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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 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
0.500% Notes due 2024	MRK 24	New York Stock Exchange
1.875% Notes due 2026	MRK/26	New York Stock Exchange
2.500% Notes due 2034	MRK/34	New York Stock Exchange
1.375% Notes due 2036	MRK 36A	New York Stock Exchange

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

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

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

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

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

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

The number of shares of common stock outstanding as of the close of business on October 31, 2021: 2,525,943,936

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Sales	$ 13,154	$ 10,929	$ 35,183	$ 30,570
Costs, Expenses and Other				
Cost of sales	3,450	3,013	9,752	8,589
Selling, general and administrative	2,336	2,060	6,804	6,336
Research and development	2,445	3,349	9,177	7,609
Restructuring costs	107	113	487	265
Other (income) expense, net	(450)	(312)	(1,007)	(637)
	7,888	8,223	25,213	22,162
Income from Continuing Operations Before Taxes	5,266	2,706	9,970	8,408
Taxes on Income from Continuing Operations	695	380	1,436	1,271
Net Income from Continuing Operations	4,571	2,326	8,534	7,137
Less: Net Income Attributable to Noncontrolling Interests	4	2	9	1
Net Income from Continuing Operations Attributable to Merck & Co., Inc.	4,567	2,324	8,525	7,136
Income from Discontinued Operations, Net of Taxes and Amounts Attributable to Noncontrolling Interests	—	617	766	2,025
Net Income Attributable to Merck & Co. Inc.	$ 4,567	$ 2,941	$ 9,291	$ 9,161
Basic Earnings per Common Share Attributable to Merck & Co., Inc. Common Shareholders:				
Income from Continuing Operations	$ 1.81	$ 0.92	$ 3.37	$ 2.82
Income from Discontinued Operations	—	0.24	0.30	0.80
Net Income	$ 1.81	$ 1.16	$ 3.67	$ 3.62
Earnings per Common Share Assuming Dilution Attributable to Merck & Co., Inc. Common Shareholders:				
Income from Continuing Operations	$ 1.80	$ 0.92	$ 3.36	$ 2.81
Income from Discontinued Operations	—	0.24	0.30	0.80
Net Income	$ 1.80	$ 1.16	$ 3.66	$ 3.61

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Net Income Attributable to Merck & Co., Inc.	$ 4,567	$ 2,941	$ 9,291	$ 9,161
Other Comprehensive Income (Loss) Net of Taxes:				
Net unrealized gain (loss) on derivatives, net of reclassifications	84	(137)	324	(153)
Net unrealized loss on investments, net of reclassifications	—	—	—	(18)
Benefit plan net gain and prior service credit, net of amortization	38	62	1,522	161
Cumulative translation adjustment	(84)	85	(251)	(180)
	38	10	1,595	(190)
Comprehensive Income Attributable to Merck & Co., Inc.	$ 4,605	$ 2,951	$ 10,886	$ 8,971

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

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

	September 30, 2021	December 31, 2020
Assets		
Current Assets		
Cash and cash equivalents	$ 10,016	$ 8,050
Accounts receivable (net of allowance for doubtful accounts of $69 in 2021 and $67 in 2020)	8,571	6,803
Inventories (excludes inventories of $2,373 in 2021 and $2,070 in 2020 classified in Other assets - see Note 7)	5,603	5,554
Other current assets	6,868	4,674
Current assets of discontinued operations	—	2,683
Total current assets	31,058	27,764
Investments	435	785
Property, Plant and Equipment, at cost, net of accumulated depreciation of $18,155 in 2021 and $18,162 in 2020	18,565	17,000
Goodwill	18,862	18,882
Other Intangibles, Net	13,384	14,101
Other Assets	11,190	9,881
Noncurrent Assets of Discontinued Operations	—	3,175
	$ 93,494	$ 91,588
Liabilities and Equity		
Current Liabilities		
Loans payable and current portion of long-term debt	$ 3,534	$ 6,431
Trade accounts payable	3,366	4,327
Accrued and other current liabilities	14,214	12,212
Income taxes payable	954	1,597
Dividends payable	1,660	1,674
Current liabilities of discontinued operations	—	1,086
Total current liabilities	23,728	27,327
Long-Term Debt	22,907	25,360
Deferred Income Taxes	1,527	1,005
Other Noncurrent Liabilities	9,469	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	44,149	39,588
Retained earnings	51,691	47,362
Accumulated other comprehensive loss	(4,590)	(6,634)
	93,038	82,104
Less treasury stock, at cost: 1,051,780,149 shares in 2021 and 1,046,877,695 shares in 2020	57,244	56,787
Total Merck & Co., Inc. stockholders' equity	35,794	25,317
Noncontrolling Interests	69	87
Total equity	35,863	25,404
	$ 93,494	$ 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)

	Nine Months Ended September 30,	
	2021	2020
Cash Flows from Operating Activities		
Net income from continuing operations	$ 8,534	$ 7,137
Adjustments to reconcile net income from continuing operations to net cash provided by operating activities:		
Amortization	1,231	1,393
Depreciation	1,148	1,210
Intangible asset impairment charges	—	35
Income from investments in equity securities, net	(1,535)	(964)
Charge for the acquisition of Pandion Therapeutics, Inc.	1,556	—
Deferred income taxes	28	32
Share-based compensation	360	329
Other	499	519
Net changes in assets and liabilities	(3,794)	(5,484)
Net Cash Provided by Operating Activities from Continuing Operations	8,027	4,207
Cash Flows from Investing Activities		
Capital expenditures	(3,240)	(2,998)
Purchases of securities and other investments	(1)	(78)
Proceeds from sales of securities and other investments	497	1,894
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	(89)	(907)
Other	15	138
Net Cash Used in Investing Activities from Continuing Operations	(4,372)	(4,496)
Cash Flows from Financing Activities		
Net change in short-term borrowings	(3,983)	(311)
Payments on debt	(1,153)	(1,954)
Distribution from Organon & Co.	9,000	—
Proceeds from issuance of debt	—	4,419
Purchases of treasury stock	(822)	(1,281)
Dividends paid to stockholders	(4,967)	(4,673)
Proceeds from exercise of stock options	68	68
Other	(253)	(472)
Net Cash Used in Financing Activities from Continuing Operations	(2,110)	(4,204)
Discontinued Operations		
Net cash provided by operating activities	1,051	2,040
Net cash used in investing activities	(134)	(169)
Net cash used in financing activities	(504)	—
Net Cash Flows Provided by Discontinued Operations	413	1,871
Effect of Exchange Rate Changes on Cash, Cash Equivalents and Restricted Cash	(65)	89
Net Increase (Decrease) in Cash, Cash Equivalents and Restricted Cash	1,893	(2,533)
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 $30 at September 30, 2021 included in Other Assets)	$ 10,046	$ 7,401

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.

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

Spin-Off of Organon & Co.

On June 2, 2021, Merck completed the spin-off of products from its women's health, biosimilars and established brands businesses into a new, independent, publicly traded company named Organon & Co. (Organon) through a distribution of Organon's publicly traded stock to Company shareholders. The established brands included in the transaction consisted of dermatology, non-opioid pain management, respiratory, select cardiovascular products, as well as the rest of Merck's diversified brands franchise. Merck's existing research pipeline programs continue to be owned and developed within Merck as planned. The historical results of the 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 Standards Not Yet Adopted

In March 2020, the FASB issued optional guidance to ease the potential burden in accounting for (or recognizing the effects of) reference rate reform on financial reporting and subsequently issued clarifying amendments. The guidance provides optional expedients and exceptions for 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.

In August 2020, the FASB issued amended guidance on the accounting for convertible instruments and contracts in an entity's own equity. The guidance removes the separation model for convertible debt instruments and preferred stock, amends requirements for conversion options to be classified in equity as well as amends diluted earnings per share (EPS) calculations for certain convertible debt instruments. The amended guidance is effective for interim and annual periods in 2022. Early adoption is permitted. The application of the amendments in the new guidance are to be applied either on a modified retrospective or a retrospective basis. The Company is currently evaluating the impact of adoption on its consolidated financial statements.

In October 2021, the FASB issued amended guidance that requires acquiring entities to recognize and measure contract assets and liabilities in a business combination in accordance with existing revenue recognition guidance. The amended guidance is effective for interim and annual periods in 2023 and is to be applied prospectively. Early adoption is permitted on a retrospective basis to the beginning of the fiscal year of adoption. The 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 third quarter and first nine months of 2021. The amount due from Organon under the above agreements was $1.4 billion at September 30, 2021 and is reflected in *Other current assets*. The amount due to Organon under these agreements was $930 million at September 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 $556 million in the nine months ended September 30, 2021, and $193 million and $483 million in the three and nine months ended September 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 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:

($ in millions)	Three Months Ended September 30, 2020	Nine Months Ended September 30, 2021 [1]	Nine Months Ended September 30, 2020
Sales	$ 1,622	$ 2,512	$ 4,911
Costs, Expenses and Other			
Cost of sales	468	789	1,362
Selling, general and administrative	390	877	1,046
Research and development	41	103	113
Restructuring costs	1	1	4
Other (income) expense, net	—	(15)	7
	900	1,755	2,532
Income from discontinued operations before taxes	722	757	2,379
Tax provision (benefit)	103	(12)	343
Income from discontinued operations, net of taxes	619	769	2,036
Less: Income of discontinued operations attributable to noncontrolling interests	2	3	11
Income from discontinued operations, net of taxes and amounts attributable to noncontrolling interests	$ 617	$ 766	$ 2,025

[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* (*AOCL*) 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 *AOCL* 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 September 2021, Merck and Acceleron Pharma Inc. (Acceleron), a publicly traded biopharmaceutical company, entered into a definitive agreement under which Merck will acquire Acceleron for $180 per share in cash for an approximate total equity value of $11.5 billion. Acceleron is focused on harnessing the power of the transforming growth factor (TGF)-beta superfamily of proteins that is known to play a central role in the regulation of cell growth, differentiation and repair. Acceleron's lead therapeutic candidate, sotatercept, has a novel mechanism of action with the potential to improve short-term and/or long-term clinical outcomes in patients with pulmonary arterial hypertension (PAH). Sotatercept is in Phase 3 trials as add-on to current standard of care for the treatment of PAH. In addition to sotatercept, Acceleron's portfolio includes Reblozyl (luspatercept-aamt), a first-in-class erythroid maturation recombinant fusion protein approved in the U.S., Europe, Canada and Australia for the treatment of anemia in certain rare blood disorders. Reblozyl is being developed and commercialized through a global collaboration with Bristol Myers Squibb. Under the terms of the acquisition agreement, Merck, through a subsidiary, initiated a tender offer to acquire all outstanding shares of Acceleron. The closing of the tender offer is subject to certain conditions, including the tender of shares representing at least a majority of the total number of Acceleron's outstanding shares, receipt of applicable regulatory approvals, and other customary conditions. The acquisition agreement includes termination provisions providing that (i) in the event Acceleron terminates in order to enter into an agreement with respect to a superior proposal (as defined in the agreement), Acceleron will be required to pay a termination fee of $345 million, and (ii) in the event the acquisition is not consummated due to antitrust conditions, Merck will be required to pay Acceleron a reverse termination fee of $650 million to $750 million depending on the time of termination. The transaction is expected to close in the fourth quarter of 2021.

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

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 $207 million in the first nine months of 2021, 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 September 2020, Merck and Seagen Inc. (Seagen, formerly known as Seattle Genetics, Inc.) announced an oncology collaboration to globally develop and commercialize Seagen's ladiratuzumab vedotin (MK-6440), an investigational antibody-drug conjugate targeting LIV-1, which is currently in Phase 2 clinical trials. The collaboration will pursue a broad joint development program evaluating ladiratuzumab vedotin as monotherapy and in combination with *Keytruda* (pembrolizumab) in triple-negative breast cancer, hormone receptor-positive breast cancer and other LIV-1-expressing solid tumors. The companies will equally share profits worldwide. Under the terms of the agreement, Merck made an upfront payment of $600 million and a $1.0 billion equity investment in 5 million shares of Seagen common stock at a price of $200 per share. Merck recorded $622 million in *Research and development* expenses in the third quarter and first nine months of 2020 related to this transaction reflecting the upfront payment as well as a $22 million mark-to-market loss on the purchase commitment (forward contract) relating to the equity shares (calculated based on the closing price of Seagen common stock on September 30, 2020). The closing of the equity investment occurred in October 2020 and resulted in the recognition of a $6 million reduction to *Research and development* expenses based on the price of Seagen common stock on the closing date. Seagen is also eligible to receive future contingent milestone payments of up to $2.6 billion, including $850 million in development milestones and $1.75 billion in sales-based milestones.

