certification decision to the Fourth Circuit. The Fourth Circuit denied that petition on September 30, 2021.

In September 2020, United Healthcare Services, Inc. filed a lawsuit in the U.S. District Court for the District of Minnesota against the Merck Defendants and others (the UHC Action). The UHC Action makes similar allegations as those made in the Zetia class action as well as allegations about Vytorin. In September 2020, the U.S. Judicial Panel on Multidistrict Litigation transferred the case to the Eastern District of Virginia to proceed with the multidistrict Zetia litigation already in progress.

In December 2020, Humana Inc. filed a lawsuit in the Superior Court of the State of California, County of San Francisco, against Merck and others, alleging defendants violated state antitrust laws in multiple states. Also, in December 2020, Centene Corporation and others filed a lawsuit in the Superior Court of the State of California, County of San Francisco, against the same defendants as Humana. Both lawsuits allege similar anticompetitive acts to those alleged in the Zetia class action.

In June 2021, Kaiser Foundation Health Plan, Inc. similarly filed a lawsuit in the Superior Court of the State of California, County of San Francisco, against the same defendants as Humana and Centene. The Kaiser lawsuit alleges similar anticompetitive acts to those alleged in the Zetia class action. The Kaiser action was removed to the U.S. District Court for the Northern District of California on July 16, 2021. In September 2021, the U.S. Judicial Panel on Multidistrict Litigation transferred the case to the Eastern District of Virginia to proceed with the multidistrict Zetia litigation already in progress.

As of December 2021, all of the insurer plaintiffs (Kaiser, Humana, and Centene) are part of the multidistrict Zetia litigation, and are proceeding with discovery in that action. On February 9, 2022, United Healthcare, Kaiser, and Humana each filed an amended complaint. 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.

Rotavirus Vaccines Antitrust Litigation

As previously disclosed, MSD is a defendant in putative class action lawsuits filed in 2018 on behalf of direct purchasers of *RotaTeq* (Rotavirus Vaccine, Live, Oral, Pentavalent), alleging violations of federal antitrust laws. The cases were consolidated in the Eastern District of Pennsylvania. In January 2019, the court denied MSD's motions to compel arbitration and to dismiss the consolidated complaint. In February 2019, MSD appealed the court's order on arbitration to the Third Circuit. In October 2019, the Third Circuit vacated the district court's order and remanded for limited discovery on the issue of arbitrability. On July 6, 2020, MSD filed a renewed motion to compel arbitration, and plaintiffs filed a cross motion for summary judgment as to arbitrability. On November 20, 2020, the district court denied MSD's motion and granted plaintiffs' motion. On December 4, 2020, MSD filed a notice of appeal to the Third Circuit. On March 21, 2022, the Third Circuit reversed the order of the district court and remanded with the instruction that the court grant MSD's motion to compel arbitration. On April 4, 2022, plaintiffs filed a petition for panel rehearing or rehearing *en banc*.

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 U.S. District Court for the District of New Jersey has set a bench trial in this matter beginning on October 12, 2022.

Mylan Pharmaceuticals Inc., Mylan API US LLC, and Mylan Inc. (Mylan) have filed motions to dismiss in the District of New Jersey for lack of venue and failure to state a claim against certain defendants, and in the Northern District of West Virginia for failure to state a claim against certain defendants. The New Jersey motion has not yet been decided, and the West Virginia action is stayed pending resolution of the New Jersey motion.

The Company has settled with four 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 J*anumet 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. The Company currently anticipates that sales of *Januvia* and *Janumet* in the U.S. will decline significantly after this date. 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 (2027 salt/polymorph patent), which, if determined to be valid, would preclude generic manufacturers from making sitagliptin phosphate salt and polymorphic forms until 2027 with the expiration of that patent, plus pediatric exclusivity. 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.

In total, the Company has settled with 21 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 has appealed the USPTO's decision to the U.S. Court of Appeals for the Federal Circuit.

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. The U.S. District Court for the District of Delaware has set a three-day bench trial in this matter beginning on October 31, 2022.

Generic companies have sought revocation of the Supplementary Protection Certificate (SPC) for *Janumet* in the following European countries: Austria, Czech Republic, Finland, France, Hungary, Italy, Portugal, Romania, Slovakia, and Sweden. If the generic companies are successful, *Janumet* could lose market exclusivity in these countries at the same time as the expiry of *Januvia* pediatric market exclusivity in September 2022. In February 2022, a Finnish court referred certain questions to the European Court of Justice 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.

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 March 31, 2022 and December 31, 2021 of approximately $235 million and $230 million, respectively, represents the Company's best estimate of the minimum amount of defense costs to be incurred in connection with its outstanding litigation; however, events such as additional trials and other events that could arise in the course of its litigation could affect the ultimate amount of legal defense costs to be incurred by the Company. The Company will continue to monitor its legal defense costs and review the adequacy of the associated reserves and may determine to increase the reserves at any time in the future if, based upon the factors set forth, it believes it would be appropriate to do so.

