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 June 30, 2021

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.)

2000 Galloping Hill Road
Kenilworth New Jersey 07033
(Address of principal executive offices) (zip code)

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

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

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

Title of each class	*Trading Symbol(s)*	*Name of each exchange on which registered*
Common Stock ($0.50 par value)	MRK	New York Stock Exchange
1.125% Notes due 2021	MRK/21	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 July 31, 2021: 2,531,374,696

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Sales	$ 11,402	$ 9,353	$ 22,029	$ 19,641
Costs, Expenses and Other				
Cost of sales	3,104	2,747	6,303	5,576
Selling, general and administrative	2,281	2,085	4,468	4,276
Research and development	4,321	2,085	6,732	4,260
Restructuring costs	82	82	380	152
Other (income) expense, net	(103)	(387)	(558)	(325)
	9,685	6,612	17,325	13,939
Income from Continuing Operations Before Taxes	1,717	2,741	4,704	5,702
Taxes on Income from Continuing Operations	503	396	741	891
Net Income from Continuing Operations	1,214	2,345	3,963	4,811
Less: Net Income (Loss) Attributable to Noncontrolling Interests	1	4	5	(1)
Net Income from Continuing Operations Attributable to Merck & Co., Inc.	1,213	2,341	3,958	4,812
Income from Discontinued Operations, Net of Taxes and Amounts Attributable to Noncontrolling Interests	332	661	766	1,409
Net Income Attributable to Merck & Co. Inc.	$ 1,545	$ 3,002	$ 4,724	$ 6,221
Basic Earnings per Common Share Attributable to Merck & Co., Inc. Common Shareholders:				
Income from Continuing Operations	$ 0.48	$ 0.93	$ 1.56	$ 1.90
Income from Discontinued Operations	0.13	0.26	0.30	0.56
Net Income	$ 0.61	$ 1.19	$ 1.87	$ 2.46
Earnings per Common Share Assuming Dilution Attributable to Merck & Co., Inc. Common Shareholders:				
Income from Continuing Operations	$ 0.48	$ 0.92	$ 1.56	$ 1.89
Income from Discontinued Operations	0.13	0.26	0.30	0.55
Net Income	$ 0.61	$ 1.18	$ 1.86	$ 2.45

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Net Income Attributable to Merck & Co., Inc.	$ 1,545	$ 3,002	$ 4,724	$ 6,221
Other Comprehensive Income (Loss) Net of Taxes:				
Net unrealized gain (loss) on derivatives, net of reclassifications	10	(120)	240	(16)
Net unrealized loss on investments, net of reclassifications	—	—	—	(18)
Benefit plan net gain and prior service credit, net of amortization	1,403	39	1,484	99
Cumulative translation adjustment	132	79	(167)	(265)
	1,545	(2)	1,557	(200)
Comprehensive Income Attributable to Merck & Co., Inc.	$ 3,090	$ 3,000	$ 6,281	$ 6,021

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

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

	June 30, 2021	December 31, 2020
Assets		
Current Assets		
Cash and cash equivalents	$ 8,575	$ 8,050
Accounts receivable (net of allowance for doubtful accounts of $72 in 2021 and $67 in 2020)	7,843	6,803
Inventories (excludes inventories of $2,412 in 2021 and $2,070 in 2020 classified in Other assets - see Note 7)	5,499	5,554
Other current assets	6,748	4,674
Current assets of discontinued operations	—	2,683
Total current assets	28,665	27,764
Investments	411	785
Property, Plant and Equipment, at cost, net of accumulated depreciation of $18,236 in 2021 and $18,162 in 2020	18,064	17,000
Goodwill	18,873	18,882
Other Intangibles, Net	13,622	14,101
Other Assets	11,053	9,881
Noncurrent Assets of Discontinued Operations	—	3,175
	$ 90,688	$ 91,588
Liabilities and Equity		
Current Liabilities		
Loans payable and current portion of long-term debt	$ 2,488	$ 6,431
Trade accounts payable	3,897	4,327
Accrued and other current liabilities	12,888	12,212
Income taxes payable	971	1,597
Dividends payable	1,662	1,674
Current liabilities of discontinued operations	—	1,086
Total current liabilities	21,906	27,327
Long-Term Debt	24,033	25,360
Deferred Income Taxes	1,489	1,005
Other Noncurrent Liabilities	9,872	12,306
Noncurrent Liabilities of Discontinued Operations	—	186
Merck & Co., Inc. Stockholders' Equity		
Common stock, $0.50 par value Authorized - 6,500,000,000 shares Issued - 3,577,103,522 shares in 2021 and 2020	1,788	1,788
Other paid-in capital	44,039	39,588
Retained earnings	48,777	47,362
Accumulated other comprehensive loss	(4,628)	(6,634)
	89,976	82,104
Less treasury stock, at cost: 1,044,351,147 shares in 2021 and 1,046,877,695 shares in 2020	56,682	56,787
Total Merck & Co., Inc. stockholders' equity	33,294	25,317
Noncontrolling Interests	94	87
Total equity	33,388	25,404
	$ 90,688	$ 91,588

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

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

	Six Months Ended June 30,	
	2021	2020
Cash Flows from Operating Activities		
Net income from continuing operations	$ 3,963	$ 4,811
Adjustments to reconcile net income from continuing operations to net cash provided by operating activities:		
Amortization	871	988
Depreciation	749	808
Intangible asset impairment charges	—	20
Charge for the acquisition of Pandion Therapeutics, Inc.	1,556	—
Deferred income taxes	29	101
Share-based compensation	243	213
Other	(526)	(204)
Net changes in assets and liabilities	(3,655)	(4,112)
Net Cash Provided by Operating Activities from Continuing Operations	3,230	2,625
Cash Flows from Investing Activities		
Capital expenditures	(2,068)	(1,553)
Purchases of securities and other investments	(1)	(77)
Proceeds from sales of securities and other investments	386	1,892
Acquisition of Pandion Therapeutics, Inc. net of cash acquired	(1,554)	—
Acquisition of ArQule, Inc., net of cash acquired	—	(2,545)
Other acquisitions, net of cash acquired	(90)	(321)
Other	16	194
Net Cash Used in Investing Activities from Continuing Operations	(3,311)	(2,410)
Cash Flows from Financing Activities		
Net change in short-term borrowings	(3,983)	1,967
Payments on debt	(1,153)	(1,952)
Distribution from Organon & Co.	9,000	—
Proceeds from issuance of debt	—	4,445
Purchases of treasury stock	(239)	(1,281)
Dividends paid to stockholders	(3,318)	(3,128)
Proceeds from exercise of stock options	51	40
Other	(194)	(444)
Net Cash Provided by (Used in) Financing Activities from Continuing Operations	164	(353)
Discontinued Operations		
Net cash provided by operating activities	1,051	1,449
Net cash used in investing activities	(134)	(100)
Net cash used in financing activities	(504)	—
Net Cash Flows Provided by Discontinued Operations	413	1,349
Effect of Exchange Rate Changes on Cash, Cash Equivalents and Restricted Cash	(19)	2
Net Increase in Cash, Cash Equivalents and Restricted Cash	477	1,213
Cash, Cash Equivalents and Restricted Cash at Beginning of Year (includes restricted cash of $103 at January 1, 2021 included in Other Assets)	8,153	9,934
Cash, Cash Equivalents and Restricted Cash at End of Period (includes restricted cash of $55 at June 30, 2021 included in Other Assets)	$ 8,630	$ 11,147

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, 2021.

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

Spin-Off of Organon & Co.

On June 2, 2021, Merck completed the spin-off of products from its women's health, biosimilars and established brands businesses into a new, independent, publicly traded company named Organon & Co. (Organon) through a distribution of Organon's publicly traded stock to Company shareholders. The 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 will continue to be owned and developed within Merck as planned. The historical results of the women's health, biosimilars and established brands 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 December 2019, the Financial Accounting Standards Board (FASB) issued amended guidance on the accounting and reporting of income taxes. The guidance is intended to simplify the accounting for income taxes by removing exceptions related to certain intraperiod tax allocations and deferred tax liabilities, clarifying guidance primarily related to evaluating the step-up tax basis for goodwill in a business combination, and reflecting enacted changes in tax laws or rates in the annual effective tax rate. The Company adopted the new guidance effective January 1, 2021. There was no impact to the Company's consolidated financial statements upon adoption.

In January 2020, the FASB issued new guidance intended to clarify certain interactions between accounting standards related to equity securities, equity method investments and certain derivatives. The guidance addresses accounting for the transition into and out of the equity method of accounting and measuring certain purchased options and forward contracts to acquire investments. The Company adopted the new guidance effective January 1, 2021. There was no impact to the Company's consolidated financial statements upon adoption.

Recently Issued Accounting Standard 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 applying GAAP to 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.

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 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 will provide Organon various services and,

similarly, Organon will provide Merck various services. The provision of services under the TSA agreement 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 will continue 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 will continue 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 will (a) manufacture and supply certain active pharmaceutical ingredients for Organon, (b) toll manufacture and supply certain formulated pharmaceutical products for Organon, and (c) package and label certain finished pharmaceutical products for Organon. Similarly, Organon and Merck entered into a number of MSAs pursuant to which Organon will (a) manufacture and supply certain formulated pharmaceutical products for Merck, and (b) package and label 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 agreements were immaterial in the second quarter of 2021. The amount due from Organon under the above agreements was $1.6 billion at June 30, 2021 and is reflected in *Other current assets*. The amount due to Organon under these agreements was $1.0 billion at June 30, 2021 and is 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, as well as interest expense related to the debt issuance in 2021, have been reflected as discontinued operations in the Company's condensed consolidated statement of income as *Income from Discontinued Operations, Net of Taxes and Amounts Attributable to Noncontrolling Interests* through June 2, 2021, the date of the spin-off. Prior periods have been recast to reflect this presentation. As a result of the spin-off of Organon, Merck incurred separation costs of $307 million and $556 million in the three and six months ended June 30, 2021, respectively, and $120 million and $290 million in the three and six months ended June 30, 2020, respectively, 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 system functions, as well as investment banking fees. As of December 31, 2020, the assets and liabilities associated with these businesses are classified as assets and liabilities of discontinued operations in the condensed consolidated balance sheet.

Details of *Income from discontinued operations, net of taxes and amounts attributable to noncontrolling interests* are as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
($ in millions)	2021 [1]	2020	2021 [1]	2020
Sales	$ 1,059	$ 1,519	$ 2,512	$ 3,288
Costs, Expenses and Other				
Cost of sales	318	412	789	895
Selling, general and administrative	431	293	877	657
Research and development	50	38	103	72
Restructuring costs	—	1	1	3
Other (income) expense, net	(23)	(4)	(15)	4
	776	740	1,755	1,631
Income from discontinued operations before taxes	283	779	757	1,657
Tax (benefit) provision	(49)	114	(12)	239
Income from discontinued operations, net of taxes	332	665	769	1,418
Less: Income of discontinued operations attributable to noncontrolling interests	—	4	3	9
Income from discontinued operations, net of taxes and amounts attributable to noncontrolling interests	$ 332	$ 661	$ 766	$ 1,409

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

Details of assets and liabilities of discontinued operations are as follows:

($ in millions)	December 31, 2020
Cash and cash equivalents	$ 12
Accounts receivable, less allowance for doubtful accounts	1,048
Inventories	756
Other current assets	867
Current assets of discontinued operations	$ 2,683
Property, plant and equipment, net	$ 986
Goodwill	1,356
Other intangibles, net	503
Other assets	330
Noncurrent Assets of Discontinued Operations	$ 3,175
Trade accounts payable	$ 267
Accrued and other current liabilities	841
Income taxes payable	(22)
Total current liabilities of discontinued operations	$ 1,086
Deferred income taxes	$ 10
Other noncurrent liabilities	176
Noncurrent Liabilities of Discontinued Operations	$ 186

As a result of the spin-off of Organon, Merck distributed net liabilities of $5.1 billion as of June 2, 2021 consisting of debt of $9.4 billion (described above), goodwill of $1.4 billion, property, plant and equipment of $981 million, cash of $929 million, inventory of $815 million, other intangibles, net, of $519 million and other net liabilities of $328 million. The spin-off also resulted in a net decrease to *Accumulated other comprehensive loss* of $449 million consisting of $421 million for the derecognition of net losses on foreign currency translation adjustments and $28 million associated with employee benefit plans. The distribution of the net liabilities and reduction to *Accumulated other comprehensive loss* resulted in a net $4.6 billion increase to *Other paid-in capital*.

The Company has share-based compensation plans under which the Company grants restricted stock units (RSUs) and performance share units (PSUs) to certain management level employees. In addition, employees and non-employee directors were granted options to purchase shares of Company common stock at the fair market value at the time of grant. In connection with the spin-off of Organon, all outstanding Merck stock options, RSUs and PSUs (whether vested or unvested) were converted into adjusted Merck awards for current and former Merck employees or Organon awards for Organon employees. Such adjusted awards preserved the same intrinsic value and general terms and conditions (including vesting) as were in place immediately prior to the adjustments. Approximately 1.3 million RSUs, 1.9 million stock options and 248 thousand PSUs were converted from Merck awards into Organon awards.

Expenses for curtailments, settlements and termination benefits provided to certain employees were incurred in connection with the spin-off. Additionally, the transfer of employees to Organon triggered remeasurements of some of the Company's pension plans (see Note 11).

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 April 2021, Merck acquired Pandion Therapeutics, Inc. (Pandion), a clinical-stage biotechnology company developing novel therapeutics designed to address the unmet needs of patients living with autoimmune diseases. Pandion is

advancing a pipeline of precision immune modulators targeting critical immune control nodes. Total consideration paid of $1.9 billion included $147 million of transaction costs primarily comprised of share-based compensation payments to settle equity awards. The transaction was accounted for as an acquisition of an asset. Merck recorded net assets of $156 million (primarily cash) and *Research and development* expenses of $1.7 billion in the second quarter and first six months of 2021 related to the transaction. There are no future contingent payments associated with the acquisition.

In March 2021, Merck and Gilead Sciences, Inc. (Gilead) entered into an agreement to jointly develop and commercialize long-acting treatments in HIV that combine Merck's investigational nucleoside reverse transcriptase translocation inhibitor, islatravir, and Gilead's investigational capsid inhibitor, lenacapavir. The collaboration will initially focus on long-acting oral formulations and long-acting injectable formulations of these combination products, with other formulations potentially added to the collaboration as mutually agreed. There was no upfront payment made by either party upon entering into the agreement.

Under the terms of the agreement, Gilead and Merck will share operational responsibilities, as well as development, commercialization and marketing costs, and any future revenues. Global development and commercialization costs will be shared 60% Gilead and 40% Merck across the oral and injectable formulation programs. For long-acting oral products, Gilead will lead commercialization in the U.S. and Merck will lead commercialization in the EU and the rest of the world. For long-acting injectable products, Merck will lead commercialization in the U.S. and Gilead will lead commercialization in the EU and the rest of the world. Gilead and Merck will co-promote in the U.S. and certain other major markets. Merck and Gilead will share global product revenues equally until product revenues surpass certain pre-agreed per formulation revenue tiers. Upon passing $2.0 billion a year in net product sales for the oral combination, the revenue split will adjust to 65% Gilead and 35% Merck for any revenues above the threshold. Upon passing $3.5 billion a year in net product sales for the injectable combination, the revenue split will adjust to 65% Gilead and 35% Merck for any revenues above the threshold.