Concurrent with the above transaction, Seagen granted Merck an exclusive license to commercialize Tukysa (tucatinib), a small molecule tyrosine kinase inhibitor, for the treatment of human epidermal growth factor receptor 2 (HER2)-

positive cancers, in Asia, the Middle East and Latin America and other regions outside of the U.S., Canada and Europe. Merck will be responsible for marketing applications seeking approval in its territories, supported by the positive results from the HER2CLIMB clinical trial. Merck will also co-fund a portion of the Tukysa global development plan, which encompasses several ongoing and planned trials across HER2-positive cancers, including breast, colorectal, gastric and other cancers set forth in a global product development plan. Merck will solely fund and conduct country-specific clinical trials necessary to support anticipated regulatory applications in its territories. Under the terms of the agreement, Merck made upfront payments aggregating $210 million, which were recorded as *Research and development* expenses in the third quarter and first nine months of 2020. Seagen is also eligible to receive future contingent regulatory approval milestones of up to $65 million and will receive tiered royalties ranging from 20% to 33% based on annual sales levels of Tukysa in Merck's territories.

Additionally in September 2020, Merck acquired a biologics manufacturing facility located in Dunboyne, Ireland from Takeda Pharmaceutical Company Limited for €256 million ($302 million). The transaction was accounted for as an acquisition of an asset. Merck recorded property, plant and equipment of $289 million and other net assets of $13 million. There are no future contingent payments associated with the acquisition.

In July 2020, Merck acquired the U.S. rights to Sentinel Flavor Tabs and Sentinel Spectrum Chews from Virbac Corporation for $410 million. Sentinel products provide protection against common parasites in dogs. The transaction was accounted for as an acquisition of an asset. Merck recognized intangible assets of $401 million related to currently marketed products and inventory of $9 million at the acquisition date. The estimated fair values of the identifiable intangible assets related to currently marketed products were determined using an income approach. Actual cash flows are likely to be different than those assumed. The intangible assets related to currently marketed products will be amortized over their estimated useful lives of 15 years. There are no future contingent payments associated with the acquisition.

Also in July 2020, Merck and Ridgeback Biotherapeutics LP (Ridgeback Bio), a closely held biotechnology company, closed a collaboration agreement to develop molnupiravir (MK-4482/EIDD-2801) an orally available antiviral candidate in clinical development for the treatment of patients with COVID-19. Merck gained exclusive worldwide rights to develop and commercialize molnupiravir and related molecules. Under the terms of the agreement, Ridgeback Bio received an upfront payment and is eligible to receive future contingent payments dependent upon the achievement of certain developmental and regulatory approval milestones. Any profits from the collaboration will be split between the partners equally. Merck and Ridgeback Bio are committed to ensure that any medicines developed for SARS-CoV-2 (the causative agent of COVID-19) will be accessible and affordable globally.

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 the fourth quarter of 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 nine 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 September 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 $1.1 billion at September 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:

($ in millions)	Three Months Ended September 30, 2021	Three Months Ended September 30, 2020	Nine Months Ended September 30, 2021	Nine Months Ended September 30, 2020
Alliance revenue - Lynparza	$ 246	$ 196	$ 721	$ 519
Alliance revenue - Koselugo	6	3	20	3
Total alliance revenue	$ 252	$ 199	$ 741	$ 522
Cost of sales [1]	42	41	125	205
Selling, general and administrative	44	40	127	112
Research and development	27	20	87	93

($ in millions)	September 30, 2021	December 31, 2020
Receivables from AstraZeneca included in *Other current assets*	$ 248	$ 215
Payables to AstraZeneca included in *Accrued and other current liabilities* [2]	415	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 nine months of 2021. As of September 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. In the third quarter of 2021, Lenvima received a regulatory approval triggering a capitalized milestone payment of $75 million from Merck to Eisai. Potential future regulatory milestone payments of $50 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 September 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 September 30, 2021	Three Months Ended September 30, 2020	Nine Months Ended September 30, 2021	Nine Months Ended September 30, 2020
Alliance revenue - Lenvima	$ 188	$ 142	$ 498	$ 421
Cost of sales [1]	49	46	143	215
Selling, general and administrative	34	18	88	48
Research and development	43	48	165	168

($ in millions)	September 30, 2021	December 31, 2020
Receivables from Eisai included in *Other current assets*	$ 223	$ 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 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. Cost of sales includes Bayer's share of profits from sales in Merck's marketing territories.

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 nine 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 $869 million at September 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 $72 million at September 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 September 30, 2021	Three Months Ended September 30, 2020	Nine Months Ended September 30, 2021	Nine Months Ended September 30, 2020
Alliance revenue - Adempas/Verquvo	$ 100	$ 83	$ 248	$ 216
Net sales of Adempas recorded by Merck	59	55	188	167
Net sales of Verquvo recorded by Merck	2	—	3	—
Total sales	$ 161	$ 138	$ 439	$ 383
Cost of sales [1]	53	81	328	229
Selling, general and administrative	31	12	84	32
Research and development	16	12	36	53

($ in millions)	September 30, 2021	December 31, 2020
Receivables from Bayer included in *Other current assets*	$ 139	$ 65
Payables to Bayer included in *Accrued and other current liabilities* [2]	467	—

[1] *Includes amortization of intangible assets. Amount in the first nine months of 2021 includes $153 million of cumulative amortization as noted above. In addition, cost of sales in all periods now includes Bayer's share of profits from sales in Merck's marketing territories.*

[2] *Includes 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 $168 million and $185 million in the third quarter of 2021 and 2020, respectively, and $630 million and $500 million for the first nine months of 2021 and 2020, respectively, related to restructuring program activities. Since inception of the Restructuring Program through September 30, 2021, Merck has recorded total pretax accumulated costs of approximately $2.4 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 September 30, 2021				Nine Months Ended September 30, 2021			
($ in millions)	Separation Costs	Accelerated Depreciation	Other	Total	Separation Costs	Accelerated Depreciation	Other	Total
Cost of sales	$ —	$ 11	$ 37	$ 48	$ —	$ 32	$ 81	$ 113
Selling, general and administrative	—	4	1	5	—	8	1	9
Research and development	—	7	1	8	—	20	1	21
Restructuring costs	17	—	90	107	310	—	177	487
	$ 17	$ 22	$ 129	$ 168	$ 310	$ 60	$ 260	$ 630

	Three Months Ended September 30, 2020				Nine Months Ended September 30, 2020			
($ in millions)	Separation Costs	Accelerated Depreciation	Other	Total	Separation Costs	Accelerated Depreciation	Other	Total
Cost of sales	$ —	$ 33	$ 5	$ 38	$ —	$ 89	$ 42	$ 131
Selling, general and administrative	—	15	—	15	—	37	—	37
Research and development	—	18	1	19	—	66	1	67
Restructuring costs	61	—	52	113	143	—	122	265
	$ 61	$ 66	$ 58	$ 185	$ 143	$ 192	$ 165	$ 500

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 nine months ended September 30, 2021:

($ in millions)	Separation Costs	Accelerated Depreciation	Other	Total
Restructuring reserves January 1, 2021	$ 567	$ —	$ 19	$ 586
Expense	310	60	260	630
(Payments) receipts, net	(305)	—	(155)	(460)
Non-cash activity	—	(60)	(84)	(144)
Restructuring reserves September 30, 2021 [(1)]	$ 572	$ —	$ 40	$ 612

[(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 *AOCL* and reclassified into *Sales* when the hedged anticipated revenue is recognized. For those derivatives which are not designated as cash flow hedges, but serve as economic hedges of forecasted sales, unrealized gains or losses are recorded in *Sales* each period. The cash flows from both designated and non-

designated contracts are reported as operating activities in the Condensed Consolidated Statement of Cash Flows. The Company does not enter into derivatives for trading or speculative purposes.

The Company manages operating activities and net asset positions at each local subsidiary in order to mitigate the effects of exchange on monetary assets and liabilities. The Company also uses a balance sheet risk management program to mitigate the exposure of net monetary assets that are denominated in a currency other than a subsidiary's functional currency from the effects of volatility in foreign exchange. In these instances, Merck principally utilizes forward exchange contracts to offset the effects of exchange on exposures denominated in developed country currencies, primarily the euro 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 *AOCL* until either the sale or complete or substantially complete liquidation of the subsidiary. The Company excludes certain portions of the change in fair value of its derivative instruments from the assessment of hedge effectiveness (excluded components). Changes in fair value of the excluded components are recognized in *OCI*. The Company recognizes in earnings the initial value of the excluded components on a straight-line basis over the life of the derivative instrument, rather than using the mark-to-market approach. The cash flows from these contracts are reported as investing activities in the Condensed Consolidated Statement of Cash Flows.

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

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

	Amount of Pretax (Gain) Loss Recognized in Other Comprehensive Income [1]				Amount of Pretax (Gain) Loss Recognized in *Other (income) expense, net* for Amounts Excluded from Effectiveness Testing			
	Three Months Ended September 30,		Nine Months Ended September 30,		Three Months Ended September 30,		Nine Months Ended September 30,	
($ in millions)	2021	2020	2021	2020	2021	2020	2021	2020
Net Investment Hedging Relationships								
Foreign exchange contracts	$ 1	$ 10	$ (27)	$ 15	$ (4)	$ (4)	$ (12)	$ (15)
Euro-denominated notes	(77)	162	(199)	182	—	—	—	—

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

Interest Rate Risk Management

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

In 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 September 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)	September 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:

($ in millions)	Carrying Amount of Hedged Liabilities		Cumulative Amount of Fair Value Hedging Adjustment Increase (Decrease) Included in the Carrying Amount	
	September 30, 2021	December 31, 2020	September 30, 2021	December 31, 2020
Loans payable and current portion of long-term debt	$ 2,274	$ 1,150	$ 25	$ —
Long-Term Debt	—	2,301	—	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:

($ in millions)		September 30, 2021			December 31, 2020		
		Fair Value of Derivative		U.S. Dollar Notional	Fair Value of Derivative		U.S. Dollar Notional
		Asset	Liability		Asset	Liability	
Derivatives Designated as Hedging Instruments	*Balance Sheet Caption*						
Interest rate swap contracts	Other current assets	$ 26	$ —	$ 2,250	$ 1	$ —	$ 1,150
Interest rate swap contracts	Other Assets	—	—	—	54	—	2,250
Foreign exchange contracts	Other current assets	224	—	7,138	12	—	3,183
Foreign exchange contracts	Other Assets	45	—	1,469	45	—	2,030
Foreign exchange contracts	Accrued and other current liabilities	—	15	1,601	—	217	5,049
Foreign exchange contracts	Other Noncurrent Liabilities	—	1	145	—	1	52
		$ 295	$ 16	$ 12,603	$ 112	$ 218	$ 13,714
Derivatives Not Designated as Hedging Instruments	*Balance Sheet Caption*						
Foreign exchange contracts	Other current assets	$ 82	$ —	$ 6,333	$ 70	$ —	$ 7,260
Foreign exchange contracts	Accrued and other current liabilities	—	117	9,522	—	307	11,810
		$ 82	$ 117	$ 15,855	$ 70	$ 307	$ 19,070
		$ 377	$ 133	$ 28,458	$ 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:

