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

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2021

OR

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

For the transition period from _____ to _____

Commission File No. 1-6571

Merck & Co., Inc.

(Exact name of registrant as specified in its charter)

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

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

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

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

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

Title of each class	*Trading Symbol(s)*	*Name of each exchange on which registered*
Common Stock ($0.50 par value)	MRK	New York Stock Exchange
1.125% Notes due 2021	MRK/21	New York Stock Exchange
0.500% Notes due 2024	MRK 24	New York Stock Exchange
1.875% Notes due 2026	MRK/26	New York Stock Exchange
2.500% Notes due 2034	MRK/34	New York Stock Exchange
1.375% Notes due 2036	MRK 36A	New York Stock Exchange

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

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

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

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

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

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

The number of shares of common stock outstanding as of the close of business on April 30, 2021: 2,532,058,364

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

	Three Months Ended March 31,	
	2021	2020
Sales	$ 12,080	$ 12,057
Costs, Expenses and Other		
Cost of sales	3,670	3,312
Selling, general and administrative	2,633	2,555
Research and development	2,465	2,209
Restructuring costs	298	72
Other (income) expense, net	(448)	71
	8,618	8,219
Income Before Taxes	3,462	3,838
Taxes on Income	276	619
Net Income	3,186	3,219
Less: Net Income Attributable to Noncontrolling Interests	7	—
Net Income Attributable to Merck & Co., Inc.	$ 3,179	$ 3,219
Basic Earnings per Common Share Attributable to Merck & Co., Inc. Common Shareholders	$ 1.26	$ 1.27
Earnings per Common Share Assuming Dilution Attributable to Merck & Co., Inc. Common Shareholders	$ 1.25	$ 1.26

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

	Three Months Ended March 31,	
	2021	2020
Net Income Attributable to Merck & Co., Inc.	$ 3,179	$ 3,219
Other Comprehensive Income (Loss) Net of Taxes:		
Net unrealized gain on derivatives, net of reclassifications	230	104
Net unrealized loss on investments, net of reclassifications	—	(18)
Benefit plan net gain and prior service credit, net of amortization	81	60
Cumulative translation adjustment	(299)	(344)
	12	(198)
Comprehensive Income Attributable to Merck & Co., Inc.	$ 3,191	$ 3,021

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

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

	March 31, 2021	December 31, 2020
Assets		
Current Assets		
Cash and cash equivalents	$ 6,981	$ 8,062
Accounts receivable (net of allowance for doubtful accounts of $78 in 2021 and $85 in 2020)	8,235	7,851
Inventories (excludes inventories of $2,175 in 2021 and $2,197 in 2020 classified in Other assets - see Note 6)	6,402	6,310
Other current assets	5,291	5,541
Total current assets	26,909	27,764
Investments	544	785
Property, Plant and Equipment, at cost, net of accumulated depreciation of $18,732 in 2021 and $18,982 in 2020	18,295	17,986
Goodwill	20,212	20,238
Other Intangibles, Net	14,401	14,604
Other Assets	10,486	10,211
	$ 90,847	$ 91,588
Liabilities and Equity		
Current Liabilities		
Loans payable and current portion of long-term debt	$ 7,251	$ 6,431
Trade accounts payable	4,034	4,594
Accrued and other current liabilities	11,911	13,053
Income taxes payable	1,490	1,575
Dividends payable	1,675	1,674
Total current liabilities	26,361	27,327
Long-Term Debt	24,002	25,360
Deferred Income Taxes	1,204	1,015
Other Noncurrent Liabilities	12,241	12,482
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	39,613	39,588
Retained earnings	48,888	47,362
Accumulated other comprehensive loss	(6,622)	(6,634)
	83,667	82,104
Less treasury stock, at cost: 1,045,799,775 shares in 2021 and 1,046,877,695 shares in 2020	56,722	56,787
Total Merck & Co., Inc. stockholders' equity	26,945	25,317
Noncontrolling Interests	94	87
Total equity	27,039	25,404
	$ 90,847	$ 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)

	Three Months Ended March 31,	
	2021	2020
Cash Flows from Operating Activities		
Net income	$ 3,186	$ 3,219
Adjustments to reconcile net income to net cash provided by operating activities:		
Amortization	534	410
Depreciation	396	411
Deferred income taxes	(10)	82
Share-based compensation	120	108
Other	(331)	143
Net changes in assets and liabilities	(2,104)	(3,666)
Net Cash Provided by Operating Activities	1,791	707
Cash Flows from Investing Activities		
Capital expenditures	(1,134)	(986)
Purchases of securities and other investments	(1)	(49)
Proceeds from sales of securities and other investments	386	1,816
Acquisition of ArQule, Inc., net of cash acquired	—	(2,545)
Other acquisitions, net of cash acquired	(14)	—
Other	25	136
Net Cash Used in Investing Activities	(738)	(1,628)
Cash Flows from Financing Activities		
Net change in short-term borrowings	788	3,583
Payments on debt	(1,153)	(1,951)
Purchases of treasury stock	—	(1,281)
Dividends paid to stockholders	(1,645)	(1,551)
Proceeds from exercise of stock options	9	26
Other	(97)	(316)
Net Cash Used in Financing Activities	(2,098)	(1,490)
Effect of Exchange Rate Changes on Cash, Cash Equivalents and Restricted Cash	(97)	(63)
Net Decrease in Cash, Cash Equivalents and Restricted Cash	(1,142)	(2,474)
Cash, Cash Equivalents and Restricted Cash at Beginning of Year (includes restricted cash of $103 at January 1, 2021 included in Other Assets)	8,165	9,934
Cash, Cash Equivalents and Restricted Cash at End of Period (includes restricted cash of $42 at March 31, 2021 included in Other Assets)	$ 7,023	$ 7,460

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 (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.