Beyond the potential combinations of investigational lenacapavir and investigational islatravir, Gilead will have the option to license certain of Merck's investigational oral integrase inhibitors to develop in combination with lenacapavir. Reciprocally, Merck will have the option to license certain of Gilead's investigational oral integrase inhibitors to develop in combination with islatravir. Each company may exercise its option for an investigational oral integrase inhibitor of the other company following completion of the first Phase 1 clinical trial of that integrase inhibitor. Upon exercise of an option, the companies will split development costs and revenues, unless the non-exercising company decides to opt-out.

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 six months of 2021, for license and other rights for the first two collaboration targets and agreed to make another upfront payment of $15 million for license and other rights for the third collaboration target when it is selected by Merck and accepted by Artiva. In addition, Artiva is eligible to receive future contingent milestone payments (which span all three collaboration targets), aggregating up to: $217.5 million in developmental milestones, $570 million in regulatory milestones, and $1.05 billion in sales-based milestones. The agreement also provides for Merck to pay tiered royalties ranging from 7% to 14% on future sales.

In December 2020, Merck acquired OncoImmune, a privately held, clinical-stage biopharmaceutical company, for an upfront payment of $423 million. OncoImmune's lead therapeutic candidate MK-7110 (formerly known as CD24Fc) was being evaluated for the treatment of patients hospitalized with coronavirus disease 2019 (COVID-19). The transaction was accounted for as an acquisition of an asset. Under the agreement, prior to the completion of the acquisition, OncoImmune spun-out certain rights and assets unrelated to the MK-7110 program to a new entity owned by the existing shareholders of OncoImmune. In connection with the closing of the acquisition, Merck invested $50 million for a 20% ownership interest in the new entity, which was valued at $33 million resulting in a $17 million premium. Merck also recognized other net liabilities of $22 million. The Company recorded *Research and development* expenses of $462 million in 2020 related to this transaction. 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 $37 million and $207 million in the second quarter and first six months of 2021, respectively, which are reflected in *Cost of sales* and relate to fixed-asset and materials write-offs, as well as the recognition of liabilities for purchase commitments.

In June 2020, Merck acquired privately held Themis Bioscience GmbH (Themis), a company focused on vaccines (including a COVID-19 vaccine candidate, V591) and immune-modulation therapies for infectious diseases and cancer for $366

million. The acquisition originally provided for Merck to make additional contingent payments of up to $740 million. The transaction was accounted for as an acquisition of a business. The Company determined the fair value of the contingent consideration was $85 million at the acquisition date utilizing a probability-weighted estimated cash flow stream using an appropriate discount rate dependent on the nature and timing of the milestone payments. Merck recognized intangible assets for in-process research and development (IPR&D) of $113 million, cash of $59 million, deferred tax assets of $72 million and other net liabilities of $32 million. The excess of the consideration transferred over the fair value of net assets acquired of $239 million was recorded as goodwill that was allocated to the Pharmaceutical segment and is not deductible for tax purposes. The fair values of the identifiable intangible assets related to IPR&D were determined using an income approach. Actual cash flows are likely to be different than those assumed. In January 2021, the Company announced it was discontinuing development of V591. As a result, in 2020, the Company recorded an IPR&D impairment charge of $90 million within *Research and development* expenses. The Company also recorded a reduction in *Research and development* expenses resulting from a decrease in the related liability for contingent consideration of $45 million since future contingent milestone payments have been reduced to $450 million in the aggregate, including up to $60 million for development milestones, up to $196 million for regulatory approval milestones, and up to $194 million for commercial milestones.

In January 2020, Merck acquired ArQule, Inc. (ArQule), a publicly traded biopharmaceutical company focused on kinase inhibitor discovery and development for the treatment of patients with cancer and other diseases. Total consideration paid of $2.7 billion included $138 million of share-based compensation payments to settle equity awards attributable to precombination service and cash paid for transaction costs on behalf of ArQule. The Company incurred $95 million of transaction costs directly related to the acquisition of ArQule, consisting almost entirely of share-based compensation payments to settle non-vested equity awards attributable to postcombination service. These costs were included in *Selling, general and administrative* expenses in the first six months of 2020. ArQule's lead investigational candidate, MK-1026 (formerly known as ARQ 531), is a novel, oral Bruton's tyrosine kinase (BTK) inhibitor currently being evaluated for the treatment of B-cell malignancies. The transaction was accounted for as an acquisition of a business.

The estimated fair value of assets acquired and liabilities assumed from ArQule is as follows:

($ in millions)		January 16, 2020
Cash and cash equivalents	$	145
IPR&D MK-1026 (formerly ARQ 531) [(1)]		2,280
Licensing arrangement for ARQ 087		80
Deferred income tax liabilities		(361)
Other assets and liabilities, net		34
Total identifiable net assets		2,178
Goodwill [(2)]		512
Consideration transferred	$	2,690

[(1)] The estimated fair value of the identifiable intangible asset related to IPR&D was determined using an income approach. The future net cash flows were discounted to present value utilizing a discount rate of 12.5%. Actual cash flows are likely to be different than those assumed.

[(2)] The goodwill was allocated to the Pharmaceutical segment and is not deductible for tax purposes.

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 2020 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* 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 additional contingent payments from Merck to AstraZeneca related to the successful achievement of sales-based and regulatory milestones. As of June 30, 2021, sales-based milestone payments accrued but not yet paid totaled $400 million. Potential future sales-based milestone payments of $2.7 billion have not yet been accrued as they are not deemed by the Company to be probable at this time. Additionally, potential future regulatory milestone payments of $1.4 billion remain under the agreement.

The intangible asset balance related to Lynparza (which includes capitalized sales-based and regulatory milestone payments) was $1.2 billion at June 30, 2021 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 June 30,		Six Months Ended June 30,	
($ in millions)	2021	2020	2021	2020
Alliance revenue - Lynparza	$ 248	$ 178	$ 475	$ 323
Alliance revenue - Koselugo	8	—	14	—
Total alliance revenue	$ 256	$ 178	$ 489	$ 323
Cost of sales [(1)]	42	137	84	164
Selling, general and administrative	43	39	83	72
Research and development	31	37	60	73

($ in millions)	June 30, 2021	December 31, 2020
Receivables from AstraZeneca included in *Other current assets*	$ 258	$ 215
Payables to AstraZeneca included in *Accrued and other current liabilities* [(2)]	418	423

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

[(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 options rights (of which the final $125 million option payment was made in March 2021). In addition, the agreement provides for additional contingent payments from Merck to Eisai related to the successful achievement of sales-based and regulatory milestones. Merck made sales-based milestone payments of $200 million to Eisai in the first six months of 2021. As of June 30, 2021, sales-based milestone payments accrued but not yet paid totaled $600 million. Potential future sales-based milestone payments of $2.6 billion have not yet been accrued as they are not deemed by the Company to be probable at this time. Additionally, potential future regulatory milestone payments of $125 million remain under the agreement.

The intangible asset balance related to Lenvima (which includes capitalized sales-based and regulatory milestone payments) was $1.0 billion at June 30, 2021 and is included in *Other Intangibles, Net*. The amount is being amortized over its estimated useful life through 2026 as supported by projected future cash flows, subject to impairment testing.

Summarized financial information related to this collaboration is as follows:

($ in millions)	Three Months Ended June 30, 2021	Three Months Ended June 30, 2020	Six Months Ended June 30, 2021	Six Months Ended June 30, 2020
Alliance revenue - Lenvima	$ 181	$ 151	$ 310	$ 279
Cost of sales [1]	47	135	94	170
Selling, general and administrative	31	19	54	31
Research and development	57	56	121	120

($ in millions)	June 30, 2021	December 31, 2020
Receivables from Eisai included in *Other current assets*	$ 212	$ 157
Payables to Eisai included in *Accrued and other current liabilities* [2]	600	335
Payables to Eisai included in *Other Noncurrent Liabilities* [3]	—	600

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

[2] *Includes accrued milestone and future option payments.*

[3] *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 clinical 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 in Bayer's marketing territories, which are product sales net of cost of sales and commercialization costs. In addition, the agreement provides for contingent payments from Merck to Bayer related to the successful achievement of sales-based milestones.

In the first quarter of 2021, following the approval of Verquvo noted above, Merck determined it was probable that sales of Adempas and Verquvo in the future would trigger the remaining $400 million sales-based milestone payment that was outstanding under this agreement. Accordingly, Merck recorded a liability of $400 million and a corresponding increase to the intangible assets related to this collaboration. Merck also recognized $153 million of cumulative amortization expense related to the recognition of this milestone in the first six months of 2021.

The intangible asset balance related to Adempas (which includes the acquired intangible asset balance, as well as capitalized sales-based milestone payments attributed to Adempas) was $920 million at June 30, 2021 and is being amortized over its estimated useful life through 2027 as supported by projected future cash flows, subject to impairment testing. The intangible asset balance related to Verquvo (which reflects the portion of the final sales-based milestone payment that was attributed to Verquvo) was $75 million at June 30, 2021 and is being amortized over its estimated useful life through 2031 as supported by projected future cash flows, subject to impairment testing.

Summarized financial information related to this collaboration is as follows:

($ in millions)	Three Months Ended June 30, 2021	Three Months Ended June 30, 2020	Six Months Ended June 30, 2021	Six Months Ended June 30, 2020
Alliance revenue - Adempas/Verquvo	$ 74	$ 79	$ 149	$ 133
Net sales of Adempas recorded by Merck	74	57	129	113
Net sales of Verquvo recorded by Merck	1	—	1	—
Total sales	$ 149	$ 136	$ 279	$ 246
Cost of sales [1]	39	28	229	57
Selling, general and administrative	32	17	58	28
Research and development	13	16	20	41

($ in millions)	June 30, 2021	December 31, 2020
Receivables from Bayer included in *Other current assets*	$ 65	$ 65
Payables to Bayer included in *Other Noncurrent Liabilities* [2]	400	—

[1] *Includes amortization of intangible assets. Amount in the first six months of 2021 includes $153 million of cumulative amortization as noted above.*

[2] *Represents accrued milestone payment.*

5. Restructuring

In 2019, Merck approved a new 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, builds on prior restructuring programs and does not include any actions associated with the spin-off of Organon. As the Company continues to evaluate its global footprint and overall operating model, it subsequently identified additional actions under the Restructuring Program, and could identify further actions over time. 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 $3.0 billion. The Company estimates that approximately 70% of the cumulative pretax costs will result in cash outlays, primarily related to employee separation expense and facility shut-down costs. Approximately 30% of the cumulative pretax costs will be non-cash, relating primarily to the accelerated depreciation of facilities to be closed or divested.

The Company recorded total pretax costs of $128 million and $149 million in the second quarter of 2021 and 2020, respectively, and $462 million and $315 million for the first six months of 2021 and 2020, respectively, related to restructuring program activities. Since inception of the Restructuring Program through June 30, 2021, Merck has recorded total pretax accumulated costs of approximately $2.3 billion. For the full year of 2021, the Company expects to record charges of approximately $700 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 June 30, 2021				Six Months Ended June 30, 2021			
($ in millions)	Separation Costs	Accelerated Depreciation	Other	Total	Separation Costs	Accelerated Depreciation	Other	Total
Cost of sales	$ —	$ 11	$ 27	$ 38	$ —	$ 21	$ 44	$ 65
Selling, general and administrative	—	2	—	2	—	4	—	4
Research and development	—	6	—	6	—	13	—	13
Restructuring costs	64	—	18	82	293	—	87	380
	$ 64	$ 19	$ 45	$ 128	$ 293	$ 38	$ 131	$ 462

	Three Months Ended June 30, 2020				Six Months Ended June 30, 2020			
($ in millions)	Separation Costs	Accelerated Depreciation	Other	Total	Separation Costs	Accelerated Depreciation	Other	Total
Cost of sales	$ —	$ 31	$ (6)	$ 25	$ —	$ 56	$ 37	$ 93
Selling, general and administrative	—	11	—	11	—	22	—	22
Research and development	—	31	—	31	—	48	—	48
Restructuring costs	35	—	47	82	82	—	70	152
	$ 35	$ 73	$ 41	$ 149	$ 82	$ 126	$ 107	$ 315

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 2021 and 2020 includes asset abandonment, facility shut-down and other related costs, as well as pretax gains and losses resulting from the sales of facilities and related assets. Additionally, other activity includes certain employee-related costs associated with pension and other postretirement benefit plans (see Note 11) and share-based compensation.

The following table summarizes the charges and spending relating to restructuring program activities for the six months ended June 30, 2021:

($ in millions)	Separation Costs	Accelerated Depreciation	Other	Total
Restructuring reserves January 1, 2021	$ 567	$ —	$ 19	$ 586
Expense	293	38	131	462
(Payments) receipts, net	(230)	—	(157)	(387)
Non-cash activity	—	(38)	48	10
Restructuring reserves June 30, 2021 [(1)]	$ 630	$ —	$ 41	$ 671

[(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 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 income* (*AOCI*) 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 and Japanese yen. For exposures in developing country currencies, the Company will enter into forward contracts to partially 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 *AOCI* 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 June 30,		Six Months Ended June 30,		Three Months Ended June 30,		Six Months Ended June 30,	
($ in millions)	2021	2020	2021	2020	2021	2020	2021	2020
Net Investment Hedging Relationships								
Foreign exchange contracts	$ (3)	$ 8	$ (28)	$ 5	$ (4)	$ (4)	$ (8)	$ (11)
Euro-denominated notes	45	72	(122)	21	—	—	—	—

[1] *No amounts were reclassified from AOCI 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 January 2021, five interest rate swaps with a total notional amount of $1.15 billion matured. These swaps effectively converted the Company's $1.15 billion, 3.875% fixed-rate notes due 2021 to variable rate debt. At June 30, 2021, the Company was a party to nine 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.