($ in millions)	September 30, 2021		December 31, 2020	
	Asset	Liability	Asset	Liability
Gross amounts recognized in the condensed consolidated balance sheet	$ 377	$ 133	$ 182	$ 525
Gross amounts subject to offset in master netting arrangements not offset in the condensed consolidated balance sheet	(120)	(120)	(156)	(156)
Cash collateral received/posted	(65)	—	—	(36)
Net amounts	$ 192	$ 13	$ 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 September 30,		Three Months Ended September 30,		Three Months Ended September 30,		Nine Months Ended September 30,		Nine Months Ended September 30,		Nine Months Ended September 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	$ 13,154	$ 10,929	$ (450)	$ (312)	$ 38	$ 10	$ 35,183	$ 30,570	$ (1,007)	$ (637)	$ 1,595	$ (190)
(Gain) loss on fair value hedging relationships												
Interest rate swap contracts												
Hedged items	—	—	(9)	(14)	—	—	—	—	(29)	54	—	—
Derivatives designated as hedging instruments	—	—	(1)	—	—	—	—	—	(1)	(76)	—	—
Impact of cash flow hedging relationships												
Foreign exchange contracts												
Amount of gain (loss) recognized in *OCI* on derivatives	—	—	—	—	72	(195)	—	—	—	—	193	(126)
(Decrease) increase in *Sales* as a result of *AOCL* reclassifications	(36)	(23)	—	—	36	23	(219)	65	—	—	219	(65)
Interest rate contracts												
Amount of gain recognized in *Other (income) expense, net* on derivatives	—	—	—	(1)	—	—	—	—	(2)	(3)	—	—
Amount of loss recognized in *OCI* on derivatives	—	—	—	—	—	(1)	—	—	—	—	(2)	(3)

[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 September 30,		Nine Months Ended September 30,	
($ in millions)		2021	2020	2021	2020
Derivatives Not Designated as Hedging Instruments	*Income Statement Caption*				
Foreign exchange contracts [1]	Other (income) expense, net	$ 18	$ (7)	$ 234	$ (138)
Foreign exchange contracts [2]	Sales	(4)	7	6	4
Interest rate contracts [3]	Other (income) expense, net	—	—	—	9
Forward contract related to Seagen common stock	Research and development	—	22	—	22

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

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

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

At September 30, 2021, the Company estimates $55 million of pretax net unrealized gains on derivatives maturing within the next 12 months that hedge foreign currency denominated sales over that same period will be reclassified from *AOCL* to *Sales*. The amount ultimately reclassified to *Sales* may differ as foreign exchange rates change. Realized gains and losses are ultimately determined by actual exchange rates at maturity.

Investments in Debt and Equity Securities

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

	September 30, 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	$ 83	$ —	$ —	$ 83	$ 84	$ —	$ —	$ 84
Corporate notes and bonds	4	—	—	4	—	—	—	—
Foreign government bonds	2	—	—	2	5	—	—	5
Total debt securities	$ 89	$ —	$ —	$ 89	$ 89	$ —	$ —	$ 89
Publicly traded equity securities [(1)]				1,915				1,787
Total debt and publicly traded equity securities				$ 2,004				$ 1,876

[(1)] *Unrealized net gains of $90 million and unrealized net losses of $109 million were recorded in* Other (income) expense, net *on equity securities still held at September 30, 2021 in the third quarter and first nine months of 2021, respectively. Unrealized net gains recorded in* Other (income) expense, net *on equity securities still held at September 30, 2020 were $43 million and $512 million in the third quarter and first nine months of 2020, respectively.*

At September 30, 2021 and September 30, 2020, the Company also had $578 million and $508 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 nine months of 2021, the Company recorded unrealized gains of $104 million and unrealized losses of $1 million in *Other (income) expense, net* related to these equity investments held at September 30, 2021. During the first nine months of 2020, the Company recorded unrealized gains of $21 million and unrealized losses of $3 million in *Other (income) expense, net* related to these equity investments held at September 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 September 30, 2021 were $229 million and $7 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)	September 30, 2021				December 31, 2020			
Assets								
Investments								
Foreign government bonds	$ —	$ 2	$ —	$ 2	$ —	$ 5	$ —	$ 5
Publicly traded equity securities	433	—	—	433	780	—	—	780
	433	2	—	435	780	5	—	785
Other assets [1]								
U.S. government and agency securities	83	—	—	83	84	—	—	84
Corporate notes and bonds	4	—	—	4	—	—	—	—
Publicly traded equity securities	1,482	—	—	1,482	1,007	—	—	1,007
	1,569	—	—	1,569	1,091	—	—	1,091
Derivative assets [2]								
Forward exchange contracts	—	230	—	230	—	90	—	90
Purchased currency options	—	121	—	121	—	37	—	37
Interest rate swaps	—	26	—	26	—	55	—	55
	—	377	—	377	—	182	—	182
Total assets	$ 2,002	$ 379	$ —	$ 2,381	$ 1,871	$ 187	$ —	$ 2,058
Liabilities								
Other liabilities								
Contingent consideration	$ —	$ —	$ 902	$ 902	$ —	$ —	$ 841	$ 841
Derivative liabilities [2]								
Forward exchange contracts	—	132	—	132	—	505	—	505
Written currency options	—	1	—	1	—	20	—	20
	—	133	—	133	—	525	—	525
Total liabilities	$ —	$ 133	$ 902	$ 1,035	$ —	$ 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 September 30, 2021 and December 31, 2020, *Cash and cash equivalents* included $9.2 billion and $6.8 billion of cash equivalents, respectively (which would be considered Level 2 in the fair value hierarchy).

Contingent Consideration

Summarized information about the changes in the fair value of liabilities for contingent consideration associated with business acquisitions is as follows:

	Nine Months Ended September 30,	
($ in millions)	2021	2020
January 1	$ 841	$ 767
Additions	—	97
Changes in estimated fair value [1]	73	71
Payments	—	(106)
Other	(12)	—
September 30 [2][3]	$ 902	$ 829

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

[2] *Balance at September 30, 2021 includes $289 million recorded as a current liability for amounts expected to be paid within the next 12 months.*

[3] *At September 30, 2021 and December 31, 2020, $747 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 September 30, 2021, was $29.1 billion compared with a carrying value of $26.4 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 September 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 $65 million at September 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)	September 30, 2021	December 31, 2020
Finished goods	$ 1,628	$ 1,610
Raw materials and work in process	6,135	5,949
Supplies	190	146
Total (approximates current cost)	7,953	7,705
Increase (decrease) to LIFO cost	23	(81)
	$ 7,976	$ 7,624
Recognized as:		
Inventories	$ 5,603	$ 5,554
Other assets	2,373	2,070

Amounts recognized as *Other Assets* are comprised almost entirely of raw materials and work in process inventories. At September 30, 2021 and December 31, 2020, these amounts included $1.9 billion and $1.8 billion, respectively, of inventories not expected to be sold within one year. In addition, these amounts included $519 million and $279 million at September 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 September 30, 2021, approximately 3,470 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 September 30, 2021, Merck is aware of approximately 730 product users alleging that *Januvia* and/or *Janumet* caused the development of pancreatic cancer and other injuries.

Most claims have been filed in multidistrict litigation before the U.S. District Court for the Southern District of California (MDL). On March 9, 2021, the MDL Court issued an omnibus order granting defendants' summary judgment motions based on preemption and failure to establish general causation, as well as granting defendants' motions to exclude

plaintiffs' expert witnesses. The plaintiffs appealed that order. Since that time, more than half of these claims have been dismissed with prejudice as to Merck, and on October 5, 2021, the U.S. Court of Appeals for the Ninth Circuit dismissed the appeal as to Merck and two of its codefendants.

Outside of the MDL, the majority of claims have been filed in coordinated proceedings before the Superior Court of California, County of Los Angeles (California State Court). On April 6, 2021, the court in California issued an omnibus order granting defendants' summary judgment motions and also granting defendants' motions to exclude plaintiffs' expert witnesses.

As of September 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 September 30, 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. In September 2021, the direct purchaser plaintiffs filed a renewed motion for class certification and briefing regarding that motion is pending.

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.

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. In August 2021, the district court overruled the Merck Defendants' objections to the report and recommendation and granted certification of a class of indirect purchasers. In September 2021, the Merck Defendants petitioned to appeal the class certification decision to the Fourth Circuit. The Fourth Circuit denied that petition on September 30, 2021.

In September 2020, United Healthcare Services, Inc. filed a lawsuit in the U.S. District Court for the District of Minnesota against the Merck Defendants and others (the UHC Action). The UHC Action makes similar allegations as those made in the *Zetia* class action. 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. Defendants have filed a motion to dismiss.

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 September 2021, the parties reached an agreement that Humana and Centene would file their claims in New Jersey federal court, seek a transfer of those claims to the multidistrict *Zetia* litigation already in progress, and subsequently dismiss the actions previously filed in California. The parties jointly sought a stay of the Superior Court action, pending filing of the federal action. The Superior Court granted the stay on September 17, 2021.

Also, on July 16, 2021, Humana and Centene filed actions against the Merck Defendants in New Jersey in the Bergen County Superior Court, re-asserting the claims that were dismissed in their California action. Those complaints have not yet been served, and Humana and Centene have agreed to dismiss those actions once they have filed their complaints in New Jersey federal court.

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

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 three generic companies providing that these generic companies can bring their generic versions of *Bridion* to the market in January 2026 (which may be delayed by any applicable pediatric exclusivity) or earlier under certain circumstances.

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. Adding this exclusivity to the term of the key patent protection extends exclusivity on these products 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 (2027 salt/polymorph patent), which, if determined to be valid, would preclude generic manufacturers from making sitagliptin phosphate salt and polymorphic forms until 2027 with the expiration of that patent, plus pediatric exclusivity. In 2019, Par Pharmaceutical filed suit against the Company in the U.S. District Court for the District of New Jersey, seeking a declaratory judgment of invalidity of the 2027 salt/polymorph patent. In response, the Company filed a patent infringement lawsuit in the U.S. District Court for the District of Delaware against Par Pharmaceutical and additional companies that also indicated an intent to market generic versions of *Januvia*, *Janumet*, and *Janumet XR* following expiration of key patent protection, but prior to the expiration of the 2027 salt/polymorph patent, and a later granted patent owned by the Company covering the *Janumet* formulation where its term plus the pediatric exclusivity ends in 2029. The Company also filed a patent infringement lawsuit against Mylan in the Northern District of West Virginia. The Judicial Panel on Multidistrict Litigation entered an order transferring the Company's lawsuit against Mylan to the U.S. District Court for the District of Delaware for coordinated and consolidated pretrial proceedings with the other cases pending in that district.

Prior to the beginning of the October 2021 trial in the U.S. District Court for the District of Delaware on invalidity issues, the Company settled with all defendants scheduled to participate in that trial. In the Company's case against Mylan, the U.S. District Court for the Northern District of West Virginia has scheduled a five-day bench trial in December 2021.

In total, the Company has settled with 16 generic companies providing that these generic companies can bring their generic versions of *Januvia* and *Janumet* to the market in May 2026 or earlier under certain circumstances, and their generic versions of *Janumet XR* to the market in July 2026 or earlier under certain circumstances.

Additionally, in 2019, Mylan filed a petition for *Inter Partes* Review (IPR) at the U.S. Patent and Trademark Office (USPTO) seeking invalidity of some, but not all, of the claims of the 2027 salt/polymorph patent. The USPTO instituted IPR proceedings in May 2020, finding a reasonable likelihood that the challenged claims are not valid. A trial was held in February 2021 and a final decision was rendered in May 2021, holding that all of the challenged claims were not invalid. Mylan has appealed the USPTO's decision to the U.S. Court of Appeals for the Federal Circuit.

On March 1, 2021, the Company filed a patent infringement lawsuit in the U.S. District Court for the District of Delaware against Zydus Worldwide DMCC, Zydus Pharmaceuticals (USA) Inc., and Cadila Healthcare Ltd. (collectively, Zydus). In that lawsuit, the Company alleged infringement of the 2027 salt/polymorph patent based on the filing of Zydus's application seeking approval under 21 U.S.C. § 355(b)(2) of its sitagliptin tablets. The U.S. District Court for the District of Delaware has set a three-day bench trial in this matter beginning on October 31, 2022.