9. Equity

	Three Months Ended March 31,								
	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.	—	—	—	3,179	—	—	—	—	3,179
Other comprehensive income, net of taxes	—	—	—	—	12	—	—	—	12
Cash dividends declared on common stock ($0.65 per share)	—	—	—	(1,653)	—	—	—	—	(1,653)
Share-based compensation plans and other	—	—	25	—	—	(1)	65	—	90
Net income attributable to noncontrolling interests	—	—	—	—	—	—	—	7	7
Balance at March 31, 2021	3,577	$ 1,788	$ 39,613	$ 48,888	$ (6,622)	1,046	$ (56,722)	$ 94	$ 27,039
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.	—	—	—	4,310	—	—	—	—	4,310
Other comprehensive income, net of taxes	—	—	—	—	60	—	—	—	60
Cash dividends declared on common stock ($0.69 per share)	—	—	—	(1,754)	—	—	—	—	(1,754)
Share-based compensation plans and other	—	—	37	—	—	—	46	—	83
Net loss attributable to noncontrolling interests	—	—	—	—	—	—	—	(3)	(3)
Balance at March 31, 2022	3,577	$ 1,788	$ 44,275	$ 56,252	$ (4,369)	1,049	$ (57,063)	$ 70	$ 40,953

10. Pension and Other Postretirement Benefit Plans

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

	Three Months Ended March 31,			
	2022		2021	
($ in millions)	U.S.	International	U.S.	International
Service cost	$ 99	$ 75	$ 100	$ 92
Interest cost	103	38	96	29
Expected return on plan assets	(196)	(101)	(188)	(104)
Amortization of unrecognized prior service credit	(8)	(4)	(10)	(4)
Net loss amortization	56	25	85	41
Termination benefits	—	—	1	—
Curtailments	3	—	7	—
Settlements	1	—	—	—
	$ 58	$ 33	$ 91	$ 54

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 March 31,	
($ in millions)	2022	2021
Service cost	$ 12	$ 13
Interest cost	11	11
Expected return on plan assets	(21)	(20)
Amortization of unrecognized prior service credit	(25)	(25)
	$ (23)	$ (21)

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.

The components of net periodic benefit cost (credit) other than the service cost component are included in *Other (income) expense, net* (see Note 11), with the exception of certain amounts for termination benefits, curtailments and settlements, which are recorded in *Restructuring costs* if the event giving rise to the termination benefits, curtailment or settlement is related to restructuring actions.

11. Other (Income) Expense, Net

Other (income) expense, net, consisted of:

	Three Months Ended March 31,	
($ in millions)	2022	2021
Interest income	$ (7)	$ (11)
Interest expense	243	200
Exchange losses	39	41
Loss (income) from investments in equity securities, net [(1)]	708	(574)
Net periodic defined benefit plan (credit) cost other than service cost	(121)	(89)
Other, net	(154)	(22)
	$ 708	$ (455)

[(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. The Company estimates that losses of approximately $300 million will be recorded in the second quarter of 2022 from ownership interests in investment funds.*

Interest paid for the three months ended March 31, 2022 and 2021 was $211 million and $217 million, respectively.

12. Taxes on Income

The effective income tax rates from continuing operations were 11.4% and 8.0% for the first quarter of 2022 and 2021, respectively, which reflect the beneficial impact of foreign earnings. The effective income tax rate from continuing operations in the first quarter of 2022 also includes the impact of lower U.S. income reflecting net unrealized losses from investments in equity securities. The effective income tax rate from continuing operations for the first quarter of 2021 also reflects a net tax benefit of $208 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 $237 million net tax benefit in the first quarter of 2021 (of which $208 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.

13. Earnings Per Share

The calculations of earnings per share are as follows:

	Three Months Ended March 31,	
($ and shares in millions except per share amounts)	2022	2021
Net Income from Continuing Operations Attributable to Merck & Co., Inc.	$ 4,310	$ 2,745
Income from Discontinued Operations, Net of Taxes and Amounts Attributable to Noncontrolling Interests	—	434
Net Income Attributable to Merck & Co., Inc.	$ 4,310	$ 3,179
Average common shares outstanding	2,528	2,531
Common shares issuable [(1)]	9	10
Average common shares outstanding assuming dilution	2,537	2,541
Basic Earnings per Common Share Attributable to Merck & Co., Inc. Common Shareholders:		
Income from Continuing Operations	$ 1.70	$ 1.08
Income from Discontinued Operations	—	0.17
Net Income	$ 1.70	$ 1.26
Earnings per Common Share Assuming Dilution Attributable to Merck & Co., Inc. Common Shareholders:		
Income from Continuing Operations	$ 1.70	$ 1.08
Income from Discontinued Operations	—	0.17
Net Income	$ 1.70	$ 1.25

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

For the first quarter of 2022 and 2021, 7 million and 14 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.