($ in millions)	June 30, 2021 Par Value of Debt	Number of Interest Rate Swaps Held	Total Swap Notional Amount
2.40% notes due 2022	$ 1,000	4	$ 1,000
2.35% notes due 2022	1,250	5	1,250

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. 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)	June 30, 2021	December 31, 2020	June 30, 2021	December 31, 2020
Loans payable and current portion of long-term debt	$ 1,261	$ 1,150	$ 11	$ —
Long-Term Debt	1,022	2,301	23	53

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:

		June 30, 2021			December 31, 2020		
		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	$ 12	$ —	$ 1,250	$ 1	$ —	$ 1,150
Interest rate swap contracts	Other Assets	24	—	1,000	54	—	2,250
Foreign exchange contracts	Other current assets	156	—	5,970	12	—	3,183
Foreign exchange contracts	Other Assets	49	—	1,601	45	—	2,030
Foreign exchange contracts	Accrued and other current liabilities	—	40	2,850	—	217	5,049
Foreign exchange contracts	Other Noncurrent Liabilities	—	1	84	—	1	52
		$ 241	$ 41	$ 12,755	$ 112	$ 218	$ 13,714
Derivatives Not Designated as Hedging Instruments	*Balance Sheet Caption*						
Foreign exchange contracts	Other current assets	$ 92	$ —	$ 6,981	$ 70	$ —	$ 7,260
Foreign exchange contracts	Accrued and other current liabilities	—	133	9,690	—	307	11,810
		$ 92	$ 133	$ 16,671	$ 70	$ 307	$ 19,070
		$ 333	$ 174	$ 29,426	$ 182	$ 525	$ 32,784

As noted above, the Company records its derivatives on a gross basis in the Condensed Consolidated Balance Sheet. The Company has master netting agreements with several of its financial institution counterparties (see *Concentrations of Credit Risk* below). The following table provides information on the Company's derivative positions subject to these master netting arrangements as if they were presented on a net basis, allowing for the right of offset by counterparty and cash collateral exchanged per the master agreements and related credit support annexes:

	June 30, 2021		December 31, 2020	
($ in millions)	Asset	Liability	Asset	Liability
Gross amounts recognized in the condensed consolidated balance sheet	$ 333	$ 174	$ 182	$ 525
Gross amounts subject to offset in master netting arrangements not offset in the condensed consolidated balance sheet	(152)	(152)	(156)	(156)
Cash collateral received/posted	(13)	—	—	(36)
Net amounts	$ 168	$ 22	$ 26	$ 333

The table below provides information regarding the location and amount of pretax (gains) losses of derivatives designated in fair value or cash flow hedging relationships (including amounts attributable to discontinued operations):

	Sales		Other (income) expense, net [1]		Other comprehensive income (loss)		Sales		Other (income) expense, net		Other comprehensive income (loss)	
	Three Months Ended June 30,		Three Months Ended June 30,		Three Months Ended June 30,		Six Months Ended June 30,		Six Months Ended June 30,		Six Months Ended June 30,	
($ in millions)	2021	2020	2021	2020	2021	2020	2021	2020	2021	2020	2021	2020
Financial Statement Line Items in which Effects of Fair Value or Cash Flow Hedges are Recorded	$ 11,402	$ 9,353	$ (103)	$ (387)	$ 1,545	$ (2)	$ 22,029	$ 19,641	$ (558)	$ (325)	$ 1,557	$ (200)
(Gain) loss on fair value hedging relationships												
Interest rate swap contracts												
Hedged items	—	—	(9)	1	—	—	—	—	(19)	68	—	—
Derivatives designated as hedging instruments	—	—	(1)	(8)	—	—	—	—	—	(76)	—	—
Impact of cash flow hedging relationships												
Foreign exchange contracts												
Amount of gain recognized in *OCI* on derivatives	—	—	—	—	(58)	(109)	—	—	—	—	121	69
(Decrease) increase in *Sales* as a result of *AOCI* reclassifications	(71)	42	—	—	71	(42)	(183)	88	—	—	183	(88)
Interest rate contracts												
Amount of gain recognized in *Other (income) expense, net* on derivatives	—	—	—	(1)	—	—	—	—	(1)	(2)	—	—
Amount of loss recognized in *OCI* on derivatives	—	—	—	—	—	(1)	—	—	—	—	(1)	(2)

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

The table below provides information regarding the income statement effects of derivatives not designated as hedging instruments (including amounts attributable to discontinued operations):

		Amount of Derivative Pretax (Gain) Loss Recognized in Income			
		Three Months Ended June 30,		Six Months Ended June 30,	
($ in millions)		2021	2020	2021	2020
Derivatives Not Designated as Hedging Instruments	*Income Statement Caption*				
Foreign exchange contracts [1]	Other (income) expense, net	$ 167	$ 49	$ 217	$ (131)
Foreign exchange contracts [2]	Sales	14	4	10	(3)
Interest rate contracts [3]	Other (income) expense, net	—	9	—	9

[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. Amounts in 2021 include a loss on forward exchange contracts entered into in conjunction with the spin-off of Organon.*

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

[3] *These derivative contracts serve as economic hedges against rising treasury rates.*

At June 30, 2021, the Company estimates $52 million of pretax net unrealized losses on derivatives maturing within the next 12 months that hedge foreign currency denominated sales over that same period will be reclassified from *AOCI* 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:

	June 30, 2021				December 31, 2020			
	Amortized	Gross Unrealized		Fair	Amortized	Gross Unrealized		Fair
($ in millions)	Cost	Gains	Losses	Value	Cost	Gains	Losses	Value
U.S. government and agency securities	$ 82	$ —	$ —	$ 82	$ 84	$ —	$ —	$ 84
Corporate notes and bonds	4	—	—	4	—	—	—	—
Foreign government bonds	2	—	—	2	5	—	—	5
Total debt securities	$ 88	$ —	$ —	$ 88	$ 89	$ —	$ —	$ 89
Publicly traded equity securities [(1)]				1,579				1,787
Total debt and publicly traded equity securities				$ 1,667				$ 1,876

[(1)] *Unrealized net losses recorded in* Other (income) expense, net *on equity securities still held at June 30, 2021 were $18 million and $199 million in the second quarter and first six months of 2021, respectively. Unrealized net gains recorded in* Other (income) expense, net *on equity securities still held at June 30, 2020 were $464 million and $469 million in the second quarter and first six months of 2020, respectively.*

At June 30, 2021 and June 30, 2020, the Company also had $694 million and $487 million, respectively, of equity investments without readily determinable fair values included in *Other Assets*. The Company recognizes unrealized gains on these equity investments based on favorable observable price changes from transactions involving similar investments of the same investee and recognizes unrealized losses based on unfavorable observable price changes. During the first six months of 2021, the Company recorded unrealized gains of $75 million and unrealized losses of $1 million in *Other (income) expense, net* related to these equity investments held at June 30, 2021. During the first six months of 2020, the Company recorded unrealized gains of $18 million and unrealized losses of $3 million in *Other (income) expense, net* related to these equity investments held at June 30, 2020. Cumulative unrealized gains and cumulative unrealized losses based on observable prices changes for investments in equity investments without readily determinable fair values still held at June 30, 2021 were $244 million and $8 million, 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)	June 30, 2021				December 31, 2020			
Assets								
Investments								
Foreign government bonds	$ —	$ 2	$ —	$ 2	$ —	$ 5	$ —	$ 5
Publicly traded equity securities	409	—	—	409	780	—	—	780
	409	2	—	411	780	5	—	785
Other assets [1]								
U.S. government and agency securities	82	—	—	82	84	—	—	84
Corporate notes and bonds	4	—	—	4	—	—	—	—
Publicly traded equity securities	1,170	—	—	1,170	1,007	—	—	1,007
	1,256	—	—	1,256	1,091	—	—	1,091
Derivative assets [2]								
Forward exchange contracts	—	203	—	203	—	90	—	90
Purchased currency options	—	94	—	94	—	37	—	37
Interest rate swaps	—	36	—	36	—	55	—	55
	—	333	—	333	—	182	—	182
Total assets	$ 1,665	$ 335	$ —	$ 2,000	$ 1,871	$ 187	$ —	$ 2,058
Liabilities								
Other liabilities								
Contingent consideration	$ —	$ —	$ 879	$ 879	$ —	$ —	$ 841	$ 841
Derivative liabilities [2]								
Forward exchange contracts	—	173	—	173	—	505	—	505
Written currency options	—	1	—	1	—	20	—	20
	—	174	—	174	—	525	—	525
Total liabilities	$ —	$ 174	$ 879	$ 1,053	$ —	$ 525	$ 841	$ 1,366

[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 June 30, 2021 and December 31, 2020, *Cash and cash equivalents* included $7.5 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 liabilities for contingent consideration associated with business acquisitions is as follows:

	Six Months Ended June 30,	
($ in millions)	2021	2020
Fair value January 1	$ 841	$ 767
Additions	—	97
Changes in estimated fair value [1]	50	40
Payments	—	(106)
Other	(12)	—
Fair value June 30 [2][3]	$ 879	$ 798

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

[2] Balance at June 30, 2021 includes $297 million recorded as a current liability for amounts expected to be paid within the next 12 months.

[3] At June 30, 2021 and December 31, 2020, $759 million and $711 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 additions to contingent consideration in 2020 relate to the acquisition of Themis (see Note 3). The payments of contingent consideration in 2020 relate to liabilities recorded in connection with the termination of the Sanofi-Pasteur MSD joint venture in 2016.

Other Fair Value Measurements

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

The estimated fair value of loans payable and long-term debt (including current portion) at June 30, 2021, was $29.5 billion compared with a carrying value of $26.5 billion and at December 31, 2020, was $36.0 billion compared with a carrying value of $31.8 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 $2.4 billion and $2.1 billion of accounts receivable at June 30, 2021 and December 31, 2020, respectively, under these factoring arrangements, which reduced outstanding accounts receivable. The cash received from the financial institutions is reported within operating activities in the 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 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 $13 million at June 30, 2021. The obligation to return such collateral is recorded in *Accrued and other current liabilities*. Cash collateral advanced by the Company to counterparties was $36 million at December 31, 2020.

7. Inventories

Inventories consisted of:

($ in millions)	June 30, 2021	December 31, 2020
Finished goods	$ 1,778	$ 1,610
Raw materials and work in process	5,954	5,949
Supplies	175	146
Total (approximates current cost)	7,907	7,705
Decrease to LIFO cost	4	(81)
	$ 7,911	$ 7,624
Recognized as:		
Inventories	$ 5,499	$ 5,554
Other assets	2,412	2,070

Amounts recognized as *Other Assets* are comprised almost entirely of raw materials and work in process inventories. At June 30, 2021 and December 31, 2020, these amounts included $1.7 billion and $1.8 billion, respectively, of inventories not expected to be sold within one year. In addition, these amounts included $681 million and $279 million at June 30, 2021 and December 31, 2020, respectively, of inventories produced in preparation for product launches.

8. Goodwill and Intangibles

In connection with the spin-off of Organon (see Note 2), goodwill was reduced by $1.4 billion. Additionally, other intangibles, on a net basis, were reduced by $519 million, including products and products rights of $394 million and licenses of $125 million.

9. Contingencies

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

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

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

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

Product Liability Litigation

Fosamax

As previously disclosed, Merck is a defendant in product liability lawsuits in the U.S. involving *Fosamax* (*Fosamax* Litigation). As of June 30, 2021, approximately 3,475 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. Briefing on the issue is closed, and the parties await the decision of the District Court.

Discovery is presently stayed in the Femur Fracture MDL and in the state court in California. 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* and/or *Janumet*. As of June 30, 2021, Merck is aware of approximately 1,470 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.

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 June 30, 2021, 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, 2021, 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, the Company's subsidiaries in China have received and may continue to 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* 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 addition, in June 2019, the representatives of the putative direct purchaser class filed an amended complaint, and in August 2019, retailer opt-out plaintiffs filed an amended complaint. In December 2019, the district court granted the Merck Defendants' motion to dismiss to the extent the motion sought dismissal of claims for overcharges paid by entities that purchased generic ezetimibe from Par Pharmaceutical, Inc. (Par Pharmaceutical) and dismissed any claims for such overcharges. 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 and, in November 2020, the U.S. Court of Appeals for the Fourth Circuit granted the Merck Defendants' motion for permission to appeal the district court's order. 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. Also, in August 2020, the magistrate judge recommended that the court grant the motion for class certification filed by the putative indirect purchaser class. The Merck Defendants objected to this report and recommendation and are awaiting a decision from the district court.

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 may hold additional hearings on the other motions. Trial in this matter has been adjourned.

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. 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 July 2021, the California Court ruled on defendants' Motion to Quash for lack of personal jurisdiction, granting the motion as to the out-of-state claims against defendants, and ordering limited jurisdictional discovery with regard to the California claims.

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 United States District Court for the Northern District of California on July 16, 2021.

Also, on July 16, 2021, Humana filed another action against the Merck Defendants in New Jersey in the Bergen County Superior Court, re-asserting the claims that were dismissed in their California action.

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, potentially significant intangible asset impairment charges.

Bridion — 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.

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 two generic companies providing that these generic companies can bring their generic versions of *Bridion* to the market in January 2026 or earlier under certain circumstances.

Januvia, Janumet, Janumet XR — As previously disclosed, the FDA has granted pediatric exclusivity with respect to *Januvia*, *Janumet*, and J*anumet XR*, 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. Including this exclusivity, key patent protection extends to January 2023. The Company anticipates that sales of *Januvia* and *Janumet* in the U.S. will decline significantly after this loss of market exclusivity. 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, which, if determined to be valid, would preclude generic manufacturers from making sitagliptin phosphate salt and polymorphic forms before that patent, inclusive of pediatric exclusivity, expires in 2027 (2027 salt/polymorph patent). In 2019, Par Pharmaceutical filed suit against the Company in the U.S. District Court for the District of New Jersey, seeking a declaratory judgment of invalidity of the 2027 salt/polymorph patent. In response, the Company filed a patent infringement lawsuit in the U.S. District Court for the District of Delaware against Par Pharmaceutical and additional companies that also indicated an intent to market generic versions of *Januvia*, *Janumet*, and *Janumet XR* following expiration of key patent protection, but prior to the expiration of the 2027 salt/

polymorph patent, and a later granted patent owned by the Company covering the *Janumet* formulation which, inclusive of pediatric exclusivity, expires in 2029. The Company also filed a patent infringement lawsuit against Mylan in the Northern District of West Virginia. The Judicial Panel of 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. In February 2021, the Company amended its complaint against Apotex Inc. and Apotex Corp., additional defendants in the patent infringement lawsuits, to add infringement claims related to a patent that expires in 2025 and covers certain processes for manufacturing sitagliptin.

The U.S. District Court for the District of Delaware has scheduled the lawsuits for a single three-day trial on invalidity issues in October 2021. The Court has scheduled separate one-day trials on infringement issues in November 2021 through January 2022, to the extent such trials are necessary. In the Company's case against Mylan, the U.S. District Court for the Northern District of West Virginia has conditionally scheduled a three-day trial in December 2021 on all issues.

The Company has settled with ten generic companies providing that these generic companies can bring their generic versions of *Januvia* and *Janumet* to the market in May 2027 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, which other manufacturers joined. The USPTO instituted IPR proceedings in May 2020, finding a reasonable likelihood that the challenged claims are not valid. Three other generic companies filed similar IPRs, which were joined with Mylan in a single proceeding by the USPTO. A trial was held in February 2021 and a final decision was rendered in May 2021, holding that all of the challenged claims were valid. Mylan and two additional challengers have appealed the USPTO's decision to the United States Court of Appeals for the Federal Circuit.

In Germany, generic companies have sought the revocation of the Supplementary Protection Certificate (SPC) for *Janumet*. If the generic companies are successful, *Janumet* could lose market exclusivity in Germany with expiry of pediatric market exclusivity in September 2022. A hearing was held in June 2021 where the SPC for *Janumet* was nullified, which the Company has appealed. Challenges to the *Janumet* SPC have also occurred in other European countries, including Austria, Czech Republic, Finland, Hungary, Italy, Portugal, and Slovakia.

Other Litigation

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

Legal Defense Reserves

Legal defense costs expected to be incurred in connection with a loss contingency are accrued when probable and reasonably estimable. Some of the significant factors considered in the review of these legal defense reserves are as follows: the actual costs incurred by the Company; the development of the Company's legal defense strategy and structure in light of the scope of its litigation; the number of cases being brought against the Company; the costs and outcomes of completed trials and the most current information regarding anticipated timing, progression, and related costs of pre-trial activities and trials in the associated litigation. The amount of legal defense reserves as of June 30, 2021 and December 31, 2020 of approximately $230 million and $235 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.