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 at the same time as the expiry of *Januvia* pediatric market exclusivity in September 2022. A hearing was held in June 2021 and the court decided that the SPC for *Janumet* is invalid, which decision the Company has appealed. Challenges to the *Janumet* SPC have also occurred in the following European countries: Austria, Czech Republic, Finland, France, Hungary, Italy, Portugal, Romania, Slovakia, and Sweden.

Other Litigation

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

Legal Defense Reserves

Legal defense costs expected to be incurred in connection with a loss contingency are accrued when probable and reasonably estimable. Some of the significant factors considered in the review of these legal defense reserves are as follows: the actual costs incurred by the Company; the development of the Company's legal defense strategy and structure in light of the

scope of its litigation; the number of cases being brought against the Company; the costs and outcomes of completed trials and the most current information regarding anticipated timing, progression, and related costs of pre-trial activities and trials in the associated litigation. The amount of legal defense reserves as of September 30, 2021 and December 31, 2020 of approximately $225 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 September 30,								
	Common Stock		Other Paid-In Capital	Retained Earnings	Accumulated Other Comprehensive Loss	Treasury Stock		Non-controlling Interests	Total
($ and shares in millions except per share amounts)	Shares	Par Value				Shares	Cost		
Balance at July 1, 2020	3,577	$ 1,788	$ 39,373	$ 49,724	$ (6,393)	1,048	$ (56,850)	$ 102	$ 27,744
Net income attributable to Merck & Co., Inc.	—	—	—	2,941	—	—	—	—	2,941
Other comprehensive income, net of taxes	—	—	—	—	10	—	—	—	10
Cash dividends declared on common stock ($0.61 per share)	—	—	—	(1,558)	—	—	—	—	(1,558)
Share-based compensation plans and other	—	—	116	—	—	(1)	35	—	151
Net income attributable to noncontrolling interests	—	—	—	—	—	—	—	4	4
Distributions attributable to noncontrolling interests	—	—	—	—	—	—	—	(22)	(22)
Balance at September 30, 2020	3,577	$ 1,788	$ 39,489	$ 51,107	$ (6,383)	1,047	$ (56,815)	$ 84	$ 29,270
Balance at July 1, 2021	3,577	$ 1,788	$ 44,039	$ 48,777	$ (4,628)	1,044	$ (56,682)	$ 94	$ 33,388
Net income attributable to Merck & Co., Inc.	—	—	—	4,567	—	—	—	—	4,567
Other comprehensive income, net of taxes	—	—	—	—	38	—	—	—	38
Cash dividends declared on common stock ($0.65 per share)	—	—	—	(1,653)	—	—	—	—	(1,653)
Treasury stock shares purchased	—	—	—	—	—	8	(583)	—	(583)
Share-based compensation plans and other	—	—	110	—	—	—	21	—	131
Net income attributable to noncontrolling interests	—	—	—	—	—	—	—	4	4
Distributions attributable to noncontrolling interests	—	—	—	—	—	—	—	(29)	(29)
Balance at September 30, 2021	3,577	1,788	44,149	51,691	(4,590)	1,052	(57,244)	69	35,863

	Nine Months Ended September 30,								
	Common Stock		Other Paid-In Capital	Retained Earnings	Accumulated Other Comprehensive Loss	Treasury Stock		Non-controlling Interests	Total
($ and shares in millions except per share amounts)	Shares	Par Value				Shares	Cost		
Balance at January 1, 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.	—	—	—	9,161	—	—	—	—	9,161
Other comprehensive loss, net of taxes	—	—	—	—	(190)	—	—	—	(190)
Cash dividends declared on common stock ($1.83 per share)	—	—	—	(4,656)	—	—	—	—	(4,656)
Treasury stock shares purchased	—	—	—	—	—	16	(1,281)	—	(1,281)
Share-based compensation plans and other	—	—	(171)	—	—	(7)	416	—	245
Net income attributable to noncontrolling interests	—	—	—	—	—	—	—	12	12
Distributions attributable to noncontrolling interests	—	—	—	—	—	—	—	(22)	(22)
Balance at September 30, 2020	3,577	1,788	39,489	51,107	(6,383)	1,047	(56,815)	84	29,270
Balance at January 1, 2021	3,577	$ 1,788	$ 39,588	$ 47,362	$ (6,634)	1,047	$ (56,787)	$ 87	$ 25,404
Net income attributable to Merck & Co., Inc.	—	—	—	9,291	—	—	—	—	9,291
Other comprehensive income, net of taxes	—	—	—	—	1,595	—	—	—	1,595
Cash dividends declared on common stock ($1.95 per share)	—	—	—	(4,962)	—	—	—	—	(4,962)
Treasury stock shares purchased	—	—	—	—	—	11	(822)	—	(822)
Spin-off of Organon & Co.	—	—	4,643	—	449	—	—	(1)	5,091
Share-based compensation plans and other	—	—	(82)	—	—	(6)	365	—	283
Net income attributable to noncontrolling interests	—	—	—	—	—	—	—	12	12
Distributions attributable to noncontrolling interests	—	—	—	—	—	—	—	(29)	(29)
Balance at September 30, 2021	3,577	1,788	44,149	51,691	(4,590)	1,052	(57,244)	69	35,863

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 September 30,				Nine Months Ended September 30,			
	2021		2020		2021		2020	
($ in millions)	U.S.	International	U.S.	International	U.S.	International	U.S.	International
Service cost	$ 104	$ 75	$ 96	$ 76	$ 302	$ 254	$ 270	$ 222
Interest cost	102	33	107	35	305	92	323	102
Expected return on plan assets	(188)	(105)	(193)	(104)	(568)	(313)	(581)	(309)
Amortization of unrecognized prior service credit	(9)	(3)	(12)	(3)	(29)	(12)	(37)	(9)
Net loss amortization	75	32	75	32	218	110	228	94
Termination benefits	2	—	1	1	54	3	5	2
Curtailments	(1)	—	1	—	15	(27)	4	(1)
Settlements	139	—	2	—	139	2	11	2
	$ 224	$ 32	$ 77	$ 37	$ 436	$ 109	$ 223	$ 103

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
($ in millions)	2021	2020	2021	2020
Service cost	$ 11	$ 13	$ 37	$ 39
Interest cost	12	14	34	43
Expected return on plan assets	(20)	(19)	(59)	(56)
Amortization of unrecognized prior service credit	(16)	(18)	(48)	(54)
Net gain amortization	(12)	(5)	(30)	(13)
Termination benefits	—	—	37	—
Curtailments	(1)	—	(29)	(1)
	$ (26)	$ (15)	$ (58)	$ (42)

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

In connection with restructuring actions (see Note 5), termination charges were recorded on pension plans related to expanded eligibility for certain employees exiting Merck. Also, in connection with these restructuring actions, curtailments and settlements were recorded on pension plans. In addition, lump sum payments to U.S. pension plan participants triggered a partial settlement resulting in a charge of approximately $125 million in the third quarter and first nine months of 2021. This partial settlement triggered a remeasurement of some of the Company's U.S. pension plans. This remeasurement, which was calculated using discount rates and asset values as of September 30, 2021, resulted in a net increase of $160 million to net pension liabilities and also resulted in a related adjustment to *AOCL*.

The components of net periodic benefit cost (credit) other than the service cost component are included in *Other (income) expense, net* (see Note 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 *AOCL* (see Note 15).

12. Other (Income) Expense, Net

Other (income) expense, net, consisted of:

	Three Months Ended September 30,		Nine Months Ended September 30,	
($ in millions)	2021	2020	2021	2020
Interest income	$ (7)	$ (9)	$ (27)	$ (48)
Interest expense	196	203	597	624
Exchange losses	46	10	202	89
Income from investments in equity securities, net [(1)]	(683)	(360)	(1,535)	(964)
Net periodic defined benefit plan cost (credit) other than service cost	40	(88)	(159)	(259)
Other, net	(42)	(68)	(85)	(79)
	$ (450)	$ (312)	$ (1,007)	$ (637)

[(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 $540 million will be recorded in the fourth quarter of 2021 from ownership interests in investment funds.*

Interest paid for the nine months ended September 30, 2021 and 2020 was $570 million and $605 million, respectively.

13. Taxes on Income

The effective income tax rates from continuing operations were 13.2% and 14.0% for the third quarter of 2021 and 2020, respectively, and 14.4% and 15.1% for the first nine months of 2021 and 2020, respectively. The effective tax rates from continuing operations in the third quarter and first nine months of 2021 reflect the beneficial impact of the settlement of a foreign tax matter. The effective income tax rate from continuing operations for the first nine months of 2021 reflects the unfavorable effect of a charge for the acquisition of Pandion for which no tax benefit was recognized, as well as a net tax benefit of $207 million related to the settlement of certain federal income tax matters as discussed below.

In the first quarter of 2021, the Internal Revenue Service (IRS) concluded its examinations of Merck's 2015-2016 U.S. federal income tax returns. As a result, the Company was required to make a payment of $190 million (of which $172 million related to 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 nine 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:

	Three Months Ended September 30,		Nine Months Ended September 30,	
($ and shares in millions except per share amounts)	2021	2020	2021	2020
Net Income from Continuing Operations Attributable to Merck & Co., Inc.	$ 4,567	$ 2,324	$ 8,525	$ 7,136
Income from Discontinued Operations, Net of Taxes and Amounts Attributable to Noncontrolling Interests	—	617	766	2,025
Net Income Attributable to Merck & Co., Inc.	$ 4,567	$ 2,941	$ 9,291	$ 9,161
Average common shares outstanding	2,530	2,529	2,531	2,530
Common shares issuable [(1)]	6	9	8	11
Average common shares outstanding assuming dilution	2,536	2,538	2,539	2,541
Basic Earnings per Common Share Attributable to Merck & Co., Inc. Common Shareholders:				
Income from Continuing Operations	$ 1.81	$ 0.92	$ 3.37	$ 2.82
Income from Discontinued Operations	—	0.24	0.30	0.80
Net Income	$ 1.81	$ 1.16	$ 3.67	$ 3.62
Earnings per Common Share Assuming Dilution Attributable to Merck & Co., Inc. Common Shareholders:				
Income from Continuing Operations	$ 1.80	$ 0.92	$ 3.36	$ 2.81
Income from Discontinued Operations	—	0.24	0.30	0.80
Net Income	$ 1.80	$ 1.16	$ 3.66	$ 3.61

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

For the third quarter of 2021 and 2020, 8 million and 5 million, respectively, and for the first nine months of 2021 and 2020, 10 million and 5 million, respectively, of common shares issuable under share-based compensation plans were excluded from the computation of earnings per common share assuming dilution because the effect would have been antidilutive.