14. Other Comprehensive Income (Loss)

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

	Three Months Ended March 31,			
($ 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	180	(4)	(211)	(35)
Tax	(38)	(1)	(88)	(127)
Other comprehensive income (loss) before reclassification adjustments, net of taxes	142	(5)	(299)	(162)
Reclassification adjustments, pretax	111 [(1)]	87 [(2)]	—	198
Tax	(23)	(1)	—	(24)
Reclassification adjustments, net of taxes	88	86	—	174
Other comprehensive income (loss), net of taxes	230	81	(299)	12
Balance March 31, 2021, net of taxes	$ (36)	$ (4,459)	$ (2,127)	$ (6,622)
Balance January 1, 2022, net of taxes	$ 144	$ (2,743)	$ (1,830)	$ (4,429)
Other comprehensive income (loss) before reclassification adjustments, pretax	148	1	(18)	131
Tax	(31)	(2)	(17)	(50)
Other comprehensive income (loss) before reclassification adjustments, net of taxes	117	(1)	(35)	81
Reclassification adjustments, pretax	(68) [(1)]	45 [(2)]	—	(23)
Tax	14	(12)	—	2
Reclassification adjustments, net of taxes	(54)	33	—	(21)
Other comprehensive income (loss), net of taxes	63	32	(35)	60
Balance March 31, 2022, net of taxes	$ 207	$ (2,711)	$ (1,865)	$ (4,369)

[(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 10).*

15. 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 March 31,					
	2022			2021		
($ in millions)	U.S.	Int'l	Total	U.S.	Int'l	Total
Pharmaceutical:						
Oncology						
Keytruda	$ 2,779	$ 2,030	$ 4,809	$ 2,181	$ 1,718	$ 3,899
Alliance revenue - Lynparza [(1)]	141	125	266	118	110	228
Alliance revenue - Lenvima [(1)]	156	71	227	85	44	130
Alliance revenue - Reblozyl [(2)]	27	25	52	—	—	—
Vaccines						
Gardasil/Gardasil 9	418	1,042	1,460	313	604	917
ProQuad/M-M-R II/*Varivax*	371	99	470	333	117	449
RotaTeq	175	41	216	118	41	158
Pneumovax 23	118	55	173	73	99	171
Vaqta	29	7	36	25	9	34
Hospital Acute Care						
Bridion	195	199	395	167	173	340
Prevymis	40	54	94	35	47	82
Primaxin	1	58	58	—	65	65
Noxafil	10	48	57	15	52	67
Cancidas	1	52	53	3	55	57
Dificid	49	3	52	25	2	27
Invanz	1	52	52	4	52	57
Zerbaxa	18	12	30	(2)	(6)	(8)
Cardiovascular						
Alliance revenue - Adempas/Verquvo [(3)]	71	1	72	68	6	74
Adempas	—	61	61	—	55	55
Virology						
Lagevrio	1,523	1,723	3,247	—	—	—
Isentress/Isentress HD	61	97	158	71	138	209
Neuroscience						
Belsomra	20	48	69	18	61	79
Immunology						
Simponi	—	186	186	—	214	214
Remicade	—	61	61	—	85	85
Diabetes						
Januvia	325	454	779	348	461	809
Janumet	63	391	454	84	401	486
Other pharmaceutical [(4)]	181	339	520	212	341	554
Total Pharmaceutical segment sales	6,773	7,334	14,107	4,294	4,944	9,238
Animal Health:						
Livestock	171	661	832	157	662	819
Companion Animals	302	348	650	280	319	599
Total Animal Health segment sales	473	1,009	1,482	437	981	1,418
Total segment sales	7,246	8,343	15,589	4,731	5,925	10,656
Other [(5)]	93	220	312	59	(88)	(29)
	$ 7,339	$ 8,563	$15,901	$ 4,790	$ 5,837	$10,627

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 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 revenues, including revenue hedging activities, as well as third-party manufacturing sales (including sales to Organon). Other for the three months ended March 31, 2022 and 2021 also includes $114 million and $56 million, respectively, related to upfront and contingent 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 $2.9 billion and $2.8 billion for the three months ended March 31, 2022 and 2021, respectively.

Consolidated sales by geographic area where derived are as follows:

	Three Months Ended March 31,	
($ in millions)	2022	2021
United States	$ 7,339	$ 4,790
Europe, Middle East and Africa	4,359	3,237
China	1,143	721
Japan	989	629
Asia Pacific (other than China and Japan)	930	575
Latin America	607	500
Other	534	175
	$ 15,901	$ 10,627

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

	Three Months Ended March 31,	
($ in millions)	2022	2021
Segment profits:		
Pharmaceutical segment	$ 9,501	$ 6,589
Animal Health segment	585	572
Total segment profits	10,086	7,161
Other profits	194	(50)
Unallocated:		
Interest income	7	11
Interest expense	(243)	(200)
Amortization	(699)	(514)
Depreciation	(378)	(340)
Research and development	(2,446)	(2,305)
Restructuring costs	(53)	(297)
Other unallocated, net	(1,607)	(479)
	$ 4,861	$ 2,987

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 sales.

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.

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 plans to donate 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 first quarter 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 the Russian government'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 conflict either directly or indirectly on the Company's business.