10. Equity

	Three Months Ended June 30,								
	Common Stock		Other Paid-In Capital	Retained Earnings	Accumulated Other Comprehensive Loss	Treasury Stock		Non-controlling Interests	Total
($ and shares in millions except per share amounts)	Shares	Par Value				Shares	Cost		
Balance at April 1, 2020	3,577	$ 1,788	$ 39,697	$ 48,272	$ (6,391)	1,053	$ (57,161)	$ 95	$ 26,300
Net income attributable to Merck & Co., Inc.	—	—	—	3,002	—	—	—	—	3,002
Other comprehensive loss, net of taxes	—	—	—	—	(2)	—	—	—	(2)
Cash dividends declared on common stock ($0.61 per share)	—	—	—	(1,550)	—	—	—	—	(1,550)
Share-based compensation plans and other	—	—	(324)	—	—	(5)	311	—	(13)
Net income attributable to noncontrolling interests	—	—	—	—	—	—	—	8	8
Distributions attributable to noncontrolling interests	—	—	—	—	—	—	—	(1)	(1)
Balance at June 30, 2020	3,577	$ 1,788	$ 39,373	$ 49,724	$ (6,393)	1,048	$ (56,850)	$ 102	$ 27,744
Balance at April 1, 2021	3,577	$ 1,788	$ 39,613	$ 48,888	$ (6,622)	1,046	$ (56,722)	$ 94	$ 27,039
Net income attributable to Merck & Co., Inc.	—	—	—	1,545	—	—	—	—	1,545
Other comprehensive income, net of taxes	—	—	—	—	1,545	—	—	—	1,545
Cash dividends declared on common stock ($0.65 per share)	—	—	—	(1,656)	—	—	—	—	(1,656)
Treasury stock shares purchased	—	—	—	—	—	3	(239)	—	(239)
Spin-off of Organon & Co.	—	—	4,643	—	449	—	—	(1)	5,091
Share-based compensation plans and other	—	—	(217)	—	—	(5)	279	—	62
Net income attributable to noncontrolling interests	—	—	—	—	—	—	—	1	1
Balance at June 30, 2021	3,577	$ 1,788	$ 44,039	$ 48,777	$ (4,628)	1,044	$ (56,682)	$ 94	$ 33,388

	Six Months Ended June 30,								
	Common Stock		Other Paid-In Capital	Retained Earnings	Accumulated Other Comprehensive Loss	Treasury Stock		Non-controlling Interests	Total
($ and shares in millions except per share amounts)	Shares	Par Value				Shares	Cost		
Balance at January 1, 2020	3,577	$ 1,788	$ 39,660	$ 46,602	$ (6,193)	1,038	$ (55,950)	$ 94	$ 26,001
Net income attributable to Merck & Co., Inc.	—	—	—	6,221	—	—	—	—	6,221
Other comprehensive loss, net of taxes	—	—	—	—	(200)	—	—	—	(200)
Cash dividends declared on common stock ($1.22 per share)	—	—	—	(3,099)	—	—	—	—	(3,099)
Treasury stock shares purchased	—	—	—	—	—	16	(1,281)	—	(1,281)
Share-based compensation plans and other	—	—	(287)	—	—	(6)	381	—	94
Net income attributable to noncontrolling interests	—	—	—	—	—	—	—	8	8
Balance at June 30, 2020	3,577	$ 1,788	$ 39,373	$ 49,724	$ (6,393)	1,048	$ (56,850)	$ 102	$ 27,744
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.	—	—	—	4,724	—	—	—	—	4,724
Other comprehensive income, net of taxes	—	—	—	—	1,557	—	—	—	1,557
Cash dividends declared on common stock ($1.30 per share)	—	—	—	(3,309)	—	—	—	—	(3,309)
Treasury stock shares purchased	—	—	—	—	—	3	(239)	—	(239)
Spin-off of Organon & Co.	—	—	4,643	—	449	—	—	(1)	5,091
Share-based compensation plans and other	—	—	(192)	—	—	(6)	344	—	152
Net income attributable to noncontrolling interests	—	—	—	—	—	—	—	8	8
Balance at June 30, 2021	3,577	$ 1,788	$ 44,039	$ 48,777	$ (4,628)	1,044	$ (56,682)	$ 94	$ 33,388

11. Pension and Other Postretirement Benefit Plans

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

	Three Months Ended June 30,				Six Months Ended June 30,			
	2021		2020		2021		2020	
($ in millions)	U.S.	International	U.S.	International	U.S.	International	U.S.	International
Service cost	$ 98	$ 87	$ 88	$ 73	$ 198	$ 179	$ 175	$ 146
Interest cost	106	30	109	33	202	59	217	68
Expected return on plan assets	(191)	(104)	(195)	(101)	(379)	(209)	(388)	(205)
Amortization of unrecognized prior service credit	(11)	(4)	(12)	(3)	(20)	(9)	(25)	(6)
Net loss amortization	58	38	76	31	142	78	152	62
Termination benefits	52	2	1	—	53	3	4	1
Curtailments	9	(27)	—	—	16	(27)	2	(1)
Settlements	—	2	9	2	—	2	9	2
	$ 121	$ 24	$ 76	$ 35	$ 212	$ 76	$ 146	$ 67

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 June 30,		Six Months Ended June 30,	
($ in millions)	2021	2020	2021	2020
Service cost	$ 13	$ 13	$ 26	$ 26
Interest cost	11	14	22	29
Expected return on plan assets	(20)	(19)	(39)	(37)
Amortization of unrecognized prior service credit	(25)	(22)	(50)	(45)
Termination benefits	37	—	37	—
Curtailments	(27)	—	(28)	(1)
	$ (11)	$ (14)	$ (32)	$ (28)

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

In connection with restructuring actions (see Note 5), termination charges were recorded on pension plans related to expanded eligibility for certain employees exiting Merck. Also, in connection with these restructuring actions, curtailments and settlements were recorded on pension plans as noted in the table above.

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

The transfer of employees to Organon in connection with the spin-off triggered remeasurements of some of the Company's pension plans. These remeasurements, which were calculated using discount rates and asset values as of the date of the spin-off, resulted in a $1.7 billion reduction to net pension liabilities primarily due to higher discount rates. In addition, $99 million of net pension liabilities were transferred to Organon. The remeasurements and plan transfers also resulted in a related adjustment to *Accumulated Other Comprehensive Income* (see Note 15).

12. Other (Income) Expense, Net

Other (income) expense, net, consisted of:

	Three Months Ended June 30,		Six Months Ended June 30,	
($ in millions)	2021	2020	2021	2020
Interest income	$ (9)	$ (14)	$ (20)	$ (39)
Interest expense	202	209	401	421
Exchange losses	114	24	155	78
Income from investments in equity securities, net [(1)]	(280)	(551)	(854)	(603)
Net periodic defined benefit plan (credit) cost other than service cost	(110)	(80)	(199)	(170)
Other, net	(20)	25	(41)	(12)
	$ (103)	$ (387)	$ (558)	$ (325)

[(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 ownership interests in investment funds are accounted for on a one quarter lag. The Company estimates that gains of approximately $380 million will be recorded in the third quarter of 2021 from ownership interests in investment funds.*

Interest paid for the six months ended June 30, 2021 and 2020 was $363 million and $387 million, respectively.

13. Taxes on Income

The effective income tax rates from continuing operations of 29.3% and 14.4% for the second quarter of 2021 and 2020, respectively, and 15.8% and 15.6% for the first six months of 2021 and 2020, respectively. The effective income tax rates from continuing operations in the second quarter and first six months of 2021 reflect the unfavorable effect of a charge for the acquisition of Pandion for which no tax benefit was recognized. Additionally, the effective income tax rate from continuing operations for the first six months of 2021 reflects a net tax benefit of $207 million related to the settlement of certain federal income tax matters as discussed below.

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

14. Earnings Per Share

The calculations of earnings per share are as follows:

($ and shares in millions except per share amounts)	Three Months Ended June 30, 2021	Three Months Ended June 30, 2020	Six Months Ended June 30, 2021	Six Months Ended June 30, 2020
Net Income from Continuing Operations Attributable to Merck & Co., Inc.	$ 1,213	$ 2,341	$ 3,958	$ 4,812
Income from Discontinued Operations, Net of Taxes and Amounts Attributable to Noncontrolling Interests	332	661	766	1,409
Net Income Attributable to Merck & Co., Inc.	$ 1,545	$ 3,002	$ 4,724	$ 6,221
Average common shares outstanding	2,533	2,527	2,532	2,531
Common shares issuable [(1)]	7	9	8	11
Average common shares outstanding assuming dilution	2,540	2,536	2,540	2,542
Basic Earnings per Common Share Attributable to Merck & Co., Inc. Common Shareholders:				
Income from Continuing Operations	$ 0.48	$ 0.93	$ 1.56	$ 1.90
Income from Discontinued Operations	0.13	0.26	0.30	0.56
Net Income	$ 0.61	$ 1.19	$ 1.87	$ 2.46
Earnings per Common Share Assuming Dilution Attributable to Merck & Co., Inc. Common Shareholders:				
Income from Continuing Operations	$ 0.48	$ 0.92	$ 1.56	$ 1.89
Income from Discontinued Operations	0.13	0.26	0.30	0.55
Net Income	$ 0.61	$ 1.18	$ 1.86	$ 2.45

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

For the second quarter of 2021 and 2020, 12 million and 8 million, respectively, and for the first six months of 2021 and 2020, 11 million and 4 million respectively, of common shares issuable under share-based compensation plans were excluded from the computation of earnings per common share assuming dilution because the effect would have been antidilutive.

15. Other Comprehensive Income (Loss)

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

	Three Months Ended June 30,				
($ in millions)	Derivatives	Investments	Employee Benefit Plans	Foreign Currency Translation Adjustment	Accumulated Other Comprehensive Income (Loss)
Balance April 1, 2020, net of taxes	$ 135	$ —	$ (4,201)	$ (2,325)	$ (6,391)
Other comprehensive income (loss) before reclassification adjustments, pretax	(110)	—	(21)	63	(68)
Tax	23	—	6	16	45
Other comprehensive income (loss) before reclassification adjustments, net of taxes	(87)	—	(15)	79	(23)
Reclassification adjustments, pretax	(42) [1]	—	69 [3]	—	27
Tax	9	—	(15)	—	(6)
Reclassification adjustments, net of taxes	(33)	—	54	—	21
Other comprehensive income (loss), net of taxes	(120)	—	39	79	(2)
Balance June 30, 2020, net of taxes	$ 15	$ —	$ (4,162)	$ (2,246)	$ (6,393)
Balance April 1, 2021, net of taxes	$ (36)	$ —	$ (4,459)	$ (2,127)	$ (6,622)
Other comprehensive income (loss) before reclassification adjustments, pretax	(59)	—	1,767	140	1,848
Tax	13	—	(400)	(8)	(395)
Other comprehensive income (loss) before reclassification adjustments, net of taxes	(46)	—	1,367	132	1,453
Reclassification adjustments, pretax	71 [1]	—	55 [3]	—	126
Tax	(15)	—	(19)	—	(34)
Reclassification adjustments, net of taxes	56	—	36	—	92
Other comprehensive income (loss), net of taxes	10	—	1,403	132	1,545
Spin-off of Organon (see Note 2)	—	—	28	421	449
Balance June 30, 2021, net of taxes	$ (26)	$ —	$ (3,028)	$ (1,574)	$ (4,628)

	Six Months Ended June 30,				
in millions)	Derivatives	Investments	Employee Benefit Plans	Foreign Currency Translation Adjustment	Accumulated Other Comprehensive Income (Loss)
alance January 1, 2020, net of taxes	$ 31	$ 18	$ (4,261)	$ (1,981)	$ (6,193)
Other comprehensive income (loss) before reclassification adjustments, pretax	68	3	(21)	(270)	(220)
Tax	(14)	—	11	5	2
ther comprehensive income (loss) before reclassification adjustments, net of taxes	54	3	(10)	(265)	(218)
Reclassification adjustments, pretax	(89)[1]	(21)[2]	138[3]	—	28
Tax	19	—	(29)	—	(10)
eclassification adjustments, net of taxes	(70)	(21)	109	—	18
ther comprehensive income (loss), net of taxes	(16)	(18)	99	(265)	(200)
alance June 30, 2020, net of taxes	$ 15	$ —	$ (4,162)	$ (2,246)	$ (6,393)
alance January 1, 2021, net of taxes	$ (266)	$ —	$ (4,540)	$ (1,828)	$ (6,634)
Other comprehensive income (loss) before reclassification adjustments, pretax	121	—	1,763	(71)	1,813
Tax	(25)	—	(401)	(96)	(522)
ther comprehensive income (loss) before reclassification adjustments, net of taxes	96	—	1,362	(167)	1,291
Reclassification adjustments, pretax	182[1]	—	142[3]	—	324
Tax	(38)	—	(20)	—	(58)
eclassification adjustments, net of taxes	144	—	122	—	266
ther comprehensive income (loss), net of taxes	240	—	1,484	(167)	1,557
pin-off of Organon (see Note 2)	—	—	28	421	449
alance June 30, 2021, net of taxes	$ (26)	$ —	$ (3,028)	$ (1,574)	$ (4,628)

[1] *Primarily relates to foreign currency cash flow hedges that were reclassified from* AOCI *to* Sales.
[2] *Represents net realized (gains) losses on the sales of available-for-sale debt securities that were reclassified from* AOCI *to* Other (income) expense, net.
[3] *Includes net amortization of prior service cost and actuarial gains and losses included in net periodic benefit cost (see Note 11).*

16. Segment Reporting

The Company's operations are principally managed on a products 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, primarily administered at physician offices. 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.

The Company previously had a Healthcare Services segment that provided services and solutions focused on engagement, health analytics and clinical services to improve the value of care delivered to patients. The Company divested the remaining businesses in this segment during the first quarter of 2020.

Sales of the Company's products were as follows:

	Three Months Ended June 30,						Six Months Ended June 30,					
	2021			2020			2021			2020		
($ in millions)	U.S.	Int'l	Total	U.S.	Int'l	Total	U.S.	Int'l	Total	U.S.	Int'l	Total
Pharmaceutical:												
Oncology												
Keytruda	$ 2,347	$ 1,829	$ 4,176	$ 2,043	$ 1,345	$ 3,388	$ 4,528	$ 3,548	$ 8,076	$ 3,949	$ 2,722	$ 6,672
Alliance revenue - Lynparza [1]	124	124	248	105	73	178	242	233	475	190	133	323
Alliance revenue - Lenvima [1]	88	93	181	98	53	151	173	137	310	188	91	279
Vaccines												
Gardasil/Gardasil 9	454	781	1,234	168	488	656	766	1,385	2,151	629	1,124	1,753
ProQuad/M-M-R II/*Varivax*	386	130	516	263	115	378	718	246	965	596	217	813
RotaTeq	111	97	208	100	68	168	229	137	366	241	150	391
Pneumovax 23	100	52	152	21	96	117	173	150	323	203	170	373
Vaqta	22	34	56	17	11	28	47	43	90	47	41	88
Hospital Acute Care												
Bridion	197	190	387	107	117	224	364	363	727	250	274	524
Prevymis	37	56	93	28	35	63	72	103	174	55	68	123
Noxafil	14	52	66	6	67	73	29	104	133	14	154	168
Primaxin	—	60	60	1	63	64	—	125	125	1	114	115
Cancidas	1	53	54	(2)	45	43	3	108	111	1	98	98
Invanz	(4)	52	48	—	43	43	—	104	104	6	102	108
Zerbaxa	(2)	1	(1)	17	15	32	(4)	(5)	(9)	37	32	69
Immunology												
Simponi	—	202	202	—	191	191	—	416	416	—	406	406
Remicade	—	75	75	—	73	73	—	160	160	—	160	160
Neuroscience												
Belsomra	14	63	78	22	61	84	32	125	157	49	114	163
Virology												
Isentress/Isentress HD	74	118	192	76	120	196	145	256	401	151	290	441
Cardiovascular												
Alliance revenue-Adempas/Verquvo [2]	81	(7)	74	73	6	79	149	—	149	122	11	133
Adempas	—	74	74	—	57	57	—	129	129	—	113	113
Diabetes												
Januvia	284	500	784	413	441	854	632	961	1,593	768	860	1,628
Janumet	74	403	477	143	348	490	158	805	962	256	737	993
Other pharmaceutical [3]	245	301	546	259	289	548	485	644	1,130	513	637	1,149
Total Pharmaceutical segment sales	4,647	5,333	9,980	3,958	4,220	8,178	8,941	10,277	19,218	8,266	8,818	17,083
Animal Health:												
Livestock	161	659	821	122	526	648	318	1,322	1,640	284	1,102	1,386
Companion Animals	298	353	651	220	233	453	578	672	1,250	442	486	928
Total Animal Health segment sales	459	1,012	1,472	342	759	1,101	896	1,994	2,890	726	1,588	2,314
Other segment sales [4]	—	—	—	—	—	—	—	—	—	23	—	23
Total segment sales	5,106	6,345	11,452	4,300	4,979	9,279	9,837	12,271	22,108	9,015	10,406	19,420
Other [5]	(6)	(44)	(50)	22	52	74	53	(132)	(79)	38	182	221
	$ 5,100	$ 6,301	$ 11,402	$ 4,322	$ 5,031	$ 9,353	$ 9,890	$ 12,139	$ 22,029	$ 9,053	$ 10,588	$ 19,641

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

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

[2] 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).