15. Other Comprehensive Income (Loss)

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

	Three Months Ended September 30,				
($ in millions)	Derivatives	Investments	Employee Benefit Plans	Foreign Currency Translation Adjustment	Accumulated Other Comprehensive Income (Loss)
Balance July 1, 2020, net of taxes	$ 15	$ —	$ (4,162)	$ (2,246)	$ (6,393)
Other comprehensive income (loss) before reclassification adjustments, pretax	(195)	—	2	50	(143)
Tax	41	—	1	35	77
Other comprehensive income (loss) before reclassification adjustments, net of taxes	(154)	—	3	85	(66)
Reclassification adjustments, pretax	22 (1)	—	72 (3)	—	94
Tax	(5)	—	(13)	—	(18)
Reclassification adjustments, net of taxes	17	—	59	—	76
Other comprehensive income (loss), net of taxes	(137)	—	62	85	10
Balance September 30, 2020, net of taxes	$ (122)	$ —	$ (4,100)	$ (2,161)	$ (6,383)
Balance July 1, 2021, net of taxes	$ (26)	$ —	$ (3,028)	$ (1,574)	$ (4,628)
Other comprehensive income (loss) before reclassification adjustments, pretax	72	—	(24)	(96)	(48)
Tax	(16)	—	16	12	12
Other comprehensive income (loss) before reclassification adjustments, net of taxes	56	—	(8)	(84)	(36)
Reclassification adjustments, pretax	36 (1)	—	68 (3)	—	104
Tax	(8)	—	(22)	—	(30)
Reclassification adjustments, net of taxes	28	—	46	—	74
Other comprehensive income (loss), net of taxes	84	—	38	(84)	38
Balance September 30, 2021, net of taxes	$ 58	$ —	$ (2,990)	$ (1,658)	$ (4,590)

	Nine Months Ended September 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	(126)	3	(19)	(220)	(362)
Tax	27	—	12	40	79
ther comprehensive income (loss) before reclassification adjustments, net of taxes	(99)	3	(7)	(180)	(283)
Reclassification adjustments, pretax	(68)(1)	(21)(2)	210(3)	—	121
Tax	14	—	(42)	—	(28)
eclassification adjustments, net of taxes	(54)	(21)	168	—	93
ther comprehensive income (loss), net of taxes	(153)	(18)	161	(180)	(190)
alance September 30, 2020, net of taxes	$ (122)	$ —	$ (4,100)	$ (2,161)	$ (6,383)
alance January 1, 2021, net of taxes	$ (266)	$ —	$ (4,540)	$ (1,828)	$ (6,634)
Other comprehensive income (loss) before reclassification adjustments, pretax	193	—	1,739	(167)	1,765
Tax	(41)	—	(385)	(84)	(510)
ther comprehensive income (loss) before reclassification adjustments, net of taxes	152	—	1,354	(251)	1,255
Reclassification adjustments, pretax	218(1)	—	210(3)	—	428
Tax	(46)	—	(42)	—	(88)
eclassification adjustments, net of taxes	172	—	168	—	340
ther comprehensive income (loss), net of taxes	324	—	1,522	(251)	1,595
pin-off of Organon (see Note 2)	—	—	28	421	449
alance September 30, 2021, net of taxes	$ 58	$ —	$ (2,990)	$ (1,658)	$ (4,590)

(1) *Primarily relates to foreign currency cash flow hedges that were reclassified from* AOCL *to* Sales.
(2) *Represents net realized gains on the sales of available-for-sale debt securities that were reclassified from* AOCL *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 September 30,						Nine Months Ended September 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	$ 2,580	$ 1,954	$ 4,534	$ 2,157	$ 1,559	$ 3,715	$ 7,108	$ 5,501	$ 12,609	$ 6,106	$ 4,281	$ 10,387
Alliance revenue - Lynparza [1]	129	117	246	107	89	196	371	350	721	297	223	519
Alliance revenue - Lenvima [1]	114	74	188	82	60	142	287	211	498	270	152	421
Vaccines												
Gardasil/Gardasil 9	839	1,154	1,993	579	608	1,187	1,605	2,539	4,144	1,209	1,732	2,941
ProQuad/M-M-R II/*Varivax*	537	125	661	437	139	576	1,255	371	1,626	1,033	356	1,390
Pneumovax 23	181	97	277	276	99	375	354	247	600	478	270	748
RotaTeq	135	92	227	114	96	210	364	229	593	355	246	601
Vaqta	32	16	48	32	19	51	80	58	138	79	60	139
Hospital Acute Care												
Bridion	181	188	369	162	157	320	545	551	1,096	412	431	843
Prevymis	39	57	96	32	46	77	111	159	270	87	113	200
Noxafil	19	45	64	13	66	79	48	149	197	27	220	247
Primaxin	—	69	70	1	73	74	—	194	194	2	187	189
Cancidas	1	56	56	1	49	50	4	164	168	2	147	148
Invanz	(2)	55	53	1	50	51	(2)	159	157	7	152	159
Zerbaxa	(1)	(1)	(2)	20	23	43	(5)	(6)	(11)	57	54	112
Immunology												
Simponi	—	203	203	—	209	209	—	619	619	—	615	615
Remicade	—	73	73	—	82	82	—	233	233	—	242	242
Neuroscience												
Belsomra	23	58	81	18	63	81	56	183	238	67	177	244
Virology												
Isentress/Isentress HD	77	112	189	92	113	205	222	368	590	243	403	646
Cardiovascular												
Alliance revenue-Adempas/Verquvo [2]	73	27	100	78	5	83	222	26	248	200	16	216
Adempas	—	59	59	—	55	55	—	188	188	—	167	167
Diabetes												
Januvia	365	487	852	342	479	821	997	1,448	2,445	1,110	1,339	2,449
Janumet	86	401	487	105	400	506	244	1,205	1,449	361	1,138	1,499
Other pharmaceutical [3]	262	308	572	193	333	526	745	957	1,704	706	969	1,675
Total Pharmaceutical segment sales	5,670	5,826	11,496	4,842	4,872	9,714	14,611	16,103	30,714	13,108	13,690	26,797
Animal Health:												
Livestock	190	675	864	165	593	758	508	1,996	2,503	448	1,697	2,145
Companion Animals	277	276	553	234	228	462	855	948	1,804	676	714	1,390
Total Animal Health segment sales	467	951	1,417	399	821	1,220	1,363	2,944	4,307	1,124	2,411	3,535
Other segment sales [4]	—	—	—	—	—	—	—	—	—	23	—	23
Total segment sales	6,137	6,777	12,913	5,241	5,693	10,934	15,974	19,047	35,021	14,255	16,101	30,355
Other [5]	139	101	241	9	(14)	(5)	192	(30)	162	46	168	215
	$ 6,276	$ 6,878	$ 13,154	$ 5,250	$ 5,679	$ 10,929	$ 16,166	$ 19,017	$ 35,183	$ 14,301	$ 16,269	$ 30,570

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. Other for the three and nine months ended September 30, 2021 also includes $135 million and $185 million, respectively, related to the achievement of milestones for an out-licensed product that triggered contingent payments to Merck.

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 $2.9 billion for the three months ended September 30, 2021 and 2020, respectively, and $9.1 billion and $8.3 billion for the nine months ended September 30, 2021 and 2020, respectively.

Consolidated sales by geographic area where derived are as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
($ in millions)	2021	2020	2021	2020
United States	$ 6,276	$ 5,250	$ 16,166	$ 14,301
Europe, Middle East and Africa	3,342	2,946	9,912	8,537
China	1,307	791	3,004	2,060
Japan	638	671	1,929	1,875
Asia Pacific (other than China and Japan)	613	545	1,782	1,560
Latin America	599	499	1,631	1,374
Other	379	227	759	863
	$ 13,154	$ 10,929	$ 35,183	$ 30,570

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
($ in millions)	2021	2020	2021	2020
Segment profits:				
Pharmaceutical segment	$ 8,606	$ 7,026	$ 22,450	$ 19,235
Animal Health segment	505	459	1,629	1,347
Other segment	—	(1)	—	1
Total segment profits	9,111	7,484	24,079	20,583
Other profits	141	(28)	29	135
Unallocated:				
Interest income	7	9	27	48
Interest expense	(196)	(203)	(597)	(624)
Amortization	(360)	(406)	(1,231)	(1,393)
Depreciation	(358)	(367)	(1,031)	(1,105)
Research and development	(2,312)	(3,231)	(8,775)	(7,251)
Restructuring costs	(107)	(113)	(487)	(265)
Other unallocated, net	(660)	(439)	(2,044)	(1,720)
	$ 5,266	$ 2,706	$ 9,970	$ 8,408

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

In September 2021, Merck and Acceleron Pharma Inc. (Acceleron), a publicly traded biopharmaceutical company, entered into a definitive agreement under which Merck will acquire Acceleron for $180 per share in cash for an approximate total equity value of $11.5 billion. Acceleron is focused on harnessing the power of the transforming growth factor (TGF)-beta superfamily of proteins that is known to play a central role in the regulation of cell growth, differentiation and repair. Under the terms of the acquisition agreement, Merck, through a subsidiary, initiated a tender offer to acquire all outstanding shares of Acceleron. The closing of the tender offer is subject to certain conditions, including the tender of shares representing at least a majority of the total number of Acceleron's outstanding shares, receipt of applicable regulatory approvals, and other customary conditions. The transaction is expected to close in the fourth quarter of 2021.

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 third quarter and first nine months of 2021, Merck continues to experience strong global underlying demand across its business.

In the third quarter and first nine months of 2021, the estimated negative impact of the COVID-19 pandemic to Merck's sales was approximately $350 million and $1.3 billion, respectively, all of which related to the Pharmaceutical segment. In the third quarter and first nine months of 2020, the estimated negative impact of the COVID-19 pandemic to Merck's Pharmaceutical sales was approximately $400 million and $1.7 billion, respectively. 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 $207 million to *Cost of sales* in the first nine months of 2021.

Operating expenses reflect a minor positive effect in the third quarter and first nine 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 third quarter and first nine months of 2020 by approximately $100 million and $500 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 November 2021, the Medicines and Healthcare products Regulatory Agency in the United Kingdom (U.K.) granted authorization for molnupiravir (MK-4482, EIDD-2801), an investigational oral antiviral medicine, for the treatment of mild-to-moderate COVID-19 in adults with a positive SARS-CoV-2 diagnostic test and who have at least one risk factor for developing severe illness. The authorization is based on positive results from a planned interim analysis from the Phase 3 MOVe-OUT clinical trial, which evaluated molnupiravir in non-hospitalized, unvaccinated adult patients with laboratory-confirmed mild-to-moderate COVID-19, symptom onset within five days of study randomization and at least one risk factor associated with poor disease outcomes. In the U.K., *Lagevrio* is the planned trademark for molnupiravir. In October 2021, Merck submitted an Emergency Use Authorization (EUA) application to the U.S. Food and Drug Administration (FDA) for molnupiravir for the treatment of mild-to-moderate COVID-19 in adults who are at risk for progressing to severe COVID-19 and/or hospitalization. The FDA subsequently announced a November 30, 2021 meeting of its Antimicrobial Drugs Advisory Committee to discuss the available data supporting the use of molnupiravir to treat mild-to-moderate COVID-19 in adults who have tested positive for COVID-19 and who are at high risk of progression to severe COVID-19, including hospitalization or death. Also in October 2021, the European Medicines Agency (EMA) initiated a rolling review for molnupiravir. Merck plans to work with the Committee for Medicinal Products for Human Use (CHMP) of the EMA to complete the rolling review process to facilitate initiating the formal review of the Marketing Authorization Application. Merck is developing molnupiravir in collaboration with Ridgeback Biotherapeutics LP (Ridgeback Bio). The companies are actively working with other regulatory agencies worldwide to submit applications for emergency use or marketing authorization in the coming months. In anticipation of the results from the MOVe-OUT trial and the potential for regulatory authorization or approval, Merck has been producing molnupiravir at risk. Merck expects to produce 10 million courses of treatment by the end of 2021, with at least 20 million additional courses expected to be produced in 2022. In June 2021, Merck announced a procurement agreement with the U.S. government under which Merck will supply approximately 1.7 million courses of molnupiravir to the U.S. government upon EUA or approval from the FDA, which will be delivered in scheduled increments. This procurement of molnupiravir will be supported in whole or in part with federal funds. Additionally, Merck has entered into supply and advance purchase commitments for molnupiravir with other governments worldwide, including Australia, South Korea and New Zealand pending regulatory authorization, as well as the U.K., and is currently in discussions with other governments. 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.

Merck is committed to providing timely access to molnupiravir globally, if it is authorized or approved, and intends to implement a tiered pricing approach based on World Bank country income criteria to reflect countries' relative ability to finance their health response to the pandemic. As part of its commitment to widespread global access, Merck has entered into non-exclusive voluntary licensing agreements for molnupiravir with established Indian generic manufacturers. Merck and the Medicines Patent Pool (MPP) also signed a voluntary licensing agreement to facilitate affordable global access for molnupiravir. Under the terms of the agreement, the MPP will be permitted to further license non-exclusive sublicenses to manufacturers and diversify the manufacturing base for the supply of quality-assured or WHO-prequalified molnupiravir to countries covered by the MPP license, subject to local regulatory authorization. Merck, Ridgeback Bio and Emory University will not receive royalties for sales of molnupiravir under this agreement (molnupiravir was invented at Emory University and licensed to Ridgeback Bio) for as long as COVID-19 remains classified as a Public Health Emergency of International Concern by the World Health Organization. These agreements will help expand access to molnupiravir in more than 100 low- and middle-income countries.