COVID-19 Update

Although COVID-19-related disruptions had some negative effects on sales for the first quarter 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 $3.2 billion in the first quarter of 2022. In the first quarter of 2021, COVID-19-related disruptions resulted in an estimated negative impact to Pharmaceutical segment sales of approximately $500 million 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 $170 million to *Cost of sales* in the first quarter of 2021.

The COVID-19 pandemic has caused some disruption and volatility in the Company's 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.

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 will be recognized as a reduction to *Cost of sales* over the production period, offsetting the depreciation expense related to the amounts that were capitalized in connection with the modification of the manufacturing facilities. Merck has also entered into agreements to support the manufacturing and supply of Johnson & Johnson's SARS-

CoV-2/COVID-19 vaccine. Merck is using certain of its facilities in the U.S. to produce drug substance, formulate and fill vials of Johnson & Johnson's vaccine.

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 quarter 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., the Biden Administration and Congress continue to discuss legislation designed to control health care costs, including the cost of drugs. The Company anticipates all of these actions and additional actions in the future will continue to negatively affect sales performance.

Operating Results

Sales

($ in millions)	Three Months Ended March 31, 2022	2021	% Change	% Change Excluding Foreign Exchange
United States	$ 7,339	$ 4,790	53 %	53 %
International	8,563	5,837	47 %	52 %
Total	$ 15,901	$ 10,627	50 %	52 %

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

Worldwide sales grew 50% to $15.9 billion in the first quarter of 2022. Revenue performance primarily reflects higher sales in the virology franchise attributable to $3.2 billion of *Lagevrio* (molnupiravir) sales, higher sales in the oncology franchise largely driven by strong growth of *Keytruda* (pembrolizumab) and increased alliance revenue from Lenvima (lenvatinib) and Lynparza (olaparib), as well as higher sales in the vaccines franchise, primarily attributable to growth in *Gardasil* (Human Papillomavirus Quadrivalent [Types 6, 11, 16 and 18] Vaccine, Recombinant)/*Gardasil* 9 (Human Papillomavirus 9-valent Vaccine, Recombinant) and *RotaTeq* (Rotavirus Vaccine, Live Oral, Pentavalent). Higher sales of hospital acute care products, including *Bridion* (sugammadex) Injection, higher third-party manufacturing sales and higher sales of Animal Health products also drove revenue growth in the first quarter of 2022. As discussed above, COVID-19-related disruptions had some negative effects on sales in the first quarter of 2022, but to a lesser extent than in the first quarter of 2021 which benefited year-over-year sales growth.

Revenue growth in the first quarter of 2022 was partially offset by lower combined sales of diabetes products *Januvia* (sitagliptin) and *Janumet* (sitagliptin and metformin HCl) and lower sales of virology products *Isentress/Isentress HD* (raltegravir).

See Note 15 to the condensed consolidated financial statements for details on sales of the Company's products. A discussion of performance for select products in the franchises follows.

Pharmaceutical Segment

Oncology

($ in millions)	Three Months Ended March 31, 2022	2021	% Change	% Change Excluding Foreign Exchange
Keytruda	$ 4,809	$ 3,899	23 %	27 %
Alliance Revenue - Lynparza [(1)]	266	228	17 %	20 %
Alliance Revenue - Lenvima [(1)]	227	130	75 %	77 %

[(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), non-small-cell lung cancer (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). *Keytruda* is also approved for certain patients with high-risk early-stage 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 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 23% in the first quarter of 2022. 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 indications, in particular for the treatment of advanced NSCLC as monotherapy, and in combination with chemotherapy for both nonsquamous and squamous metastatic NSCLC, along with continued uptake in the TNBC, RCC, HNSCC, and MSI-H cancer indications. *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 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 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 data from KEYNOTE-164 and KEYNOTE-158.

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 advanced ovarian, breast, pancreatic and prostate cancers. Alliance revenue related to Lynparza increased 17% in the first quarter of 2022 largely driven by continued uptake across the multiple approved indications globally, particularly in the U.S. 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 based on the OlympiA 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 75% in the first quarter of 2022 primarily reflecting higher demand in the U.S. and China. The growth in alliance revenue in the first quarter of 2022 also benefited from lower shared expenses.

Vaccines

($ in millions)	Three Months Ended March 31, 2022	2021	% Change	% Change Excluding Foreign Exchange
Gardasil/Gardasil 9	$ 1,460	$ 917	59 %	60 %
ProQuad	162	165	(2)%	(1)%
M-M-R II	103	80	29 %	31 %
Varivax	204	204	— %	1 %
RotaTeq	216	158	36 %	38 %
Pneumovax 23	173	171	1 %	3 %

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 59% in the first quarter of 2022 driven primarily by strong demand outside of the U.S., particularly in China, which also benefited from increased supply. Additionally, sales increased in the U.S. due to public sector buying patterns.

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 29% in the first quarter of 2022 primarily due to public sector buying patterns in the U.S. and higher demand in Latin America.

Global sales of *Varivax* (Varicella Virus Vaccine Live), a vaccine to help prevent chickenpox (varicella), were flat in the first quarter of 2022 as higher demand and pricing in the U.S. were offset by lower government tenders in Brazil.