[3] Other pharmaceutical primarily reflects sales of other human health pharmaceutical products, including products within the franchises not listed separately.

[4] Represents sales for the Healthcare Services segment. All the businesses in the Healthcare Services segment were fully divested in the first quarter of 2020.

[5] Other is primarily comprised of miscellaneous corporate revenues, including revenue hedging activities, as well as third-party manufacturing sales.

Product sales are recorded net of the provision for discounts, including chargebacks, which are customer discounts that occur when a contracted customer purchases through an intermediary wholesale purchaser, and rebates that are owed based upon definitive contractual agreements or legal requirements with private sector and public sector (Medicaid and Medicare Part D) benefit providers, after the final dispensing of the product by a pharmacy to a benefit plan participant. These discounts, in the aggregate, reduced U.S. sales by $3.1 billion and $2.6 billion for the three months ended June 30, 2021 and 2020, respectively, and $6.0 billion and $5.4 billion for the six months ended June 30, 2021 and 2020, respectively.

Consolidated sales by geographic area where derived are as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
($ in millions)	2021	2020	2021	2020
United States	$ 5,100	$ 4,322	$ 9,890	$ 9,053
Europe, Middle East and Africa	3,333	2,622	6,569	5,591
China	975	623	1,697	1,269
Japan	661	621	1,291	1,204
Asia Pacific (other than China and Japan)	594	489	1,168	1,015
Latin America	532	423	1,032	875
Other	207	253	382	634
	$ 11,402	$ 9,353	$ 22,029	$ 19,641

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

	Three Months Ended June 30,		Six Months Ended June 30,	
($ in millions)	2021	2020	2021	2020
Segment profits:				
Pharmaceutical segment	$ 7,257	$ 5,832	$ 13,845	$ 12,209
Animal Health segment	552	408	1,124	887
Other segment	—	—	—	2
Total segment profits	7,809	6,240	14,969	13,098
Other profits	(79)	43	(113)	163
Unallocated:				
Interest income	9	14	20	39
Interest expense	(202)	(209)	(401)	(421)
Amortization	(357)	(599)	(871)	(988)
Depreciation	(332)	(367)	(673)	(733)
Research and development	(4,175)	(1,956)	(6,480)	(4,020)
Restructuring costs	(82)	(82)	(380)	(152)
Other unallocated, net	(874)	(343)	(1,367)	(1,284)
	$ 1,717	$ 2,741	$ 4,704	$ 5,702

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 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 will continue to be owned and developed within Merck as planned. The historical results of the women's health, biosimilars and established brands 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

Business Developments

Below is a summary of significant business development activity thus far in 2021. See Note 3 to the condensed consolidated financial statements for additional information.

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 six months of 2021, for license and other rights for the first two collaboration targets and agreed to make another upfront payment of $15 million for license and other rights for the third collaboration target when it is selected by Merck and accepted by Artiva. In addition, Artiva is eligible to receive future contingent milestone payments and tiered royalties on future sales.

In March 2021, Merck and Gilead Sciences, Inc. (Gilead) entered into an agreement to jointly develop and commercialize long-acting treatments in HIV that combine Merck's investigational nucleoside reverse transcriptase translocation inhibitor, islatravir, and Gilead's investigational capsid inhibitor, lenacapavir. The collaboration will initially focus on long-acting oral formulations and long-acting injectable formulations of these combination products, with other formulations potentially added to the collaboration as mutually agreed. There was no upfront payment made by either party upon entering into the agreement.

In April 2021, Merck acquired Pandion Therapeutics, Inc. (Pandion), a clinical-stage biotechnology company developing novel therapeutics designed to address the unmet needs of patients living with autoimmune diseases, for total consideration of $1.9 billion. Pandion is advancing a pipeline of precision immune modulators targeting critical immune control nodes.

Coronavirus Disease 2019 (COVID-19) Update

Overall, in response to the COVID-19 pandemic, Merck is focused on protecting the safety of its employees, ensuring that its supply of medicines and vaccines reaches its patients, contributing its scientific expertise to the development of an antiviral therapy, supporting efforts to expand manufacturing capacity and supply of SARS-CoV-2/COVID-19 medicines and vaccines (see below), and supporting health care providers and Merck's communities. Although COVID-19-related disruptions negatively affected results for the second quarter and first six months of 2021, Merck continues to experience strong global underlying demand across its business.

In the second quarter and first six months of 2021, the estimated negative impact of the COVID-19 pandemic to Merck's Pharmaceutical sales was approximately $400 million and $1.0 billion, respectively. There was no impact to Animal Health sales. In the second quarter of 2020, the estimated negative impact of the COVID-19 pandemic to Merck's sales was $1.4 billion, including approximately $1.3 billion for Pharmaceutical revenue and $100 million for Animal Health revenue. The impact to sales in the first quarter of 2020 was immaterial. Roughly 75% of Merck's Pharmaceutical segment revenue is comprised of physician-administered products, which, despite strong underlying demand, have been affected by social distancing measures and fewer well visits.

In April 2021, Merck announced it was discontinuing the development of MK-7110 (formerly known as CD24Fc) for the treatment of hospitalized patients with COVID-19 (see Note 3 to the condensed consolidated financial statements). This decision resulted in charges of $37 million and $207 million to *Cost of sales* in the second quarter and first six months of 2021, respectively.

Operating expenses reflect a minor positive effect in the second quarter and first six months of 2021 as investments in COVID-19-related research programs largely offset the favorable impact of lower spending in other areas due to the COVID-19 pandemic. Operating expenses were positively affected in the second quarter and first six months of 2020 by approximately $300 million and $400 million, respectively, primarily driven by lower promotional and selling costs, as well as lower research and development expenses due to the COVID-19 pandemic.

Merck continues to believe that global health systems and patients have largely adapted to the impacts of the COVID-19 pandemic, and that while certain negative impacts will persist, the trend will continue to improve. For the full year of 2021, Merck assumes a net unfavorable impact to sales of less than 3% due to the COVID-19 pandemic, all of which relates to the Pharmaceutical segment. In addition, for the full year of 2021, Merck expects a negligible impact to operating expenses, as spending on the development of its COVID-19 antiviral program, molnupiravir, is expected to offset the favorable impact of lower spending in other areas due to the COVID-19 pandemic.

In June 2021, Merck announced a procurement agreement with the U.S. government for molnupiravir (MK-4482/EIDD-2801). Molnupiravir is currently being evaluated in a Phase 3 clinical trial, the MOVe-OUT study, for the treatment of non-hospitalized patients with laboratory-confirmed COVID-19 and at least one risk factor associated with poor disease outcomes. Merck has also initiated a clinical program to evaluate molnupiravir for post-exposure prophylaxis. Through the agreement, if molnupiravir receives Emergency Use Authorization or approval by the U.S. Food and Drug Administration (FDA), Merck will receive approximately $1.2 billion to supply approximately 1.7 million courses of molnupiravir to the U.S. government. This procurement of molnupiravir will be supported in whole or in part with federal funds. Merck has been investing at risk to support development and scale-up production of molnupiravir and expects to have more than 10 million courses of therapy available by the end of 2021. Merck also plans to submit applications for emergency use or approval to regulatory bodies outside of the U.S. and is currently in discussions with other countries interested in advance purchase agreements for molnupiravir. Merck is committed to providing timely access to molnupiravir globally and intends to implement a tiered pricing approach based on World Bank data that recognizes countries' relative ability to finance their public health response to the pandemic. As part of its access strategy, Merck has also entered into non-exclusive voluntary licensing agreements for molnupiravir with established generic manufacturers to accelerate availability of molnupiravir in low- and middle-income countries following approvals or emergency authorization by local regulatory agencies. Merck is developing molnupiravir in collaboration with Ridgeback Biotherapeutics LP (Ridgeback Bio). If approved, Merck will be the principal on sales transactions, recognizing sales and related costs, with profit sharing amounts recorded within *Cost of sales*. Profits from the collaboration will be split equally between the partners.

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, will provide Merck with funding to adapt and make available a number of existing manufacturing facilities for the production of SARS-CoV-2/COVID-19 vaccines and medicines. Merck has also entered into agreements to support the manufacturing and supply of Johnson & Johnson's SARS-CoV-2/COVID-19 vaccine. Merck will use 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 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 six months of 2021 was negatively affected by other cost-reduction measures taken by governments and other third-parties to lower health care costs. The Company anticipates all of these actions and additional actions in the future will continue to negatively affect sales performance.

Operating Results

Sales

($ in millions)	Three Months Ended June 30, 2021	2020	% Change	% Change Excluding Foreign Exchange	Six Months Ended June 30, 2021	2020	% Change	% Change Excluding Foreign Exchange
United States	$ 5,100	$ 4,322	18 %	18 %	$ 9,890	$ 9,053	9 %	9 %
International	6,301	5,031	25 %	20 %	12,139	10,588	15 %	11 %
Total	$ 11,402	$ 9,353	22 %	19 %	$ 22,029	$ 19,641	12 %	10 %

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

Worldwide sales grew 22% to $11.4 billion in the second quarter of 2021 and rose 12% to $22.0 billion in the first six months of 2021. Revenue performance in both periods reflects higher sales in the oncology franchise primarily driven by strong growth of *Keytruda* (pembrolizumab) and increased alliance revenue from Lynparza (olaparib), as well as higher sales of vaccines, including *Gardasil* 9 (Human Papillomavirus 9-valent Vaccine, Recombinant), *Varivax* (Varicella Virus Vaccine Live) and *ProQuad* (Measles, Mumps, Rubella and Varicella Virus Vaccine Live). Higher sales of certain hospital acute care products, including *Bridion* (sugammadex) Injection and *Prevymis* (letermovir), as well as higher sales of Animal Health products also drove revenue growth in the second quarter and first six months of 2021. As discussed above, the COVID-19 pandemic unfavorably affected sales in the second quarter and first six months of 2021, but to a lesser extent than in the comparable periods of 2020, which benefited year-over-year sales growth.

Revenue growth in both periods was partially offset by lower sales of diabetes products *Januvia* (sitagliptin) and *Janumet* (sitagliptin/metformin HCl), as well as lower sales of hospital acute care product *Zerbaxa* (ceftolozane and tazobactam) for injection.

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

Pharmaceutical Segment

Oncology

($ in millions)	Three Months Ended June 30, 2021	2020	% Change	% Change Excluding Foreign Exchange	Six Months Ended June 30, 2021	2020	% Change	% Change Excluding Foreign Exchange
Keytruda	$ 4,176	$ 3,388	23 %	20 %	$ 8,076	$ 6,672	21 %	18 %
Alliance Revenue - Lynparza [(1)]	248	178	39 %	34 %	475	323	47 %	42 %
Alliance Revenue - Lenvima [(1)]	181	151	19 %	15 %	310	279	11 %	8 %

[(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 (cHL), cutaneous squamous cell carcinoma (cSCC), esophageal cancer, gastric or gastroesophageal junction adenocarcinoma, 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 including MSI-H/dMMR colorectal cancer, primary mediastinal large B-cell lymphoma, tumor mutational burden-high solid tumors, and urothelial carcinoma including non-muscle invasive bladder cancer. *Keytruda* is also approved for the treatment of certain patients in combination with chemotherapy for metastatic squamous and nonsquamous NSCLC, in combination with chemotherapy for esophageal cancer, in combination with chemotherapy for gastric cancer, in combination with chemotherapy for HNSCC, in combination with chemotherapy for triple-negative-breast cancer (TNBC), in combination with axitinib for renal cell carcinoma (RCC), and in combination with Lenvima for endometrial carcinoma. The *Keytruda* clinical development program includes studies across a broad range of cancer types. See "Research and Development Update" below.

Global sales of *Keytruda* grew 23% and 21% in the second quarter and first six months of 2021, respectively. Sales growth in both periods was driven by higher demand as the Company continues to launch *Keytruda* with multiple new indications globally, although the COVID-19 pandemic had a dampening effect on growing demand negatively affecting the number of new patients starting treatment. 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 uptake in the RCC, adjuvant melanoma, HNSCC, bladder cancer and endometrial carcinoma indications. *Keytruda* sales growth in international markets was driven by continued uptake in

approved indications, particularly in Europe. Sales growth in the second quarter and first six months of 2021 was partially offset by lower pricing in Europe and, for the year-to-date period, also in Japan.

In March 2021, the FDA approved *Keytruda* for the treatment of certain patients with locally advanced or metastatic esophageal or gastroesophageal junction carcinoma that is not amenable to surgical resection or definitive chemoradiation in combination with chemotherapy. The approval was based on the results of the KEYNOTE-590 trial.

In May 2021, the FDA approved *Keytruda* in combination with chemotherapy for the first-line treatment of patients with locally advanced unresectable or metastatic human epidermal growth factor receptor 2 (HER2) positive gastric or gastroesophageal junction adenocarcinoma based on the results of the KEYNOTE-811 trial. This indication is approved under accelerated approval based on tumor response rate and durability of response; continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials.

In July 2021, the FDA approved *Keytruda* for the treatment of 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, based on the KEYNOTE-522 trial. Additionally, the FDA converted the accelerated approval of *Keytruda* in combination with chemotherapy for the treatment of patients with locally recurrent unresectable or metastatic TNBC whose tumors express PD-L1 that was originally granted in 2020 to a full (regular) approval based on confirmatory data from KEYNOTE-522.

Also in July 2021, the FDA approved *Keytruda* as monotherapy for the treatment of patients with locally advanced cSCC that is not curable by surgery or radiation based on data from the KEYNOTE-629 trial.

Additionally, in July 2021, the FDA approved the combination of *Keytruda* plus Lenvima (lenvatinib) for the treatment of patients with advanced endometrial carcinoma that is not MSI-H or dMMR, who have disease progression following prior systemic therapy in any setting and are not candidates for curative surgery or radiation. The approval for this population is based on results from the KEYNOTE-775/Study 309 trial, which was the confirmatory trial for the accelerated approval by the FDA in 2019.

In March 2021, Merck announced it was voluntarily withdrawing the U.S. indication for *Keytruda* for the treatment of patients with metastatic SCLC with disease progression on or after platinum-based chemotherapy and at least one other prior line of therapy. The withdrawal of this indication was done in consultation with the FDA and does not affect other indications for *Keytruda*. Accelerated approval for this indication was granted in 2019 and was contingent upon completion of the post-marketing requirement establishing superiority of *Keytruda* as determined by overall survival (OS). As announced in January 2020, KEYNOTE-604, the confirmatory Phase 3 trial for this indication, met one of its dual primary endpoints of progression-free survival (PFS) but did not reach statistical significance for the other primary endpoint of OS.