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 nine months of 2021 was negatively affected by other cost-reduction measures taken by governments and other third parties to lower health care costs. In the U.S., the Biden Administration and Congress continue to discuss legislation designed to control health care costs, including the cost of drugs. The Company anticipates all of these actions and additional actions in the future will continue to negatively affect sales performance.

Operating Results

Sales

	Three Months Ended September 30,			% Change Excluding Foreign	Nine Months Ended September 30,			% Change Excluding Foreign
($ in millions)	2021	2020	% Change	Exchange	2021	2020	% Change	Exchange
United States	$ 6,276	$ 5,250	20 %	20 %	$ 16,166	$ 14,301	13 %	13 %
International	6,878	5,679	21 %	18 %	19,017	16,269	17 %	13 %
Total	$ 13,154	$ 10,929	20 %	19 %	$ 35,183	$ 30,570	15 %	13 %

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

Worldwide sales grew 20% to $13.2 billion in the third quarter of 2021 and rose 15% to $35.2 billion in the first nine months of 2021. Revenue performance in both periods primarily reflects higher sales in the oncology franchise largely driven by strong growth of *Keytruda* (pembrolizumab) and increased alliance revenue from Lynparza (olaparib) and Lenvima (lenvatinib), as well as higher sales in the vaccines franchise, primarily attributable to growth in *Gardasil* (Human Papillomavirus Quadrivalent [Types 6, 11, 16 and 18] Vaccine, Recombinant)/*Gardasil* 9 (Human Papillomavirus 9-valent Vaccine, Recombinant), *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 third quarter and first nine months of 2021. Additionally, sales in the third quarter and first nine months of 2021 also benefited from the achievement of milestones for an out-licensed product that triggered contingent payments to Merck. As discussed above, the COVID-19 pandemic unfavorably affected sales in the third quarter and first nine 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 *Pneumovax* 23 (pneumococcal vaccine polyvalent) and the suspension of sales of hospital acute care product *Zerbaxa* (ceftolozane and tazobactam) for injection. Lower sales of diabetes product *Janumet* (sitagliptin/metformin HCl) also partially offset revenue growth in the first nine months of 2021.

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

Pharmaceutical Segment

Oncology

($ in millions)	Three Months Ended September 30, 2021	2020	% Change	% Change Excluding Foreign Exchange	Nine Months Ended September 30, 2021	2020	% Change	% Change Excluding Foreign Exchange
Keytruda	$ 4,534	$ 3,715	22 %	21 %	$ 12,609	$ 10,387	21 %	19 %
Alliance Revenue - Lynparza [(1)]	246	196	25 %	25 %	721	519	39 %	35 %
Alliance Revenue - Lenvima [(1)]	188	142	32 %	30 %	498	421	18 %	15 %

[(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 (TMB-H) 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 both endometrial carcinoma and RCC. The *Keytruda* clinical development program includes studies across a broad range of cancer types. See "Research and Development Update" below.

Global sales of *Keytruda* grew 22% and 21% in the third quarter and first nine 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, TNBC, MSI-H cancer, esophageal cancer and HNSCC indications. *Keytruda* sales growth in international markets was driven by continued uptake predominately for the NSCLC, HNSCC and RCC indications, particularly in Europe. Sales growth in the third quarter and first nine months of 2021 was partially offset by lower pricing in Europe, China and 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 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 August 2021, Merck announced a label update for *Keytruda* for its indication in first-line advanced urothelial carcinoma (bladder cancer) in the U.S. The FDA has converted this indication from an accelerated to a full (regular) approval.

In addition, as part of the label update, this indication has been revised to be for the treatment of patients with locally advanced or metastatic urothelial carcinoma who are not eligible for any platinum-containing chemotherapy.

Also in August 2021, the FDA approved the combination of *Keytruda* and Lenvima for the first-line treatment of adult patients with advanced RCC based on results from the KEYNOTE-581 trial/Study 307 trial.

In October 2021, the FDA approved *Keytruda* in combination with chemotherapy, with or without bevacizumab, for the treatment of patients with persistent, recurrent or metastatic cervical cancer based on the KEYNOTE-826 trial. Additionally, the FDA converted the accelerated approval of *Keytruda* as a single agent for the treatment of patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy to a regular approval based on confirmatory data from KEYNOTE-826. This approval was originally granted in June 2018 based on results from the KEYNOTE-158 trial.

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.

In October 2021, the EC approved *Keytruda* in combination with chemotherapy for the first-line 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 KEYNOTE-355 trial.

In August 2021, *Keytruda* received two new approvals from the Japan Pharmaceuticals and Medical Devices Agency: for the treatment of patients with PD-L1-positive, hormone receptor-negative and HER2-negative, inoperable or recurrent breast cancer, based on the results of the KEYNOTE-355 trial; and as a monotherapy for the treatment of patients with unresectable, advanced or recurrent MSI-H colorectal cancer, based on results of the KEYNOTE-177 trial.

In June 2021, *Keytruda* was approved by the China National Medical Products Administration (NMPA) as a first-line treatment in adult patients with MSI-H or dMMR colorectal cancer that is KRAS, NRAS and BRAF (all wild-type) based on the results of the KEYNOTE-177 study. In September 2021, *Keytruda* was approved by the China NMPA in combination with chemotherapy for the first-line treatment of patients with locally advanced unresectable or metastatic carcinoma of the esophagus or gastroesophageal junction based on 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 25% and 39% in the third quarter and first nine months of 2021, respectively. Sales growth in both periods was largely driven by continued uptake across the multiple approved indications in the U.S. and Europe. Higher demand in China also contributed to sales growth in the year-to-date period. In June 2021, Lynparza was granted conditional approval in China as monotherapy for the treatment of certain previously treated 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, RCC, HCC, in combination with everolimus for certain patients with RCC, in combination with *Keytruda* for the treatment of certain patients with endometrial carcinoma, and in combination with *Keytruda* for the treatment of certain patients with RCC. Alliance revenue related to Lenvima grew 32% and 18% in the third quarter and first nine months of 2021, respectively. Sales growth in both periods reflects higher demand in China and the U.S.

In June 2021, Koselugo (selumetinib) was granted conditional approval in the EU for the treatment of pediatric patients three 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.

In August 2021, the FDA approved *Welireg* (belzutifan), an oral hypoxia-inducible factor-2 alpha (HIF-2α) inhibitor, for the treatment of adult patients with von Hippel-Lindau (VHL) disease who require therapy for associated RCC, central nervous system hemangioblastomas, or pancreatic neuroendocrine tumors, not requiring immediate surgery. The approval was based on results from the open-label Study 004 trial. *Welireg* was obtained as part of Merck's 2019 acquisition of Peloton Therapeutics, Inc. (Peloton). Pursuant to the acquisition agreement, Merck made a $50 million capitalized milestone payment to former Peloton shareholders upon first commercial sale of *Welireg* in the U.S.

Vaccines

	Three Months Ended September 30,			% Change Excluding Foreign Exchange	Nine Months Ended September 30,			% Change Excluding Foreign Exchange
($ in millions)	2021	2020	% Change		2021	2020	% Change	
Gardasil/Gardasil 9	$ 1,993	$ 1,187	68 %	63 %	$ 4,144	$ 2,941	41 %	35 %
ProQuad	244	218	12 %	12 %	598	507	18 %	17 %
M-M-R II	127	115	11 %	10 %	295	287	3 %	2 %
Varivax	290	243	19 %	19 %	733	595	23 %	23 %
Pneumovax 23	277	375	(26)%	(26) %	600	748	(20)%	(21) %
RotaTeq	227	210	8 %	7 %	593	601	(1)%	(3) %

Worldwide sales of *Gardasil/Gardasil* 9, vaccines to help prevent certain cancers and other diseases caused by certain types of human papillomavirus (HPV), grew 68% and 41% in the third quarter and first nine months of 2021, respectively. Sales growth in both periods was driven primarily by strong global demand, particularly in China which also benefited from increased supply, and in the U.S. which also benefited from the timing of public sector purchases. 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 12% and 18% in the third quarter and first nine 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 11% and 3% in the third quarter and first nine months of 2021, respectively, primarily due to higher sales in the U.S. reflecting the ongoing COVID-19 pandemic recovery inclusive of higher public sector mix of business. Lower demand and lower government tenders in international markets partially offset *M-M-R* II sales growth in both periods.

Global sales of *Varivax*, a vaccine to help prevent chickenpox (varicella), grew 19% and 23% in the third quarter and first nine months of 2021, respectively, primarily reflecting the ongoing COVID-19 pandemic recovery and higher pricing in the U.S. Higher government tenders in Brazil also contributed to *Varivax* sales growth for the first nine months of 2021.

Worldwide sales of *Pneumovax* 23, a vaccine to help prevent pneumococcal disease, declined 26% and 20% in the third quarter and first nine months of 2021, respectively, primarily driven by lower demand in the U.S. reflecting prioritization of COVID-19 vaccination.

Global sales of *RotaTeq* (Rotavirus Vaccine, Live Oral, Pentavalent), a vaccine to help protect against rotavirus gastroenteritis in infants and children, grew 8% in the third quarter of 2021 largely attributable to higher public sector purchases in the U.S., partially offset by lower demand in certain international markets. Worldwide sales of *RotaTeq* declined 1% in the first nine months of 2021 reflecting lower demand in certain international markets, partially offset by higher public sector purchases in the U.S.

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. In October 2021, the U.S. Centers for Disease Control and Prevention's (CDC's) Advisory Committee on Immunization Practices (ACIP) voted to provisionally recommend vaccination either with a sequential regimen of *Vaxneuvance* followed by *Pneumovax* 23, or with a single dose of 20-valent pneumococcal conjugate vaccine both for adults 65 years and older and for adults ages 19 to 64 with certain underlying medical conditions. These provisional recommendations will be reviewed by the director of the CDC and the U.S. Department of Health and Human Services, and final recommendations will become official when published in the CDC's *Morbidity and Mortality Weekly Report*. In September 2021, Merck announced a settlement and license agreement with Pfizer Inc., (Pfizer) resolving all worldwide patent infringement litigation related to the use of Merck's investigational and licensed pneumococcal conjugate vaccine (PCV) products, including *Vaxneuvance*. Under the terms of the agreement, Merck will make certain regulatory milestone payments to Pfizer, as well as royalty payments on the worldwide sales of its PCV products. The Company will pay royalties of 7.25% of net sales of all Merck PCV products through 2026; and 2.5% of net sales of all Merck PCV products from 2027 through 2035.

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 September 30,			% Change Excluding Foreign	Nine Months Ended September 30,			% Change Excluding Foreign
($ in millions)	2021	2020	% Change	Exchange	2021	2020	% Change	Exchange
Bridion	$ 369	$ 320	16 %	15 %	$ 1,096	$ 843	30 %	27 %
Prevymis	96	77	23 %	22 %	270	200	35 %	31 %
Noxafil	64	79	(19)%	(20)%	197	247	(20)%	(23)%
Zerbaxa	(2)	43	(105)%	(105)%	(11)	112	(110)%	(110)%

Worldwide sales of *Bridion*, for the reversal of two types of neuromuscular blocking agents used during surgery, grew 16% and 30% in the third quarter and first nine months of 2021, respectively, due to higher demand globally, particularly in the U.S. and Europe, attributable in part to the COVID-19 pandemic recovery. *Bridion* was also 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 23% and 35% in the third quarter and first nine 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 19% and 20% in the third quarter and first nine 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 expects a phased resupply for *Zerbaxa* beginning with the U.S. market in the fourth quarter of 2021.