Global sales of *RotaTeq*, a vaccine to help protect against rotavirus gastroenteritis in infants and children, grew 36% in the first quarter of 2022 due to public sector buying patterns in the U.S.

Worldwide sales of *Pneumovax* 23 (pneumococcal vaccine polyvalent), a vaccine to help prevent pneumococcal disease, grew 1% in the first quarter of 2022 primarily reflecting higher demand in the U.S. that was largely offset by lower demand in Europe and Japan attributable in part to the COVID-19 pandemic.

Hospital Acute Care

($ in millions)	Three Months Ended March 31, 2022	2021	% Change	% Change Excluding Foreign Exchange
Bridion	$ 395	$ 340	16 %	20 %
Zerbaxa	30	(8)	*	*

**Calculation not meaningful.*

Worldwide sales of *Bridion*, for the reversal of two types of neuromuscular blocking agents used during surgery, grew 16% in the first quarter of 2022 due to higher demand globally, particularly in the U.S. and Europe, largely attributable to an increase in surgical procedures resulting from the ongoing COVID-19 pandemic recovery.

In December 2020, the Company temporarily suspended sales of *Zerbaxa* (ceftolozane and tazobactam), 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. A phased resupply for *Zerbaxa* was initiated in the fourth quarter of 2021 and was expanded to additional markets in the first quarter of 2022.

Cardiovascular

($ in millions)	Three Months Ended March 31, 2022	2021	% Change	% Change Excluding Foreign Exchange
Alliance Revenue - Adempas/Verquvo [(1)]	$ 72	$ 74	(3)%	(3)%
Adempas	61	55	11 %	20 %

[(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 was nearly flat in the first quarter of 2022. Revenue also includes sales of Adempas and Verquvo in Merck's marketing territories. Sales of Adempas in Merck's marketing territories grew 11% in the first quarter of 2022 primarily reflecting higher demand.

Virology

($ in millions)	Three Months Ended March 31, 2022	2021	% Change	% Change Excluding Foreign Exchange
Lagevrio	$ 3,247	$ —	—	—
Isentress/Isentress HD	158	209	(24)%	(21)%

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, including in the United Kingdom (UK) (under Conditional Marketing Authorization), the U.S. (under Emergency Use Authorization), and Japan (under Special Approval for Emergency). Sales of *Lagevrio* were $3.2 billion in the first quarter 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 30 markets. The Company expects that sales of *Lagevrio* in each of the remaining quarters of 2022 will be lower than sales in the first quarter of 2022, with full-year 2022 *Lagevrio* sales anticipated to be between $5.0 billion to $5.5 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 24% in the first quarter of 2022 due to lower global demand, reflecting competitive pressure particularly in Europe and the U.S., as well as the timing of a government tender. The Company expects competitive pressure for *Isentress/Isentress HD* to continue.

Diabetes

($ in millions)	Three Months Ended March 31, 2022	2021	% Change	% Change Excluding Foreign Exchange
Januvia/Janumet	$ 1,233	$ 1,295	(5)%	(1)%

Worldwide combined sales of *Januvia* and *Janumet*, medicines that help lower blood sugar levels in adults with type 2 diabetes, declined 5% in the first quarter of 2022 primarily due to lower demand in the U.S., partially offset by higher demand in China, as well as Latin America reflecting in part the timing of government tenders. The Company anticipates U.S. pricing pressure will unfavorably affect sales of *Januvia* and *Janumet* in future periods. *Januvia* and *Janumet* will lose market exclusivity in China in July 2022, in the EU in September 2022, and in the U.S. in January 2023. The Company anticipates sales of *Januvia* and *Janumet* in these markets will decline substantially after the loss of exclusivity. Combined sales of *Januvia* and *Janumet* in China, Europe and the U.S. represented 11%, 23% and 31%, respectively, of total combined *Januvia* and *Janumet* sales in the first quarter of 2022.

Animal Health Segment

($ in millions)	Three Months Ended March 31, 2022	2021	% Change	% Change Excluding Foreign Exchange
Livestock	$ 832	$ 819	2 %	7 %
Companion Animal	650	599	9 %	13 %

Sales of livestock products grew 2% in the first quarter of 2022 primarily due to higher demand globally for ruminant and poultry products. Sales of companion animal products grew 9% in the first quarter of 2022 primarily due to higher demand for the *Bravecto* (fluralaner) line of products, as well as higher demand for vaccines. Sales of the *Bravecto* line of products represented approximately 20% of animal health sales in the first quarter of 2022.