In July 2021, Merck announced that it plans to voluntarily withdraw the U.S. accelerated approval indication for *Keytruda* for the treatment of patients with recurrent locally advanced or metastatic gastric or gastroesophageal junction adenocarcinoma whose tumors express PD-L1, with disease progression on or after two or more prior lines of therapy. The decision was made in consultation with the FDA following the Oncologic Drugs Advisory Committee evaluation of this third-line gastric cancer indication for *Keytruda* as a monotherapy because it failed to meet its post-marketing requirement of demonstrating an OS benefit in a Phase 3 study. The withdrawal of this indication was done in consultation with the FDA and does not affect other indications for *Keytruda*. As agreed with the FDA, Merck will initiate the withdrawal in January 2022.

In January 2021, *Keytruda* was approved by the European Commission (EC) as a first-line treatment in adult patients with MSI-H or dMMR colorectal cancer based on the results of the KEYNOTE-177 study.

In March 2021, the EC approved an expanded label for *Keytruda* as monotherapy for the treatment of adult and pediatric patients aged 3 years and older with relapsed or refractory cHL who have failed autologous stem cell transplant (ASCT) or following at least two prior therapies when ASCT is not a treatment option. This approval is based on results from the KEYNOTE-204 and KEYNOTE-087 trials. This is the first pediatric approval for *Keytruda* in the European Union (EU).

In May 2021, the EC approved the addition of the 400 mg every six weeks (Q6W) dosing regimen to indications where *Keytruda* is administered in combination with other anticancer agents.

Also in May 2021, the EC approved an update to the European label for *Keytruda* to include data from KEYNOTE-361. In the EU, *Keytruda* is approved for the treatment of adult patients with advanced or metastatic urothelial carcinoma (bladder cancer) who are not eligible for cisplatin-containing chemotherapy and whose tumors express PD-L1. This approval was based on KEYNOTE-052; KEYNOTE-361 was conducted as part of a post-marketing commitment following the initial approval of *Keytruda* for these patients.

In June 2021, the EC approved *Keytruda* in combination with chemotherapy for the first-line treatment of patients with locally advanced unresectable or metastatic carcinoma of the esophagus or HER2-negative gastroesophageal junction adenocarcinoma in adults whose tumors express PD-L1. This approval was based on results from the KEYNOTE-590 trial.

Lynparza is an oral poly (ADP-ribose) polymerase (PARP) inhibitor being developed as part of a collaboration with AstraZeneca PLC (AstraZeneca) (see Note 4 to the condensed consolidated financial statements). Lynparza is approved for the treatment of certain types of advanced ovarian, breast, pancreatic and prostate cancers. Alliance revenue related to Lynparza increased 39% and 47% in the second quarter and first six months of 2021, respectively. Sales growth was largely driven by continued uptake across the multiple approved indications in the U.S., Europe and China. In June 2021, Lynparza was granted conditional approval in China as monotherapy for the treatment of certain adult patients with germline or somatic *BRCA*-mutated metastatic castration-resistant prostate cancer based on the results of the PROfound 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, HCC, in combination with everolimus for certain patients with RCC, and in combination with *Keytruda* for the treatment of certain patients with endometrial carcinoma. Alliance revenue related to Lenvima grew 19% and 11% in the second quarter and first six months of 2021, respectively. Sales growth in both periods reflects higher demand in China.

In June 2021, Koselugo (selumetinib) was approved in the EU for the treatment of pediatric patients two years of age and older with neurofibromatosis type 1 who have symptomatic, inoperable plexiform neurofibromas based on positive results from the National Cancer Institute Cancer Therapy Evaluation Program-sponsored SPRINT Stratum 1 trial. Koselugo was approved by the FDA in April 2020. Koselugo is part of the same collaboration with AstraZeneca referenced above that includes Lynparza

Vaccines

($ in millions)	Three Months Ended June 30, 2021	2020	% Change	% Change Excluding Foreign Exchange	Six Months Ended June 30, 2021	2020	% Change	% Change Excluding Foreign Exchange
Gardasil/Gardasil 9	$ 1,234	$ 656	88 %	78 %	$ 2,151	$ 1,753	23 %	17 %
ProQuad	189	133	42 %	40 %	354	290	22 %	20 %
M-M-R II	87	72	22 %	19 %	167	172	(3)%	(4) %
Varivax	240	173	38 %	37 %	444	352	26 %	25 %
RotaTeq	208	168	23 %	19 %	366	391	(6)%	(8) %
Pneumovax 23	152	117	30 %	27 %	323	373	(13)%	(16) %
Vaqta	56	28	101 %	96 %	90	88	2 %	— %

Worldwide sales of *Gardasil* (Human Papillomavirus Quadrivalent [Types 6, 11, 16 and 18] Vaccine, Recombinant)*/Gardasil* 9, vaccines to help prevent certain cancers and other diseases caused by certain types of human papillomavirus (HPV), grew 88% and 23% in the second quarter and first six months of 2021, respectively. Sales growth in both periods was driven primarily by the ongoing COVID-19 pandemic recovery and strong underlying demand in the U.S., as well as continued uptake in certain ex-U.S. markets, including China which also benefited from increased supply. Higher pricing in China and the U.S. also contributed to sales growth in both periods.

Global sales of *ProQuad*, a pediatric combination vaccine to help protect against measles, mumps, rubella and varicella, grew 42% and 22% in the second quarter and first six months of 2021, respectively, primarily due to higher sales in the U.S. reflecting higher demand driven by the ongoing COVID-19 pandemic recovery, as well as higher pricing.

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 22% in the second quarter of 2021 primarily due to higher sales in the U.S. as demand continues to recover from the unfavorable effects of the COVID-19 pandemic. Global sales of *M-M-R* II declined 3% in the first six months of 2021 reflecting declines in international markets that were largely offset by higher demand in the U.S.

Global sales of *Varivax*, a vaccine to help prevent chickenpox (varicella), grew 38% and 26% in the second quarter and first six months of 2021, respectively, reflecting the ongoing COVID-19 pandemic recovery and higher pricing in the U.S., as well as the timing of government tenders in Brazil.

Global sales of *RotaTeq* (Rotavirus Vaccine, Live Oral, Pentavalent), a vaccine to help protect against rotavirus gastroenteritis in infants and children, grew 23% in the second quarter of 2021 largely attributable to the timing of shipments in China and the ongoing COVID-19 pandemic recovery in the U.S. that resulted in higher demand. Worldwide sales of *RotaTeq* declined 6% in the first six months of 2021 reflecting lower demand in the U.S. and certain international markets.

Worldwide sales of *Pneumovax* 23 (pneumococcal vaccine polyvalent), a vaccine to help prevent pneumococcal disease, grew 30% in the second quarter of 2021 primarily driven by higher sales in the U.S. reflecting higher pricing and higher volumes as demand continues to recover from the unfavorable effects of the COVID-19 pandemic. Sales growth in the second quarter of 2021 was partially offset by lower demand in Europe as heightened awareness of pneumococcal vaccination

in the prior year drove higher volumes in the second quarter of 2020. Global sales of *Pneumovax* 23 declined 13% in the first six months of 2021 primarily driven by lower demand in the U.S. and Europe attributable to the COVID-19 pandemic, partially offset by higher sales in China reflecting the timing of shipments.

Worldwide sales of *Vaqta* (hepatitis A vaccine, inactivated), a vaccine indicated for the prevention of disease caused by hepatitis A virus, doubled in the second quarter of 2021 primarily reflecting higher volumes in Latin America, China and the U.S. as demand continues to recover from the unfavorable effects of the COVID-19 pandemic. Global sales of *Vaqta* were nearly flat in the first six months of 2021 reflecting higher demand in Latin America and China that was largely offset by lower government tenders in Turkey.

In July 2021, the FDA approved *Vaxneuvance* (Pneumococcal 15-valent Conjugate Vaccine) for active immunization for the prevention of invasive disease caused by 15 *Streptococcus pneumoniae* serotypes in adults 18 years of age and older. The approval was based on data from seven clinical studies assessing safety, tolerability, and immunogenicity in adults. The U.S. Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) is expected to meet in October 2021 to discuss and make recommendations on the use of *Vaxneuvance* in adults. The Company is involved in litigation challenging the validity of several Pfizer Inc. (Pfizer) patents that relate to pneumococcal vaccine technology in the U.S. and several foreign jurisdictions. The resolution of this litigation may result in the payment of royalties or other financial consideration to Pfizer.

Vaxelis (Diphtheria and Tetanus Toxoids and Acellular Pertussis, Inactivated Poliovirus, Haemophilus b Conjugate and Hepatitis B Vaccine), developed as part of a U.S.-based partnership between Merck and Sanofi Pasteur, is now available in the U.S. for active immunization of children six weeks through four years of age to help prevent diphtheria, tetanus, pertussis, poliomyelitis, hepatitis B, and invasive disease due to *Haemophilus influenzae* type b. In February 2021, the CDC's ACIP included *Vaxelis* as a combination vaccine option in the CDC's Recommended Child and Adolescent Immunization Schedule. Sales of *Vaxelis* in the U.S. are made through the U.S.-based Merck/Sanofi Pasteur partnership, the results of which are reflected in equity income from affiliates included in *Other (income) expense, net.* Supply sales to the partnership are recorded within *Sales*. *Vaxelis* is also approved in the EU where it is marketed directly by Merck and Sanofi Pasteur.

Hospital Acute Care

	Three Months Ended June 30,			% Change Excluding Foreign	Six Months Ended June 30,			% Change Excluding Foreign
($ in millions)	2021	2020	% Change	Exchange	2021	2020	% Change	Exchange
Bridion	$ 387	$ 224	72 %	67 %	$ 727	$ 524	39 %	35 %
Prevymis	93	63	47 %	41 %	174	123	42 %	36 %
Noxafil	66	73	(10)%	(14)%	133	168	(21)%	(24)%
Zerbaxa	(1)	32	(104)%	(104)%	(9)	69	(113)%	(113)%

Worldwide sales of *Bridion*, for the reversal of two types of neuromuscular blocking agents used during surgery, grew 72% and 39% in the second quarter and first six months of 2021, respectively, due to higher demand globally, particularly in the U.S. and Europe, attributable in part to the COVID-19 pandemic. *Bridion* was approved by the FDA in June 2021 for pediatric patients aged 2 years and older undergoing surgery.

Worldwide sales of *Prevymis*, a medicine for prophylaxis (prevention) of cytomegalovirus (CMV) infection and disease in adult CMV-seropositive recipients of an allogenic hematopoietic stem cell transplant, grew 47% and 42% in the second quarter and first six months of 2021, respectively, due to continued uptake since launch in several international markets, particularly in Europe and the U.S. *Prevymis* was approved by the EC in January 2018 and by the FDA in November 2017.

Global sales of *Noxafil* (posaconazole), an antifungal agent for the prevention of certain invasive fungal infections, declined 10% and 21% in the second quarter and first six months of 2021, respectively, primarily due to generic competition in Europe, partially offset by higher demand in China. The patent that provided market exclusivity for *Noxafil* in a number of major European markets expired in December 2019. As a result, the Company is experiencing lower demand for *Noxafil* in these markets as a result of generic competition and expects the decline to continue.

In December 2020, the Company temporarily suspended sales of *Zerbaxa*, a combination antibacterial and beta-lactamase inhibitor for the treatment of certain bacterial infections, and subsequently issued a product recall, following the identification of product sterility issues. The Company does not anticipate that *Zerbaxa* will return to the market before 2022.

Immunology

($ in millions)	Three Months Ended June 30, 2021	2020	% Change	% Change Excluding Foreign Exchange	Six Months Ended June 30, 2021	2020	% Change	% Change Excluding Foreign Exchange
Simponi	$ 202	$ 191	5 %	(3) %	$ 416	$ 406	2 %	(6) %

Sales of *Simponi* (golimumab), a once-monthly subcutaneous treatment for certain inflammatory diseases (marketed by the Company in Europe, Russia and Turkey), grew 5% and 2% in the second quarter and first six months of 2021, respectively. Excluding the favorable effect of foreign exchange, sales performance in both periods was largely attributable to lower pricing in Company's marketing territories in Europe. Sales of *Simponi* are being unfavorably affected by biosimilar competition for competing products. The Company expects this competition will continue to unfavorably affect sales of *Simponi*.

The Company's marketing rights with respect to *Simponi* will revert to Janssen Pharmaceuticals, Inc. in the second half of 2024.

Virology

($ in millions)	Three Months Ended June 30, 2021	2020	% Change	% Change Excluding Foreign Exchange	Six Months Ended June 30, 2021	2020	% Change	% Change Excluding Foreign Exchange
Isentress/Isentress HD	$ 192	$ 196	(2) %	(5) %	$ 401	$ 441	(9) %	(11) %

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 2% and 9% in the second quarter and first six months of 2021, respectively, due to competitive pressure in most markets. The Company expects competitive pressure for *Isentress/Isentress HD* to continue.

Cardiovascular

($ in millions)	Three Months Ended June 30, 2021	2020	% Change	% Change Excluding Foreign Exchange	Six Months Ended June 30, 2021	2020	% Change	% Change Excluding Foreign Exchange
Alliance Revenue - Adempas/Verquvo [(1)]	$ 74	$ 79	(7) %	(7) %	$ 149	$ 133	12 %	11 %
Adempas	74	57	29 %	31 %	129	113	15 %	7 %

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

Adempas (riociguat), a cardiovascular drug for the treatment of certain types of pulmonary arterial hypertension, is part of a worldwide collaboration with Bayer AG (Bayer) to market and develop soluble guanylate cyclase (sGC) modulators including Adempas (see Note 4 to the condensed consolidated financial statements). Alliance revenue from the collaboration declined 7% in the second quarter of 2021, reflecting higher costs associated with the launch of Verquvo (vericiguat), and grew 12% in the first six months of 2021. Revenue from the collaboration also includes sales in Merck's marketing territories, which grew 29% and 15% in the second quarter and first six months of 2021, respectively.

In January 2021, the FDA approved Verquvo, an sGC stimulator, 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. The approvals were based on the results of the VICTORIA trial. Verquvo is part of the same collaboration with Bayer referenced above that includes Adempas.

Diabetes

($ in millions)	Three Months Ended June 30, 2021	2020	% Change	% Change Excluding Foreign Exchange	Six Months Ended June 30, 2021	2020	% Change	% Change Excluding Foreign Exchange
Januvia/Janumet	$ 1,261	$ 1,344	(6) %	(10) %	$ 2,556	$ 2,621	(3) %	(6) %

Worldwide combined sales of *Januvia* and *Janumet*, medicines that help lower blood sugar levels in adults with type 2 diabetes, declined 6% and 3% in the second quarter and first six months of 2021, respectively. The sales declines were primarily due to continued pricing pressure in the U.S., partially offset by higher demand in certain international markets. The

Company expects U.S. pricing pressure to continue. *Januvia* and *Janumet* will lose market exclusivity in the U.S. in January 2023. The supplementary patent certificates that provide market exclusivity for *Januvia* and *Janumet* in the EU expire in September 2022 and April 2023, respectively. The Company anticipates sales of *Januvia* and *Janumet* in these markets will decline substantially after loss of market exclusivity.

Animal Health Segment

($ in millions)	Three Months Ended June 30, 2021	2020	% Change	% Change Excluding Foreign Exchange	Six Months Ended June 30, 2021	2020	% Change	% Change Excluding Foreign Exchange
Livestock	$ 821	$ 648	27 %	20 %	$ 1,640	$ 1,386	18 %	15 %
Companion Animal	651	453	44 %	38 %	1,250	928	35 %	31 %

Sales of livestock products grew 27% and 18% in the second quarter and first six months of 2021, respectively, primarily due to higher demand for ruminant, poultry and swine products, as well as higher demand for animal health intelligence solutions for animal identification, monitoring and traceability. Sales of companion animal products grew 44% and 35% in the second quarter and first six months of 2021, respectively, primarily due to higher demand for companion animal vaccines, as well as higher demand for parasiticides, including the *Bravecto* (fluralaner) line of products. As noted above, the COVID-19 pandemic unfavorably affected Animal Health segment sales in 2020.