Immunology

	Three Months Ended September 30,			% Change Excluding Foreign	Nine Months Ended September 30,			% Change Excluding Foreign
($ in millions)	2021	2020	% Change	Exchange	2021	2020	% Change	Exchange
Simponi	$ 203	$ 209	(3) %	(5) %	$ 619	$ 615	1 %	(5) %

Sales of *Simponi* (golimumab), a once-monthly subcutaneous treatment for certain inflammatory diseases (marketed by the Company in Europe, Russia and Turkey), declined 3% in the third quarter of 2021 and increased 1% in the first nine months of 2021. Excluding the effect of foreign exchange, sales performance in both periods was largely attributable to lower pricing in Company's marketing territories in Europe, partially offset by higher volumes. 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

	Three Months Ended September 30,			% Change Excluding Foreign	Nine Months Ended September 30,			% Change Excluding Foreign
($ in millions)	2021	2020	% Change	Exchange	2021	2020	% Change	Exchange
Isentress/Isentress HD	$ 189	$ 205	(8) %	(7) %	$ 590	$ 646	(9) %	(9) %

Global combined sales of *Isentress/Isentress HD* (raltegravir), an HIV integrase inhibitor for use in combination with other antiretroviral agents for the treatment of HIV-1 infection, declined 8% and 9% in the third quarter and first nine months of 2021, respectively, primarily due to competitive pressure particularly in Europe and the U.S. The Company expects competitive pressure for *Isentress/Isentress HD* to continue.

Cardiovascular

	Three Months Ended September 30,			% Change Excluding Foreign	Nine Months Ended September 30,			% Change Excluding Foreign
($ in millions)	2021	2020	% Change	Exchange	2021	2020	% Change	Exchange
Alliance Revenue - Adempas/Verquvo [(1)]	$ 100	$ 83	20 %	20 %	$ 248	$ 216	15 %	15 %
Adempas	59	55	7 %	8 %	188	167	13 %	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 grew 20% and 15% in the third quarter and first nine months of 2021, respectively. Revenue from the collaboration also includes sales of Adempas in Merck's marketing territories, which grew 7% and 13% in the third quarter and first nine months of 2021, respectively, primarily reflecting higher demand.

In January 2021, the FDA approved Verquvo (vericiguat), 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 September 30, 2021	2020	% Change	% Change Excluding Foreign Exchange	Nine Months Ended September 30, 2021	2020	% Change	% Change Excluding Foreign Exchange
Januvia/Janumet	$ 1,339	$ 1,327	1 %	— %	$ 3,895	$ 3,948	(1) %	(4) %

Worldwide combined sales of *Januvia* (sitagliptin) and *Janumet*, medicines that help lower blood sugar levels in adults with type 2 diabetes, declined 1% in the first nine months of 2021 primarily due to continued pricing pressure and lower demand in the U.S., largely offset by higher demand in China and Latin America. 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 September 30, 2021	2020	% Change	% Change Excluding Foreign Exchange	Nine Months Ended September 30, 2021	2020	% Change	% Change Excluding Foreign Exchange
Livestock	$ 864	$ 758	14 %	12 %	$ 2,503	$ 2,145	17 %	14 %
Companion Animal	553	462	20 %	18 %	1,804	1,390	30 %	26 %

Sales of livestock products grew 14% and 17% in the third quarter and first nine months of 2021, respectively, primarily due to higher demand for ruminant products, including animal health intelligence solutions for animal identification, monitoring and traceability, as well as higher demand for poultry and swine products. Sales of companion animal products grew 20% and 30% in the third quarter and first nine months of 2021, respectively, primarily due to higher demand for parasiticides, including the *Bravecto* (fluralaner) line of products, as well as higher demand for vaccines.

Costs, Expenses and Other

($ in millions)	Three Months Ended September 30, 2021	2020	% Change	Nine Months Ended September 30, 2021	2020	% Change
Cost of sales	$ 3,450	$ 3,013	15 %	$ 9,752	$ 8,589	14 %
Selling, general and administrative	2,336	2,060	13 %	6,804	6,336	7 %
Research and development	2,445	3,349	(27)%	9,177	7,609	21 %
Restructuring costs	107	113	(5)%	487	265	84 %
Other (income) expense, net	(450)	(312)	44 %	(1,007)	(637)	58 %
	$ 7,888	$ 8,223	(4)%	25,213	22,162	14 %

Cost of Sales

Cost of sales increased 15% and 14% in the third quarter and first nine months of 2021, respectively. Cost of sales includes the amortization of intangible assets recorded in connection with acquisitions, collaborations, and licensing arrangements, which totaled $346 million and $403 million in the third quarter of 2021 and 2020, respectively, and $1.2 billion and $1.4 billion for the first nine months of 2021 and 2020, respectively. Costs in the first nine months of 2021 also include charges of $225 million related to the discontinuation of COVID-19 development programs. Also included in cost of sales are expenses associated with restructuring activities which amounted to $48 million and $38 million in the third quarter of 2021 and 2020, respectively, and $113 million and $131 million for the first nine 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 73.8% in the third quarter of 2021 compared with 72.4% in the third quarter of 2020. The gross margin increase reflects lower amortization of intangible assets (noted above), as well as the favorable effect of product mix, partially offset by higher manufacturing costs, including asset write-offs. Gross margin was 72.3% in the first nine months of 2021 compared with 71.9% in the first nine months of 2020. The gross margin increase reflects lower amortization of intangible assets and the favorable effect of product mix, partially offset by 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, higher manufacturing costs and foreign exchange.

Selling, General and Administrative

Selling, general and administrative (SG&A) expenses increased 13% and 7% in the third quarter and first nine months of 2021, respectively, primarily due to higher administrative costs, including compensation and benefits, higher promotional expenses in support of the Company's key growth pillars, as well as the unfavorable effect of foreign exchange. The COVID-19 pandemic contributed to lower spending in the prior year periods.

Research and Development

Research and development (R&D) expenses declined 27% in the third quarter of 2021 primarily due to lower upfront payments related to collaborations, partially offset by higher oncology and COVID-19 clinical development spending, increased investment in discovery research and early drug development, as well as higher compensation and benefit costs. R&D expenses increased 21% in the first nine months of 2021 primarily due to higher upfront payments related to acquisitions and collaborations, as well as higher clinical development spending and increased investment in discovery research and early drug development. The COVID-19 pandemic contributed to lower spending in the prior year periods.

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 $1.6 billion in the third quarter of 2021 and 2020, respectively, and $5.3 billion and $4.6 billion in the first nine 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 $710 million and $625 million for the third quarter of 2021 and 2020, respectively, and $2.1 billion and $1.9 billion in the first nine months of 2021 and 2020, respectively. Additionally, R&D expenses in the first nine months of 2021 include a $1.7 billion charge for the acquisition of Pandion as noted above. R&D expenses in the third quarter and first nine months of 2020 include charges of $832 million related to transactions with Seagen Inc. (Seagen) (see Note 3 to the condensed consolidated financial statements).

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 will result in annual net cost savings of approximately $900 million by the end of 2023.

Restructuring costs, primarily representing separation and other related costs associated with these restructuring activities, were $107 million and $113 million for the third quarter of 2021 and 2020, respectively, and were $487 million and $265 million for the first nine 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 $168 million and $185 million in the third quarter of 2021 and 2020, respectively, and $630 million and $500 million, for the first nine 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 $450 million of income in the third quarter of 2021 compared with $312 million of income in the third quarter of 2020 primarily due to higher income from investments in equity securities, net, largely related to higher realized and unrealized gains on certain investments, partially offset by higher pension settlement costs. Other income (expense), net, was $1.0 billion of income in the first nine months of 2021 compared with $637 million of income in the first nine months of 2020 primarily due to higher income from investments in equity securities, net, largely related to higher realized and unrealized gains on certain investments including 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. The favorability in the year-to-date period was partially offset by higher pension settlement costs.

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

Segment Profits

	Three Months Ended September 30,		Nine Months Ended September 30,	
($ in millions)	2021	2020	2021	2020
Pharmaceutical segment profits	$ 8,606	$ 7,026	$ 22,450	$ 19,235
Animal Health segment profits	505	459	1,629	1,347
Other non-reportable segment profits	—	(1)	—	1
Other	(3,845)	(4,778)	(14,109)	(12,175)
Income from continuing operations before taxes	$ 5,266	$ 2,706	$ 9,970	$ 8,408

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 expense or income related to changes in the estimated fair value measurement of liabilities for contingent consideration. Additionally, segment profits do not reflect other expenses from corporate and manufacturing cost centers and other miscellaneous income or expense. These unallocated items are reflected in "Other" in the above table. Also included in "Other" are miscellaneous corporate profits (losses), as well as operating profits (losses) related to third-party manufacturing sales.

Pharmaceutical segment profits increased 22% and 17% in the third quarter and first nine months of 2021, respectively, reflecting higher sales and the favorable effect of foreign exchange, partially offset by higher administrative and promotional costs. Animal Health segment profits grew 10% and 21% in the third quarter and first nine months of 2021, respectively, reflecting higher sales, partially offset by higher promotional, selling and administrative costs.

Taxes on Income

The effective income tax rates from continuing operations were 13.2% and 14.0% for the third quarter of 2021 and 2020, respectively, and 14.4% and 15.1% for the first nine months of 2021 and 2020, respectively. The effective tax rates from continuing operations in the third quarter and first nine months of 2021 reflect the beneficial impact of the settlement of a foreign tax matter. The effective income tax rate from continuing operations for the first nine months of 2021 reflects the unfavorable effect of a charge for the acquisition of Pandion for which no tax benefit was recognized, as well as a net tax benefit of $207 million related to the settlement of certain federal income tax matters as discussed below.

In the first quarter of 2021, the Internal Revenue Service (IRS) concluded its examinations of Merck's 2015-2016 U.S. federal income tax returns. As a result, the Company was required to make a payment of $190 million (of which $172 million related to 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 nine 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 September 30,		Nine Months Ended September 30,	
($ in millions except per share amounts)	2021	2020	2021	2020
Income from continuing operations before taxes as reported under GAAP	$ 5,266	$ 2,706	$ 9,970	$ 8,408
Increase (decrease) for excluded items:				
Acquisition and divestiture-related costs	445	447	1,445	1,600
Restructuring costs	168	185	630	500
Income from investments in equity securities, net	(684)	(346)	(1,503)	(944)
Other items:				
Charge for the acquisition of Pandion	—	—	1,704	—
Charges for the discontinuation of COVID-19 development programs	—	—	225	—
Charges for the formation of collaborations [(1)]	—	1,082	—	1,082
Other	(87)	(1)	(26)	(17)
Non-GAAP income from continuing operations before taxes	5,108	4,073	12,445	10,629
Taxes on income from continuing operations as reported under GAAP	695	380	1,436	1,271
Estimated tax (expense) benefit on excluded items [(2)]	(30)	272	86	411
Net tax benefit from the settlement of certain federal income tax matters	—	—	207	—
Adjustment to tax benefits recorded in conjunction with the 2015 Cubist Pharmaceuticals, Inc. acquisition	—	(67)	—	(67)
Non-GAAP taxes on income from continuing operations	665	585	1,729	1,615
Non-GAAP net income from continuing operations	4,443	3,488	10,716	9,014
Less: Net income attributable to noncontrolling interests as reported under GAAP	4	2	9	1
Non-GAAP net income from continuing operations attributable to Merck & Co., Inc.	$ 4,439	$ 3,486	$ 10,707	$ 9,013
EPS from continuing operations assuming dilution as reported under GAAP	$ 1.80	$ 0.92	$ 3.36	$ 2.81
EPS difference	(0.05)	0.45	0.86	0.74
Non-GAAP EPS from continuing operations assuming dilution	$ 1.75	$ 1.37	$ 4.22	$ 3.55

[(1)] Includes $832 million related to transactions with Seagen (see Note 3 to the condensed consolidated financial statements).

[(2)] 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 for 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). Excluded from non-GAAP income and non-GAAP EPS in 2020 are upfront payments related to collaborations, including transactions with Seagen (see Note 3 to the condensed consolidated financial statements), and an adjustment to tax benefits recorded in conjunction with the 2015 Cubist Pharmaceuticals, Inc. acquisition.