Costs, Expenses and Other

($ in millions)	Three Months Ended March 31, 2022	2021	% Change
Cost of sales	$ 5,380	$ 3,199	68 %
Selling, general and administrative	2,323	2,187	6 %
Research and development	2,576	2,412	7 %
Restructuring costs	53	297	(82)%
Other (income) expense, net	708	(455)	*
	$ 11,040	$ 7,640	45 %

**Calculation not meaningful.*

Cost of Sales

Cost of sales increased 68% in the first quarter of 2022. Cost of sales includes the amortization of intangible assets recorded in connection with acquisitions, collaborations and licensing arrangements, which totaled $683 million and $495 million in the first quarter of 2022 and 2021, respectively. Amortization expense in the first quarter 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 quarter of 2021 include a charge of $188 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 $46 million and $27 million in the first quarter 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 66.2% in the first quarter of 2022 compared with 69.9% in the first quarter of 2021. The gross margin decline reflects the impact of *Lagevrio* (which has a lower gross margin due to profit sharing with Ridgeback as discussed in Note 4 to the condensed consolidation financial statements), as well as higher manufacturing costs and higher amortization of intangible assets (noted above). The gross margin decline in 2022 was partially offset by the favorable effects of product mix and a charge in 2021 related to the discontinuation of COVID-19 development programs.

Selling, General and Administrative

Selling, general and administrative (SG&A) expenses increased 6% in the first quarter of 2022 primarily due to higher acquisition-related costs and higher administrative costs, including compensation and benefits, partially offset by the favorable effect of foreign exchange.

Research and Development

Research and development (R&D) expenses increased 7% in the first quarter of 2022 primarily due to higher clinical development spending, including compensation and benefit costs, as well as increased investments in technology in support of the digital enablement of Merck's research operations, partially offset by the favorable effect of foreign exchange.

R&D expenses are comprised of the costs directly incurred by Merck Research Laboratories (MRL), the Company's research and development division that focuses on human health-related activities, which were $1.8 billion and $1.7 billion in the first quarter 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 $750 million and $665 million for the first quarter of 2022 and 2021, respectively.

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 $400 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 $53 million and $297 million for the first quarter 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 $127 million and $334 million in the first quarter 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 $708 million of expense in the first quarter of 2022 compared with $455 million of income in the first quarter of 2021 primarily due to net losses from investments in equity securities recorded in the first quarter of 2022, related to net unrealized losses, compared with net income from investments in equity securities recorded in the first quarter of 2021, related both to higher net realized and unrealized gains.

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

Segment Profits

	Three Months Ended March 31,	
($ in millions)	2022	2021
Pharmaceutical segment profits	$ 9,501	$ 6,589
Animal Health segment profits	585	572
Other	(5,225)	(4,174)
Income from Continuing Operations Before Taxes	$ 4,861	$ 2,987

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 sales.

Pharmaceutical segment profits increased 44% in the first quarter of 2022 reflecting higher sales, partially offset by higher administrative costs and the unfavorable effect of foreign exchange. Animal Health segment profits grew 2% in the first quarter of 2022 reflecting higher sales, partially offset by higher selling and administrative costs, higher R&D costs and the unfavorable effect of foreign exchange.

Taxes on Income

The effective income tax rates from continuing operations were 11.4% and 8.0% for the first quarter of 2022 and 2021, respectively, which reflect the beneficial impact of foreign earnings. The effective income tax rate from continuing operations in the first quarter of 2022 also includes the impact of lower U.S. income reflecting net unrealized losses from investments in equity securities. The effective income tax rate from continuing operations for the first quarter of 2021 also reflects a net tax benefit of $208 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 $237 million net tax benefit in the first quarter of 2021 (of which $208 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 will no longer exclude charges related to these items. This change did not affect non-GAAP results reported in the first quarter of 2022, nor did it affect previously reported first quarter 2021 non-GAAP results because the Company had no significant charges related to those items during these periods.

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

	Three Months Ended March 31,	
($ in millions except per share amounts)	2022	2021
Income from continuing operations before taxes as reported under GAAP	$ 4,861	$ 2,987
Increase (decrease) for excluded items:		
Acquisition and divestiture-related costs	637	497
Restructuring costs	127	334
Loss (income) from investments in equity securities, net	684	(561)
Other items:		
Charge for the discontinuation of COVID-19 development programs	—	188
Non-GAAP income from continuing operations before taxes	6,309	3,445
Taxes on income from continuing operations as reported under GAAP	554	238
Estimated tax benefit on excluded items [(1)]	329	48
Net tax benefit from the settlement of certain federal income tax matters	—	208
Non-GAAP taxes on income from continuing operations	883	494
Non-GAAP net income from continuing operations	5,426	2,951
Less: Net (loss) income attributable to noncontrolling interests as reported under GAAP	(3)	4
Non-GAAP net income from continuing operations attributable to Merck & Co., Inc.	$ 5,429	$ 2,947
EPS assuming dilution from continuing operations as reported under GAAP	$ 1.70	$ 1.08
EPS difference	0.44	0.08
Non-GAAP EPS assuming dilution from continuing operations	$ 2.14	$ 1.16

[(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 is a charge 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 12 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; as updated in February 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 (CHMP) 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.

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. The New Drug Application (NDA) for gefapixant is 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 NDA for gefapixant. In the CRL, the FDA requested additional information related to measurement of efficacy. The CRL was not related to the safety of gefapixant. Merck is reviewing the letter and considering next steps. Gefapixant is also under review in the EU, although the review period has been extended pending the receipt of additional information from the Company.