Costs, Expenses and Other

($ in millions)	Three Months Ended June 30, 2021	2020	% Change	Six Months Ended June 30, 2021	2020	% Change
Cost of sales	$ 3,104	$ 2,747	13 %	$ 6,303	$ 5,576	13 %
Selling, general and administrative	2,281	2,085	9 %	4,468	4,276	4 %
Research and development	4,321	2,085	107 %	6,732	4,260	58 %
Restructuring costs	82	82	— %	380	152	150 %
Other (income) expense, net	(103)	(387)	(73)%	(558)	(325)	72 %
	$ 9,685	$ 6,612	46 %	17,325	13,939	24 %

Cost of Sales

Cost of sales increased 13% in both the second quarter and first six months of 2021. Cost of sales includes the amortization of intangible assets recorded in connection with acquisitions, collaborations, and licensing arrangements, which totaled $342 million and $582 million in the second quarter of 2021 and 2020, respectively, and $837 million and $967 million for the first six months of 2021 and 2020, respectively. Costs in the second quarter and first six months of 2021 also include charges of $37 million and $225 million, respectively, related to the discontinuation of COVID-19 development programs. Also included in cost of sales are expenses associated with restructuring activities which amounted to $38 million and $25 million in the second quarter of 2021 and 2020, respectively, and $65 million and $93 million for the first six months of 2021 and 2020, 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 72.8% in the second quarter of 2021 compared with 70.6% in the second quarter of 2020. The gross margin increase reflects lower amortization of intangible assets (noted above), as well as favorable product mix, partially offset by the unfavorable effects of foreign exchange, pricing pressure and higher manufacturing costs. Gross margin was 71.4% in the first six months of 2021 compared with 71.6% in the first six months of 2020. The gross margin decline reflects higher costs associated with COVID-19 development programs, including charges related to the discontinuation of certain COVID-19 development programs, as well as the unfavorable effects of pricing pressure and foreign exchange, largely offset by lower amortization of intangible assets and the favorable effect of product mix.

Selling, General and Administrative

Selling, general and administrative (SG&A) expenses increased 9% and 4% in the second quarter and first six months of 2021, respectively, primarily due to higher promotion and administrative costs, as well as the unfavorable effect of foreign exchange. Lower acquisition-related costs, primarily reflecting $95 million of costs in the prior year related to the acquisition of ArQule, Inc. (ArQule), partially offset the increase in SG&A expenses in the first six months of 2021.

Research and Development

Research and development (R&D) expenses were $4.3 billion in the second quarter of 2021 compared with $2.1 billion in the second quarter of 2020 and were $6.7 billion in the first six months of 2021 compared with $4.3 billion in the first six months of 2020. The increase in both periods was primarily due to a $1.7 billion charge in the second quarter of 2021 for the acquisition of Pandion (see Note 3 to the condensed consolidated financial statements), as well as higher clinical development spending and increased investment in discovery research and early drug development.

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 $1.5 billion in the second quarter of 2021 and 2020, respectively, and $3.5 billion and $3.0 billion in the first six months of 2021 and 2020, 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 $625 million for the second quarter of 2021 and 2020, respectively, and $1.4 billion and $1.2 billion in the first six months of 2021 and 2020, respectively. Additionally, R&D expenses in the second quarter and first six months of 2021 include $1.8 billion of charges for acquisitions, including $1.7 billion for Pandion as noted above. In addition, R&D expenses include expense or income related to changes in the estimated fair value measurement of liabilities for contingent consideration recorded in connection with business acquisitions. The Company recorded a net reduction in expenses of $82 million and $49 million in the second quarter and first six months of 2020, respectively, related to the changes in these estimates.

Restructuring Costs

In 2019, Merck approved a new 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, builds on prior restructuring programs and does not include any actions associated with the spin-off of Organon. As the Company continues to evaluate its global footprint and overall operating model, it subsequently identified additional actions under the Restructuring Program, and could identify further actions over time. 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 $3.0 billion. The Company expects to record charges of approximately $700 million in 2021 related to the Restructuring Program. The Company anticipates the actions under the Restructuring Program to 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 $82 million for both the second quarter of 2021 and 2020, and were $380 million and $152 million for the first six months of 2021 and 2020, 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 $128 million and $149 million in the second quarter of 2021 and 2020, respectively, and $462 million and $315 million, for the first six months of 2021 and 2020, respectively, related to restructuring program activities (see Note 5 to the condensed consolidated financial statements).

Other (Income) Expense, Net

Other (income) expense, net, was $103 million of income in the second quarter of 2021 compared with $387 million of income in the second quarter of 2020 primarily due to lower income from investments in equity securities, net, largely related to lower unrealized gains on certain investments, most of which related to Moderna, Inc., as well as NGM Biopharmaceuticals, Inc. Other income (expense), net, was $558 million of income in the first six months of 2021 compared with $325 million of income in the first six months of 2020 primarily due to higher income from investments in equity securities, net, largely related to the disposition in 2021 of the Company's ownership interest in Preventice Solutions Inc. (Preventice) as a result of the acquisition of Preventice by Boston Scientific.

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

Segment Profits

($ in millions)	Three Months Ended June 30, 2021	Three Months Ended June 30, 2020	Six Months Ended June 30, 2021	Six Months Ended June 30, 2020
Pharmaceutical segment profits	$ 7,257	$ 5,832	$ 13,845	$ 12,209
Animal Health segment profits	552	408	1,124	887
Other non-reportable segment profits	—	—	—	2
Other	(6,092)	(3,499)	(10,265)	(7,396)
Income from continuing operations before taxes	$ 1,717	$ 2,741	$ 4,704	$ 5,702

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 purchase accounting adjustments, intangible asset impairment charges, and 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 24% and 13% in the second quarter and first six months of 2021, respectively, reflecting higher sales and the favorable effect of foreign exchange, partially offset by higher promotional costs. Animal Health segment profits grew 35% and 27% in the second quarter and first six months of 2021, respectively, reflecting higher sales, partially offset by higher R&D costs, higher promotional, selling and administrative costs, as well as the unfavorable effect of foreign exchange.

Taxes on Income

The effective income tax rates from continuing operations of 29.3% and 14.4% for the second quarter of 2021 and 2020, respectively, and 15.8% and 15.6% for the first six months of 2021 and 2020, respectively. The effective income tax rates from continuing operations in the second quarter and first six months of 2021 reflect the unfavorable effect of a charge for the acquisition of Pandion for which no tax benefit was recognized. Additionally, the effective income tax rate from continuing operations for the first six months of 2021 reflects a net tax benefit of $207 million related to the settlement of certain federal income tax matters as discussed below.

In the first quarter of 2021, the Internal Revenue Service (IRS) concluded its examinations of Merck's 2015-2016 U.S. federal income tax returns. As a result, the Company was required to make a payment of $190 million (of which $172 million related to Merck continuing operations and $18 million related to Organon discontinued operations). The Company's reserves for unrecognized tax benefits for the years under examination exceeded the adjustments relating to this examination period and therefore the Company recorded a $236 million net tax benefit in the first six months of 2021 (of which $207 million related to Merck continuing operations and $29 million related to Organon 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 as it permits investors to understand how management assesses 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 non-GAAP EPS. Management uses these 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 non-GAAP pretax income. Since non-GAAP income and non-GAAP EPS are not

measures determined in accordance with GAAP, they have no standardized meaning prescribed by GAAP and, therefore, may not be comparable to the calculation of similar measures of other companies. The information on non-GAAP income and non-GAAP EPS should be considered in addition to, but not as a substitute for or superior to, net income and EPS prepared in accordance with generally accepted accounting principles in the U.S. (GAAP).

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

	Three Months Ended June 30,		Six Months Ended June 30,	
($ in millions except per share amounts)	2021	2020	2021	2020
Income from continuing operations before taxes as reported under GAAP	$ 1,717	$ 2,741	$ 4,704	$ 5,702
Increase (decrease) for excluded items:				
Acquisition and divestiture-related costs	503	624	1,000	1,153
Restructuring costs	128	149	462	315
Income from investments in equity securities, net	(258)	(511)	(819)	(598)
Other items:				
Charge for the acquisition of Pandion	1,704	—	1,704	—
Charges for the discontinuation of COVID-19 development programs	37	—	225	—
Other	61	(16)	61	(16)
Non-GAAP income from continuing operations before taxes	3,892	2,987	7,337	6,556
Taxes on income as reported under GAAP	503	396	741	891
Estimated tax benefit on excluded items [(1)]	68	1	116	139
Net tax (expense) benefit from the settlement of certain federal income tax matters	(1)	—	207	—
Non-GAAP taxes on income	570	397	1,064	1,030
Non-GAAP net income from continuing operations	3,322	2,590	6,273	5,526
Less: Net income (loss) attributable to noncontrolling interests as reported under GAAP	1	4	5	(1)
Non-GAAP net income from continuing operations attributable to Merck & Co., Inc.	$ 3,321	$ 2,586	$ 6,268	$ 5,527
EPS from continuing operations assuming dilution as reported under GAAP	$ 0.48	$ 0.92	$ 1.56	$ 1.89
EPS difference	0.83	0.10	0.91	0.28
Non-GAAP EPS from continuing operations assuming dilution	$ 1.31	$ 1.02	$ 2.47	$ 2.17

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

Restructuring Costs

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

Income and Losses from Investments in Equity Securities

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

Certain Other Items

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

Research and Development Update

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 July 2021, the FDA informed Merck of its decision to extend the goal date for the NDA to provide time for a full review of the submission. The extended Prescription Drug User Fee Act (PDUFA) date, or target action date, is March 21, 2022. Gefapixant is also under review in the EU and Japan.

V114 is an investigational 15-valent pneumococcal conjugate vaccine under review by the European Medicines Agency (EMA) for the prevention of invasive pneumococcal disease in adults. V114 was approved in the U.S. in July 2021 for use in adults where it is marketed as *Vaxneuvance*. Merck presented new data from the Phase 3 PNEU-AGE study of *Vaxneuvance* at the European Congress of Clinical Microbiology & Infectious Diseases (ECCMID) 2021. Additionally, the Company has several ongoing Phase 3 trials evaluating V114 in pediatric patients. In May 2021, Merck announced V114 met its primary immunogenicity and safety endpoints in two trials of the V114 Phase 3 pediatric clinical program. Full results from PNEU-DIRECTION and PNEU-PLAN will be presented at a future scientific congress. Plans are on track for submission of a supplemental regulatory licensure application to the FDA for use in children before the end of 2021. V114 previously received Breakthrough Therapy designation from the FDA for the prevention of invasive pneumococcal disease in pediatric patients 6 weeks to 18 years of age. The Company is involved in litigation challenging the validity of several Pfizer patents that relate to pneumococcal vaccine technology in the U.S. and several foreign jurisdictions. The resolution of this litigation may result in the payment of royalties or other financial consideration to Pfizer.

MK-6482, belzutifan, is an investigational hypoxia-inducible factor-2α (HIF-2α) inhibitor under priority review by the FDA for the potential treatment of patients with von Hippel-Lindau (VHL) disease-associated RCC not requiring immediate surgery. In July 2020, the FDA granted Breakthrough Therapy designation to belzutifan and has also granted orphan drug designation to belzutifan for VHL disease. The NDA is based on data from the Phase 2 Study-004 trial. The FDA set a PDUFA date of September 15, 2021. Merck is also studying belzutifan in advanced RCC and other tumor types through a broad clinical program, including Phase 3 trials as monotherapy, as part of a combination regimen in previously treated patients, and as part of a combination regimen as a first-line treatment for advanced clear cell RCC.

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 1,550 clinical trials, including more than 1,100 trials that combine *Keytruda* with other cancer treatments. These studies encompass more than 30 cancer types including: biliary tract, estrogen receptor positive breast cancer, cervical, colorectal, cutaneous squamous cell, endometrial, esophageal, gastric, glioblastoma, head and neck, hepatocellular, Hodgkin lymphoma, non-Hodgkin lymphoma, non-small-cell lung, small-cell lung, melanoma, mesothelioma, ovarian, prostate, renal, triple-negative breast, and urothelial, many of which are currently in Phase 3 clinical development. Further trials are being planned for other cancers.

Keytruda is under priority review by the FDA for the adjuvant treatment of adult and pediatric (12 years and older) patients with Stage IIB or IIC melanoma following complete resection. This submission is based on data from the Phase 3 KEYNOTE-716 trial. In August 2021, Merck announced that the KEYNOTE-716 trial met its primary endpoint of recurrence-free survival for the adjuvant treatment of patients with surgically resected high-risk stage II melanoma. These results will be presented at an upcoming medical meeting. The FDA set a PDUFA date of December 4, 2021.

Keytruda is also under review by the FDA for the treatment of patients with advanced endometrial cancer 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. This submission is based on data from the KEYNOTE-158 trial.

Keytruda in combination with chemotherapy is under review in the EU for the treatment of locally recurrent unresectable or metastatic TNBC in adults whose tumors express PD-L1 and who have not received prior chemotherapy for metastatic disease based on the results of the KEYNOTE-355 trial. *Keytruda* in combination with chemotherapy is also under review in Japan for the treatment of patients with locally recurrent unresectable or metastatic TNBC based on data from the KEYNOTE-355 trial.

Keytruda is also under review in the EU as monotherapy for the potential adjuvant treatment of patients with RCC at intermediate-high or high risk of recurrence following nephrectomy (surgical removal of a kidney) or following nephrectomy and resection of metastatic lesions based on the results from the KEYNOTE-564 trial.

Keytruda is under review in Japan as monotherapy for the first-line treatment of adult patients with metastatic MSI-H or dMMR colorectal cancer based on the results of the KEYNOTE-177 trial. *Keytruda* was approved for this indication by the FDA in June 2020 and by the EC in January 2021.

Keytruda is also under review in Japan in combination with chemotherapy for the first-line treatment of patients with locally advanced unresectable or metastatic carcinoma of the esophagus or HER2-negative gastroesophageal junction adenocarcinoma in adults whose tumors express PD-L1 based on the results from the KEYNOTE-590 trial. *Keytruda* was approved for this indication by the FDA in March 2021 and by the EC in June 2021.

Additionally, *Keytruda* is under review in Japan for 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.

In April 2021, the FDA began a priority review of the combination of *Keytruda* plus Lenvima for the first-line treatment of patients with advanced RCC based on the results of the KEYNOTE-581 trial. The FDA set a PDUFA date of August 26, 2021. The combination of *Keytruda* plus Lenvima is also under review for this indication in the EU and Japan.

Also in April 2021, the Committee for Medicinal Products for Human Use of the EMA announced the start of a procedure to extend the indication to include *Keytruda* in combination with lenvatinib for the treatment of advanced endometrial carcinoma in adults who have disease progression following prior systemic therapy in any setting and who are not candidates for curative surgery or radiation, based on the KEYNOTE-775 trial. *Keytruda* is also under review for this indication in Japan.

In June 2021, Merck announced that the Phase 3 KEYNOTE-826 trial investigating *Keytruda* in combination with chemotherapy with or without bevacizumab, met its primary endpoints of OS and PFS for the first-line treatment of patients with persistent, recurrent or metastatic cervical cancer. Results will be presented at an upcoming medical meeting and will be submitted to regulatory authorities. KEYNOTE-826 is also the confirmatory trial for the current accelerated approval for *Keytruda* in cervical cancer for the second-line treatment of patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy whose tumors express PD-L1.