Research and Development Update

MK-4482 (EIDD-2801), molnupiravir, is an investigational oral antiviral medicine, for the treatment of mild-to-moderate COVID-19 in adults who are at risk for progressing to severe COVID-19 and/or hospitalization. In October 2021, Merck submitted an EUA application to the FDA for molnupiravir based on positive results from a planned interim analysis of the Phase 3 MOVe-OUT clinical trial in which molnupiravir significantly reduced the risk of hospitalization or death in at risk, non-hospitalized adult patients with mild-to-moderate COVID-19. The FDA subsequently announced a November 30, 2021 meeting of its Antimicrobial Drugs Advisory Committee to discuss the available data supporting the use of molnupiravir to treat mild-to-moderate COVID-19 in adults who have tested positive for COVID-19 and who are at high risk of progression to severe COVID-19, including hospitalization or death. In October 2021, the EMA initiated a rolling review for molnupiravir. Merck plans to work with the CHMP of the EMA to complete the rolling review process to facilitate initiating the formal review of the Marketing Authorization Application. Merck is developing molnupiravir in collaboration with Ridgeback Bio. The companies are actively working with other regulatory agencies worldwide to submit applications for emergency use or marketing authorization in the coming months. Molnupiravir is also being evaluated for post-exposure prophylaxis in the Phase 3 MOVe-AHEAD trial, which is evaluating the efficacy and safety of molnupiravir in preventing the spread of COVID-19 within households. As previously announced, data from the MOVe-IN clinical trial indicated 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 was made not to proceed to Phase 3.

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, *Vaxneuvance* (Pneumococcal 15-valent Conjugate Vaccine), is an investigational 15-valent pneumococcal conjugate vaccine under review by the EMA for the prevention of invasive disease and pneumonia in adults. In October 2021, the EMA's CHMP recommended the approval of *Vaxneuvance* for active immunization for the prevention of invasive disease and pneumonia caused by *Streptococcus pneumoniae* in individuals 18 years of age and older. The CHMP recommendation will now be reviewed by the EC for marketing authorization in the EU, and a final decision is expected by the end of 2021. The CHMP opinion was based on data from seven randomized, double-blind clinical studies evaluating *Vaxneuvance* in a variety of adult populations and clinical circumstances. The Company has several ongoing Phase 3 trials evaluating V114 in pediatric patients. In August 2021, Merck announced positive topline results from the pivotal Phase 3 PNEU-PED study evaluating the immunogenicity, safety, and tolerability of *Vaxneuvance* in infants and has submitted a supplemental licensure application to the FDA for pediatric use. 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.

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 1,600 clinical trials, including nearly 1,200 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 IIB and IIC melanoma. These results were presented at the European Society of Medical Oncology (ESMO) Congress in September 2021. The FDA set a PDUFA date of December 4, 2021. *Keytruda* is also under review in the EU for this indication.

Keytruda is also under priority review by the FDA for the 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 data from the Phase 3 KEYNOTE-564 trial. The FDA set a PDUFA date of December 10, 2021. *Keytruda* is also under review in the EU and Japan for this indication.

Additionally, *Keytruda* is 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. The FDA set a PDUFA date of March 28, 2022.

Keytruda in combination with chemotherapy is under review in the EU and Japan for the treatment of patients with high-risk, early-stage TNBC as neoadjuvant treatment, and then as a single agent as adjuvent treatment after surgery based on the KEYNOTE-522 trial.

Keytruda is 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.

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.

Keytruda in combination with platinum-based chemotherapy with or without bevacizumab is also under review in Japan for the first-line treatment of patients with persistent, recurrent or metastatic cervical cancer based on the KEYNOTE-826 trial.

In October 2021, the CHMP of the EMA adopted a positive opinion recommending approval of the combination of *Keytruda* plus Lenvima for the first-line treatment of adult patients with advanced RCC based on data from the Phase 3 KEYNOTE-581 trial/Study 307. The CHMP also adopted a positive opinion recommending approval of *Keytruda* in combination with Lenvima for the treatment of adult patients with advanced or recurrent endometrial carcinoma who have disease progression following prior treatment with a platinum-containing therapy in any setting and who are not candidates for curative surgery or radiation, based on data from the Phase 3 KEYNOTE-775 trial/Study 309. The CHMP's recommendations will now be reviewed by the EC for marketing authorization in the EU and decisions are expected in the fourth quarter of 2021. *Keytruda* is also under review for both of these indications in Japan.

Merck and Eisai have stopped 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 with no *EGFR* or *ALK* genomic tumor aberrations. The trial has been 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.

Merck and Eisai have closed LEAP-011 for further enrollment. LEAP-011 is a Phase 3 study evaluating Lenvima in combination with *Keytruda* for the first-line treatments of patients with platinum-ineligible urotherial carcinoma. Enrollment was closed following the recommendation of the eDMC, which met, as scheduled, to assess safety and futility. Data from the study will be presented at an upcoming medical meeting.

In April 2021, Merck announced the discontinuation of development of MK-7110 (formerly known as CD24Fc) which was being evaluated 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 EUA application and therefore the Company did not expect MK-7110 would become available until the first half of 2022. Given this timeline and the technical, clinical and regulatory uncertainties, the availability of a number of medicines for patients hospitalized with COVID-19, and the need to concentrate Merck's resources on accelerating the development and manufacture of the most viable therapeutics and vaccines, Merck decided to discontinue development of MK-7110 for the treatment of COVID-19. Due to the discontinuation, the Company recorded charges of $207 million in the first nine months of 2021, which are reflected in *Cost of sales* and relate to fixed-asset and materials write-offs, as well as the recognition of liabilities for purchase commitments.

In September 2021, the FDA approved updated labeling for Steglatro, Steglujan and Segluromet, medicines for adults with type 2 diabetes, to include the primary efficacy and safety results from the VERTIS CV trial, which assessed the effect of Steglatro compared with placebo on cardiovascular outcomes in adult patients with type 2 diabetes and established atherosclerotic cardiovascular disease. The FDA issued a Complete Response Letter (CRL) concerning the Company's application for a new indication, based on additional results from the VERTIS CV trial, to reduce the risk of hospitalization for heart failure. The Company is reviewing the CRL to assess next steps.

The chart below reflects the Company's research pipeline as of October 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-0482 Non-Small Cell Lung MK-1026 Hematological Malignancies MK-1308 (quavonlimab)[2] Non-Small-Cell Lung MK-1308A (quavonlimab+pembrolizumab) Advanced Solid Tumors Colorectal Hepatocellular Melanoma Small-Cell Lung MK-2140 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 Small-Cell Lung MK-4830 Non-Small-Cell Lung Small-Cell Lung MK-5890[2] Non-Small-Cell Lung 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 *Welireg*[3] Biliary Colorectal Pancreatic Rare cancers Von Hippel-Lindau Disease-Associated Tumors (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-7684A (vibostolimab+pembrolizumab) Biliary Breast Cervical Endometrial Esophageal Hematological Malignancies Prostate MK-7902 Lenvima[1][2] Biliary Tract Glioblastoma Pancreatic Prostate Small-Cell Lung V937 Breast Cutaneous Squamous Cell Head and Neck Melanoma Solid Tumors **Cardiovascular** MK-2060 **Chikungunya Virus Vaccine** V184 **HIV-1 Infection** MK-8591B (islatravir+MK-8507) MK-8591D (islatravir+lenacapavir)[1] **Nonalcoholic Steatohepatitis (NASH)** MK-3655 MK-6024 **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	**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-3475 (pembrolizumab subcutaneous) Non-Small-Cell Lung (August 2021) MK-6482 *Welireg*[3] Renal Cell (February 2020) MK-7119 Tukysa[1] Breast (October 2019) MK-7339 Lynparza[1][3] Colorectal (August 2020) Non-Small-Cell Lung (June 2019) Small-Cell Lung (December 2020) MK-7684A (vibostolimab+pembrolizumab) Non-Small-Cell Lung (April 2021) MK-7902 Lenvima[1][2] Colorectal (April 2021) Esophageal (July 2021) Gastric (December 2020) Head and Neck (February 2020) Melanoma (March 2019) Non-Small-Cell Lung (March 2019) **HIV-1 Infection** MK-8591A (doravirine+islatravir) (February 2020) **HIV-1 Prevention** MK-8591 (islatravir) (February 2021)	**New Molecular Entities/Vaccines** **Antiviral COVID-19** MK-4482 (molnupiravir) (U.S.)[4] (EU) **Cough** MK-7264 (gefapixant) (U.S.) (EU) (JPN) **Pneumococcal Vaccine Adult** V114 (EU) (JPN) **Certain Supplemental Filings** **Cancer** MK-3475 *Keytruda* • Resected Stage IIB and IIC Melanoma (KEYNOTE-716) (U.S.) (EU) • Adjuvent Renal Cell Cancer (KEYNOTE-564) (U.S.) (EU) (JPN) • MSI-H or dMMR Endometrial Cancer (KEYNOTE-158) (U.S.) • High-Risk Early-Stage Triple-Negative Breast Cancer (KEYNOTE-522) (EU) (JPN) • Advanced Unresectable Metastatic Esophageal Cancer (KEYNOTE-590) (JPN) • Tumor Mutational Burden-High (KEYNOTE-158) (JPN) • Cervical Cancer (KEYNOTE-826) (JPN) MK-7902 Lenvima[1][2] • First-Line Metastatic Hepatocellular Carcinoma (KEYNOTE-524) (U.S.)[5] • Advanced Unresectable Renal Cell Carcinoma (KEYNOTE-581) (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] Under review for Emergency Use Authorization.

[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)	September 30, 2021	December 31, 2020
Cash and investments	$ 10,451	$ 8,835
Working capital	7,330	437
Total debt to total liabilities and equity	28.3 %	34.7 %

Cash provided by operating activities from continuing operations was $8.0 billion in the first nine months of 2021 compared with $4.2 billion in the first nine months of 2020 reflecting stronger operating performance. Cash provided by operating activities from continuing operations in the first nine months of 2021 includes $400 million of payments related to collaborations compared with $2.1 billion in the first nine 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 $4.4 billion in the first nine months of 2021 compared with $4.5 billion in the first nine months of 2020. The lower use of cash in investing activities was driven primarily by lower cash used for acquisitions, largely offset by lower proceeds from sales of securities and other investments and higher capital expenditures.

Cash used in financing activities of continuing operations was $2.1 billion in the first nine months of 2021 compared with $4.2 billion in the first nine months of 2020. The lower use of cash in financing activities 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 payments on debt (see below) and lower purchases of treasury stock, partially offset by lower proceeds from the issuance of debt (see below), a higher net decrease in short-term borrowings and higher dividends paid to shareholders.

Capital expenditures totaled $3.2 billion and $3.0 billion for the first nine 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 September 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 $5.0 billion and $4.7 billion for the first nine 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 was 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 October 2021, the Company's €1.0 billion, 1.125% 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 $822 million (11 million shares) of its common stock during the first nine months of 2021. As of September 30, 2021, the Company's remaining share repurchase authorization was $5.1 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 September 30, 2021, the Company's disclosure controls and procedures are effective. For the third 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, in the Company's Form 10-Q for the quarterly period ended June 30, 2021, as filed on August 9, 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. To the extent these assumptions prove to be incorrect, the Company's results may differ materially from the estimates set forth herein.

For the third quarter and first nine months of 2021, the estimated negative impact of the COVID-19 pandemic to Merck's sales was approximately $350 million and $1.3 billion, respectively, all of which related to the Pharmaceutical segment. 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 third quarter and first nine 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 September 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)]
July 1 - July 31	1,636,842	$77.33	$5,522
August 1 - August 31	2,029,851	$76.37	$5,367
September 1 - September 30	4,104,249	$73.35	$5,066
Total	7,770,942	$74.97	$5,066

[(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: November 5, 2021

/s/ Jennifer Zachary

JENNIFER ZACHARY

Executive Vice President, General Counsel and Corporate Secretary

Date: November 5, 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: November 5, 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: November 5, 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 September 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: November 5, 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 September 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: November 5, 2021

/s/ Caroline Litchfield

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