V114, (Pneumococcal 15-valent Conjugate Vaccine), is an investigational 15-valent pneumococcal conjugate vaccine under review in Japan for use in adults. V114 was approved in the U.S. in 2021 for use in adults where it is marketed as *Vaxneuvance*. *Vaxneuvance* is also under priority review by the FDA for the prevention of invasive pneumococcal disease in children 6 weeks through 17 years of age. The FDA grants priority review to medicines and vaccines that, if approved, would provide a significant improvement in the safety or effectiveness of the treatment or prevention of a serious condition. The supplemental biologics license application (BLA) is supported by results from Phase 2 and Phase 3 clinical studies in pediatric populations including infants, children, and adolescents. In April 2022, Merck announced that the FDA extended the Prescription Drug User Fee Act (PDUFA) date of the supplemental BLA for *Vaxneuvance* in infants and children to July 1, 2022. The FDA requested additional analyses of data from the pediatric studies, which Merck has submitted to the FDA. No new studies have been requested by the FDA.

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 1,750 clinical trials, including more than 1,300 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.

In April 2022, the CHMP adopted a positive opinion recommending approval of *Keytruda* 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. The CHMP's recommendation was based on results from the Phase 3 KEYNOTE-522 trial. The CHMP's recommendation will now be reviewed by the EC for marketing authorization in the EU, and a final decision is expected in the second quarter of 2022. *Keytruda* is also under review for this indication in Japan.

Keytruda is also under review in the EU for the adjuvant treatment of adult and pediatric (12 years and older) patients with Stage IIB or IIC melanoma following complete resection based on data from the Phase 3 KEYNOTE-716 trial.

Keytruda is under review in Japan in combination with chemotherapy, with or without bevacizumab, for the treatment of persistent, recurrent or metastatic cervical cancer in adults whose tumors express PD-L1 based on results from the Phase 3 KEYNOTE-826 trial.

Keytruda is also under review in Japan for the adjuvant treatment of patients with RCC at intermediate-high or high risk of recurrence following nephrectomy (surgical removal of a kidney) based on data from the Phase 3 KEYNOTE-564 trial.

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 KEYNOTE-240 and KEYNOTE-224.

MK-7339, Lynparza, is an oral PARP inhibitor currently approved for certain types of advanced ovarian, breast, pancreatic and prostate cancers being co-developed for multiple cancer types as part of a collaboration with AstraZeneca. Lynparza is under review in the EU and Japan for the adjuvant treatment of patients with *BRCA*-mutated, HER2-negative high-risk, early-stage breast cancer who have already been treated with chemotherapy either before or after surgery based on the results from the Phase 3 OlympiA trial. Lynparza is also under review in the EU 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 will 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 is discontinuing 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. Data from this study will be presented at an upcoming scientific congress.

In April 2022, Merck announced that V116, the Company's investigational 21-valent pneumococcal conjugate vaccine, has 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. Phase 3 clinical trials for V116 are expected to be initiated later this year. 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.

The charts below reflect the Company's research pipeline as of May 3, 2022. Candidates shown in Phase 3 include specific products and 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[3] Non-Small-Cell Lung MK-1026 (nemtabrutinib) Hematological Malignancies MK-1308 (quavonlimab)[2] Non-Small-Cell Lung MK-1308A (quavonlimab+pembrolizumab) Advanced Solid Tumors Colorectal Hepatocellular Melanoma Small-Cell Lung MK-2140 (zilovertamab vedotin) Breast Hematological Malignancies Non-Small-Cell Lung Solid Tumors MK-3475 *Keytruda* Advanced Solid Tumors MK-4280 (favezelimab)[2] Hematological Malignancies Non-Small-Cell Lung MK-4280A (favezelimab+pembrolizumab) Renal Cell Small-Cell Lung MK-4830[2] Colorectal Non-Small-Cell Lung Renal Cell Small-Cell Lung MK-5890[3] 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 Hepatocellular Pancreatic Rare cancers Von Hippel-Lindau Disease-Associated Tumors (EU) MK-7119 Tukysa[1] Advanced Solid Tumors Biliary Bladder Cervical Colorectal 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 Endometrial Esophageal Head and Neck Hematological Malignancies Hepatocellular Prostate	**Cancer** MK-7902 Lenvima[1][2] Biliary Glioblastoma Pancreatic Prostate Small-Cell Lung V937 Breast Cutaneous Squamous Cell Head and Neck Melanoma Solid Tumors **Cardiovascular** MK-2060 **Chikungunya Virus Vaccine** V184 **HIV-1 Infection** MK-8591B (islatravir+MK-8507)[4] MK-8591D (islatravir+lenacapavir)[1][4] **Hypercholesterolemia** MK-0616 **Nonalcoholic Steatohepatitis (NASH)** MK-3655 MK-6024 **Overgrowth Syndrome** MK-7075 (miransertib) **Pneumococcal Vaccine Adult** V116 **Pulmonary Arterial Hypertension** MK-5475 **Schizophrenia** MK-8189 **Treatment Resistant Depression** MK-1942