In July 2021, Merck announced positive OS results from the Phase 3 KEYNOTE-355 trial evaluating *Keytruda* in combination with chemotherapy for the treatment of patients with metastatic triple-negative breast cancer (mTNBC). Findings from the final analysis show first-line treatment with *Keytruda* in combination with chemotherapy demonstrated a statistically significant and clinically meaningful improvement in OS compared with chemotherapy alone in patients with mTNBC whose tumors expressed PD-L1. These OS results will be presented at an upcoming medical meeting and submitted to regulatory authorities. These OS results follow a previous interim analysis that showed *Keytruda* in combination with chemotherapy significantly improved PFS compared with chemotherapy alone in these patients.

In June 2021, Merck and AstraZeneca announced the first presentation of data from the Phase 3 OlympiA trial in which Lynparza demonstrated a statistically significant improvement in its primary endpoint of invasive disease-free survival versus placebo in the adjuvant treatment of patients with germline *BRCA*1/2 mutations and high-risk HER2-negative early breast cancer following definitive local treatment and neoadjuvant or adjuvant chemotherapy. Results were presented at the 2021 American Society of Clinical Oncology Annual Meeting and published in the *New England Journal of Medicine*. Results also showed an improvement in the key secondary endpoint of distant disease-free survival in the overall trial population. At the time of data cut-off, OS data, while directionally encouraging, did not reach statistical significance and were not mature. The trial will continue to assess OS as a secondary endpoint.

Merck and Eisai are stopping LEAP-007, the Phase 3 study evaluating the first-line treatment of Lenvima in combination with *Keytruda* in participants with metastatic squamous or non-squamous NSCLC, whose tumors are PD-L1 positive (TPS ≥ 1%) with no *EGFR* or *ALK* genomic tumor aberrations. The trial is being discontinued following the recommendation of the external Data Monitoring Committee (eDMC) which met, as scheduled, to assess safety and futility. The eDMC determined that the study had met the criteria for declaring futility and the benefit/risk profile of the combination did not support continuing the trial.

In July 2021, Phase 2 interim results from two Phase 2/3 clinical trials (MOVe-OUT and MOVe-IN) of molnupiravir (MK-4482/EIDD-2801), an investigational oral antiviral therapeutic were presented during the late-breaking clinical trials session at the ECCMID 2021. The Phase 3 portion of the global MOVe-OUT trial studying molnupiravir in non-hospitalized adult patients with laboratory-confirmed COVID-19 and at least one risk factor associated with poor disease outcomes is underway. As previously announced, data from MOVe-IN indicate that molnupiravir is unlikely to demonstrate a clinical benefit in hospitalized patients, who generally had a longer duration of symptoms prior to study entry; therefore, the

decision has been made not to proceed to Phase 3. Merck has also initiated a clinical program to evaluate molnupiravir for post-exposure prophylaxis.

In April 2021, Merck announced the discontinuation of development of MK-7110 (formerly known as CD24Fc) for the treatment of hospitalized patients with COVID-19. Merck acquired MK-7110 in December 2020 through its acquisition of OncoImmune, a privately held clinical-stage biopharmaceutical company. In 2021, Merck received feedback from the 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 $37 million and $207 million in the second quarter and first six months of 2021, respectively, which are reflected in *Cost of sales* and relate to fixed-asset and materials write-offs, as well as the recognition of liabilities for purchase commitments.

The chart below reflects the Company's research pipeline as of July 27, 2021. 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	Phase 3 (Phase 3 entry date)	Under Review
Cancer MK-1026 Hematological Malignancies MK-1308 (quavonlimab)[2] Non-Small-Cell Lung MK-1308A (quavonlimab+pembrolizumab) Advanced Solid Tumors Colorectal Hepatocellular Melanoma MK-2140 Breast Non-Small-Cell Lung MK-3475 *Keytruda* Advanced Solid Tumors MK-4280 (favezelimab)[2] Hematological Malignancies Non-Small-Cell Lung MK-4280A (favezelimab+pembrolizumab) Renal Cell MK-4830 Non-Small-Cell Lung Small-Cell Lung MK-5890[2] Non-Small-Cell Lung MK-6440 (ladiratuzumab vedotin)[1][3] Breast Esophageal Gastric Head and Neck Melanoma Non-Small-Cell Lung Prostate Small-Cell Lung MK-6482 (belzutifan)[3] Von Hippel-Lindau Disease-Associated Renal Cell (EU) MK-7119 Tukysa[1] Advanced Solid Tumors Biliary Tract Bladder Cervical Colorectal Endometrial Gastric Non-Small-Cell Lung MK-7339 Lynparza[1][3] Advanced Solid Tumors MK-7684 (vibostolimab)[2] Melanoma MK-7902 Lenvima[1][2] Biliary Tract Glioblastoma Pancreatic V937 Breast Cutaneous Squamous Cell Head and Neck Melanoma Solid Tumors **Chikungunya Virus Vaccine** V184 **Cytomegalovirus Vaccine** V160 **HIV-1 Infection** MK-8591B (islatravir+MK-8507) **Nonalcoholic Steatohepatitis (NASH)** MK-3655 **Overgrowth Syndrome** MK-7075 (miransertib) **Pneumococcal Vaccine Adult** V116 **Pulmonary Arterial Hypertension** MK-5475 **Respiratory Syncytial Virus** MK-1654 **Schizophrenia** MK-8189 **Treatment Resistant Depression** MK-1942	**Antiviral COVID-19** MK-4482 (molnupiravir)[1] (May 2021) **Cancer** MK-1308A (quavonlimab+pembrolizumab) Renal Cell (April 2021) MK-3475 *Keytruda* Biliary Tract (September 2019) Cervical (October 2018) (EU) 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-6482 (belzutifan)[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 (pembrolizumab+vibostolimab) Non-Small-Cell Lung (April 2021) MK-7902 Lenvima[1][2] Bladder (May 2019) Colorectal (April 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) **HIV-1 Prevention** MK-8591 (islatravir) (February 2021)	**New Molecular Entities/Vaccines** **Cough** MK-7264 (gefapixant) (U.S.) (JPN) (EU) **Pneumococcal Vaccine Adult** V114 (EU) **Von Hippel-Lindau Disease-Associated Renal Cell Carcinoma** MK-6482 (belzutifan) (U.S.) **Certain Supplemental Filings** **Cancer** MK-3475 *Keytruda* • Resected Stage IIB and IIC Melanoma (KEYNOTE-716) (U.S.)[4] • MSI-H or dMMR Endometrial Cancer (KEYNOTE-158) (U.S.) • Metastatic Triple-Negative Breast Cancer (KEYNOTE-355) (EU) (JPN) • Adjuvent Renal Cell Cancer (KEYNOTE-564) EU • Unresectable or Metastatic MSI-H or dMMR Colorectal Cancer (KEYNOTE-177) (JPN) • Advanced Unresectable Metastatic Esophageal Cancer (KEYNOTE-590) (JPN) • Tumor Mutational Burden-High (KEYNOTE-158) (JPN) MK-7902 Lenvima[1][2] • First-Line Metastatic Hepatocellular Carcinoma (KEYNOTE-524) (U.S.)[5] • Advanced Unresectable Renal Cell Carcinoma (KEYNOTE-581) (U.S.) (EU) (JPN) • Advanced Endometrial Cancer (KEYNOTE-775) (EU) (JPN)

Footnotes:

[1] Being developed in a collaboration.

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

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

[4] Announced on August 5, 2021.

[5] In July 2020, the FDA issued a Complete Response Letter 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)	June 30, 2021	December 31, 2020
Cash and investments	$ 8,986	$ 8,835
Working capital	6,759	437
Total debt to total liabilities and equity	29.2 %	34.7 %

Cash provided by operating activities from continuing operations was $3.2 billion in the first six months of 2021 compared with $2.6 billion in the first six months of 2020. Cash provided by operating activities from continuing operations in the first six months of 2021 includes $325 million of payments related to collaborations compared with $1.1 billion in the first six months of 2020. Cash provided by operating activities from continuing operations continues to be the Company's primary source of funds to finance operating needs, capital expenditures, treasury stock purchases and dividends paid to shareholders.

Cash used in investing activities of continuing operations was $3.3 billion in the first six months of 2021 compared with $2.4 billion in the first six months of 2020. The higher use of cash in investing activities was driven primarily by lower proceeds from sales of securities and other investments and higher capital expenditures, partially offset by lower cash used for acquisitions.

Cash provided by financing activities of continuing operations was $164 million in the first six months of 2021 compared with cash used in financing activities of continuing operations of $353 million in the first six months of 2020. The change was primarily driven by the cash distribution received from Organon in connection with the spin-off (see Note 2 to the condensed consolidated financial statements), lower purchases of treasury stock and lower payments on debt (see below), partially offset by a net decrease in short-term borrowings compared with a net increase in short-term borrowings in the prior year period, lower proceeds from the issuance of debt (see below) and higher dividends paid to shareholders.

Capital expenditures totaled $2.1 billion and $1.6 billion for the first six months of 2021 and 2020, respectively.

The Company has accounts receivable factoring agreements with financial institutions in certain countries to sell accounts receivable. The Company factored $2.4 billion and $2.1 billion of accounts receivable at June 30, 2021 and December 31, 2020, 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 $3.3 billion and $3.1 billion for the first six months of 2021 and 2020, respectively. In May 2021, the Board of Directors declared a quarterly dividend of $0.65 per share on the Company's stock for the third quarter that was paid in July 2021. In July 2021, the Board of Directors declared a quarterly dividend of $0.65 per share on the Company's stock for the fourth quarter that will be paid in October 2021.

In January 2021, the Company's $1.15 billion, 3.875% notes matured in accordance with their terms and were repaid.

In February 2020, the Company's $1.25 billion, 1.85% notes and $700 million floating-rate notes matured in accordance with their terms and were repaid.

In June 2020, the Company issued $4.5 billion principal amount of senior unsecured notes consisting of $1.0 billion of 0.75% notes due 2026, $1.25 billion of 1.45% notes due 2030, $1.0 billion of 2.35% notes due 2040 and $1.25 billion of 2.45% notes due 2050. Merck used the net proceeds from the offering for general corporate purposes, including without limitation the repayment of outstanding commercial paper borrowings and other indebtedness with upcoming maturities.

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. In May 2021, Merck restarted its share repurchase program, which the Company had temporarily suspended in March 2020. The Company purchased $239 million (3 million shares) of its common stock during the second quarter of 2021. As of June 30, 2021, the Company's remaining share repurchase authorization was $5.6 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, 2020 included in Merck's Form 10-K filed on February 25, 2021. See Note 1 to the condensed consolidated financial statements for information on the adoption of new accounting standards during 2021. 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, 2020.

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 2020 Form 10-K filed on February 25, 2021.

Item 4. Controls and Procedures

Management of the Company, with the participation of its Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of the Company's disclosure controls and procedures over financial reporting. Based on their evaluation, the Company's Chief Executive Officer and Chief Financial Officer have concluded that as of June 30, 2021, the Company's disclosure controls and procedures are effective. For the second quarter of 2021, 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 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, 2020, filed on February 25, 2021, in the Company's Form 10-Q for the quarterly period ended March 31, 2021, filed on May 5, 2021, and in this Form 10-Q, the Company discusses in more detail various important risk factors that could cause actual results to differ from expected or historic results. The Company notes these factors for investors as permitted by the Private Securities Litigation Reform Act of 1995. One should understand that it is not possible to predict or identify all such factors. Consequently, the reader should not consider any such list to be a complete statement of all potential risks or uncertainties.

PART II - Other Information

Item 1. Legal Proceedings

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

Item 1A. Risk Factors

For a discussion of risks that affect the Company's business, please refer to Part I, Item IA, "Risk Factors" in the Company's Annual Report on Form 10-K for the year ended December 31, 2020. 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 global COVID-19 pandemic is having an adverse impact on the Company's business, operations and financial performance. The Company is unable to predict the full extent to which the pandemic and related impacts will continue to adversely impact its business, operations, financial performance, results of operations, and financial condition.

The Company's business and financial results have been negatively impacted by the outbreak of Coronavirus Disease 2019 (COVID-19). The duration, spread and severity of the COVID-19 pandemic is uncertain, rapidly changing and difficult to predict. The degree to which COVID-19 impacts the Company's results will depend on future developments, beyond the Company's knowledge or control, including, but not limited to, the duration and spread of the outbreak, its severity, the actions taken to contain the virus or treat its impact, and how quickly and to what extent normal economic and operating conditions can resume.

Merck continues to believe that global health systems and patients have largely adapted to the impacts of the COVID-19 pandemic, and that while negative impacts will persist, the trend will continue to improve. For the full year of 2021, Merck assumes a net unfavorable impact to sales of less than 3% due to the COVID-19 pandemic, all of which relates to the Pharmaceutical segment. In addition, for the full year of 2021, Merck expects a negligible impact to operating expenses, as spending on the development of its COVID-19 antiviral program is expected to largely offset the favorable impact of lower spending in other areas due to the COVID-19 pandemic. To the extent these assumptions prove to be incorrect, the Company's results may differ materially from the estimates set forth herein.

For the second quarter and first six months of 2021, the estimated negative impact of the COVID-19 pandemic to Merck's Pharmaceutical sales was approximately $400 million and $1.0 billion, respectively. There was no impact to Animal Health sales. Roughly 75% of Merck's Pharmaceutical segment revenue is comprised of physician-administered products, which, despite strong underlying demand, have been affected by social distancing measures and fewer well visits.

Operating expenses reflect a minor positive effect in the second quarter and first six months of 2021 as investments in COVID-19-related research programs largely offset the favorable impact of lower spending in other areas due to the COVID-19 pandemic.

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

Issuer purchases of equity securities for the three months ended June 30, 2021 were as follows:

ISSUER PURCHASES OF EQUITY SECURITIES

			($ in millions)
Period	Total Number of Shares Purchased [(1)]	Average Price Paid Per Share	Approximate Dollar Value of Shares That May Yet Be Purchased Under the Plans or Programs [(1)]
April 1 - April 30	—	$0.00	$5,888
May 1 - May 31	671,000	$76.93	$5,836
June 1 - June 30	2,502,900	$74.99	$5,648
Total	3,173,900	$75.40	$5,648

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

Item 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 July 22, 2015) – Incorporated by reference to Current Report on Form 8-K filed on July 28, 2015 (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: August 9, 2021

/s/ Jennifer Zachary

JENNIFER ZACHARY
Executive Vice President, General Counsel and Corporate Secretary

Date: August 9, 2021

/s/ Rita A. Karachun

RITA A. KARACHUN
Senior Vice President Finance - Global Controller

Exhibit 31.1

CERTIFICATION

I, Robert M. Davis, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: August 9, 2021

By: /s/ Robert M. Davis

ROBERT M. DAVIS
President and Chief Executive Officer

Exhibit 31.2

CERTIFICATION

I, Caroline Litchfield, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: August 9, 2021

By: /s/ Caroline Litchfield

CAROLINE LITCHFIELD
Executive Vice President, Chief Financial Officer

Exhibit 32.1

Section 1350
Certification of Chief Executive Officer

Pursuant to 18 U.S.C. Section 1350, the undersigned officer of Merck & Co., Inc. (the "Company"), hereby certifies that the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2021 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 9, 2021

/s/ Robert M. Davis

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

Exhibit 32.2

Section 1350
Certification of Chief Financial Officer

Pursuant to 18 U.S.C. Section 1350, the undersigned officer of Merck & Co., Inc. (the "Company"), hereby certifies that the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2021 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: August 9, 2021

/s/ Caroline Litchfield

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