Phase 3 (Phase 3 entry date)	Under Review	
Antiviral COVID-19 MK-4482 *Lagevrio* (U.S.) (May 2021)[1][5] **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) MK-6482 *Welireg*[3] Renal Cell (February 2020) MK-7119 Tukysa[1] Breast (October 2019) MK-7339 Lynparza[1][3] Colorectal (August 2020) 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)[4] **HIV-1 Prevention** MK-8591 (islatravir) (February 2021)[4] **Pulmonary Arterial Hypertension** MK-7962 (sotatercept) (January 2021) **Respiratory Syncytial Virus** MK-1654 (clesrovimab) (November 2021)	**New Molecular Entities/Vaccines** **Antiviral COVID-19** MK-4482 *Lagevrio* (EU)[1] **Cough** MK-7264 (gefapixant) (U.S.)[6] (EU) **Pneumococcal Vaccine Adult** V114 (JPN)	**Certain Supplemental Filings** **Cancer** MK-3475 *Keytruda* • High-Risk Early-Stage Triple-Negative Breast Cancer (KEYNOTE-522) (EU) (JPN) • Adjuvent Treatment of Stage IIB and IIC Melanoma (KEYNOTE-716) (EU) • Cervical Cancer (KEYNOTE-826) (JPN) • Adjuvent Renal Cell Cancer (KEYNOTE-564) (JPN) • Second-Line Hepatocellular Cancer (KEYNOTE-394) (U.S.) MK-7339 Lynparza[1] • *BRCA*-Mutated HER2-Negative Adjuvant Breast Cancer (OlympiA) (EU) (JPN) • First-Line Metastatic Prostate Cancer (PROpel) EU) MK-7902 Lenvima[1][2] • First-Line Metastatic Hepatocellular Carcinoma (KEYNOTE-524) (U.S.)[7]
	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] Available in the U.S. under Emergency Use Authorization. [6] In January 2022, the FDA issued a CRL for this application. Merck is reviewing the CRL and considering next steps. [7] In July 2020, the FDA issued a CRL for Merck's and Eisai's applications. Merck and Eisai intend to submit additional data when available to the FDA.	

Liquidity and Capital Resources

($ in millions)	March 31, 2022	December 31, 2021
Cash and investments	$ 9,244	$ 8,466
Working capital	8,868	6,394
Total debt to total liabilities and equity	29.8 %	31.3 %

Cash provided by operating activities of continuing operations was $4.8 billion in the first three months of 2022 compared with $1.2 billion in the first three months of 2021 reflecting stronger operating performance, including sales of *Lagevrio* for which the related profit sharing payment to Ridgeback will be made in the second quarter of 2022 (see Note 4 to the condensed consolidated financial statements). Cash provided by operating activities from continuing operations in the first three months of 2022 was reduced by $1.2 billion of milestone payments related to collaborations compared with $325 million of milestone and option payments related to collaborations in the first three months of 2021. Cash provided by operating activities from 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, treasury stock purchases and dividends paid to shareholders. 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 expects taxes paid in the U.S. to increase significantly for the full year of 2022.

Cash used in investing activities of continuing operations was $1.2 billion in the first three months of 2022 compared with $686 million in the first three months of 2021. The higher use of cash in investing activities was primarily due to lower proceeds from sales of securities and other investments coupled with higher purchases of securities and other investments, partially offset by lower capital expenditures.

Cash used in financing activities of continuing operations was $3.1 billion in the first three months of 2022 compared with $2.1 billion in the first three months of 2021. The higher use of cash in financing activities was primarily due

to a net increase in short-term borrowings in the prior period compared with no increase in short-term borrowings in the current period, higher dividends paid to stockholders and higher payments on debt (see below).

Capital expenditures totaled $1.0 billion and $1.1 billion for the first three months of 2022 and 2021, respectively.

The Company has accounts receivable factoring agreements with financial institutions in certain countries to sell accounts receivable. The Company factored $2.2 billion and $2.8 billion of accounts receivable at March 31, 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 $1.7 billion and $1.6 billion for the first three months of 2022 and 2021, respectively. In January 2022, the Board of Directors declared a quarterly dividend of $0.69 per share on the Company's stock for the second quarter that was paid in April 2022.

In February 2022, the Company's $1.25 billion, 2.35% 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 three months of 2022. As of March 31, 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 will change beginning in the second quarter of 2022. This change will have 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 March 31, 2022, the Company's disclosure controls and procedures are effective. For the first 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 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, 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 8 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 plans to donate 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 first quarter 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 conflict, 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 March 31, 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]
January 1 - January 31	—	$0.00	—	$5,047
February 1 - February 28	—	$0.00	—	$5,047
March 1 - March 31	—	$0.00	—	$5,047
Total	—	$0.00	—	

[1] *The Company did not purchase any shares during the three months ended March 31, 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: May 5, 2022

/s/ Jennifer Zachary

JENNIFER ZACHARY

Executive Vice President and General Counsel

Date: May 5, 2022

/s/ Rita A. Karachun

RITA A. KARACHUN

Senior Vice President Finance - Global Controller