Planned Spin-Off of Organon

In February 2020, Merck announced its intention to spin-off 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 consist of dermatology, non-opioid pain management, respiratory, and select cardiovascular products including *Zetia* (ezetimibe) and *Vytorin* (ezetimibe and simvastatin), as well as the rest of Merck's diversified brands franchise. Merck's existing research pipeline programs will continue to be owned and developed within Merck as planned. Organon will have development capabilities initially focused on late-stage development and life-cycle management and is expected over time to develop research capabilities in selected therapeutic areas. The spin-off is expected to be completed on June 2, 2021, subject to market and certain other conditions. Subsequent to the spin-off, the historical results of the women's health, biosimilars and established brands businesses will be reflected as discontinued operations in the Company's consolidated financial statements.

Recently Adopted Accounting Standards

In December 2019, the FASB issued amended guidance on the accounting and reporting of income taxes. The guidance is intended to simplify the accounting for income taxes by removing exceptions related to certain intraperiod tax allocations and deferred tax liabilities, clarifying guidance primarily related to evaluating the step-up tax basis for goodwill in a business combination, and reflecting enacted changes in tax laws or rates in the annual effective tax rate. The Company adopted the new guidance effective January 1, 2021. There was no impact to the Company's consolidated financial statements upon adoption.

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

Recently Issued Accounting Standard Not Yet Adopted

In March 2020, the FASB issued optional guidance to ease the potential burden in accounting for (or recognizing the effects of) reference rate reform on financial reporting and subsequently issued clarifying amendments. The guidance provides optional expedients and exceptions for applying GAAP to contracts, hedging relationships, and other transactions that reference the London Interbank Offered Rate (LIBOR) or another reference rate expected to be discontinued because of reference rate reform. The optional guidance is effective upon issuance and can be applied on a prospective basis at any time between January 1, 2020 through December 31, 2022. The Company is currently evaluating the impact of adoption on its consolidated financial statements.

2. Acquisitions, Research Collaborations and License Agreements

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

In April 2021, Merck acquired Pandion Therapeutics, Inc. (Pandion), a clinical-stage biotechnology company developing novel therapeutics designed to address the unmet needs of patients living with autoimmune diseases, for an approximate total equity value of $1.85 billion. Pandion is advancing a pipeline of precision immune modulators targeting critical immune control nodes. The Company is in the process of determining the preliminary fair value of assets acquired and liabilities assumed in this transaction, which will be accounted for as an acquisition of an asset.

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

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 a charge of $170 million in the first quarter of 2021, which is reflected in *Cost of sales* and related to fixed-asset and materials write-offs, as well as the recognition of liabilities for purchase commitments.

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 quarter 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.*

3. Collaborative Arrangements

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

AstraZeneca

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. Lynparza is an oral poly (ADP-ribose) polymerase (PARP) inhibitor currently approved for certain types of advanced ovarian, breast, pancreatic and prostate cancers. The companies are jointly developing and commercializing Lynparza, both as monotherapy and in combination trials with other potential medicines. 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), an oral, selective inhibitor of MEK, part of the mitogen-activated protein kinase (MAPK) pathway for multiple indications. In April 2020, Koselugo was approved by the FDA for the treatment of pediatric patients two years of age and older with neurofibromatosis type 1 who have symptomatic, inoperable plexiform neurofibromas. 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. Merck will fund all development and commercialization costs of *Keytruda* in combination with Lynparza or Koselugo. AstraZeneca will fund all development and commercialization costs of Imfinzi in combination with Lynparza or Koselugo. 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 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.

Prior to 2021, Merck accrued sales-based milestone payments aggregating $1.4 billion related to Lynparza, of which $1.0 billion was paid to AstraZeneca. 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.

Prior to 2021, Lynparza received regulatory approvals triggering capitalized milestone payments of $360 million in the aggregate from Merck to AstraZeneca. Potential future regulatory milestone payments of $1.4 billion remain under the agreement.

The intangible asset balance related to Lynparza (which includes capitalized sales-based and regulatory milestone payments) was $1.2 billion at March 31, 2021 and is included in *Other Intangibles, Net*. The amount is being amortized over its estimated useful life through 2028 as supported by projected future cash flows, subject to impairment testing.

Summarized financial information related to this collaboration is as follows:

	Three Months Ended March 31,	
($ in millions)	2021	2020
Alliance revenue - Lynparza	$ 228	$ 145
Alliance revenue - Koselugo	5	—
Total alliance revenue	$ 233	$ 145
Cost of sales [1]	42	28
Selling, general and administrative	40	33
Research and development	29	36

($ in millions)	March 31, 2021	December 31, 2020
Receivables from AstraZeneca included in *Other current assets*	$ 236	$ 215
Payables to AstraZeneca included in *Accrued and other current liabilities* [2]	417	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. Lenvima is currently approved for the treatment of certain types of thyroid cancer, hepatocellular carcinoma, in combination with everolimus for certain patients with renal cell carcinoma, and in combination with *Keytruda* for the treatment of certain patients with endometrial carcinoma. 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 of $750 million in 2018 and agreed to make payments of up to $650 million for certain option rights through 2021 (of which $325 million was paid in March 2019, $200 million was paid in March 2020 and $125 million was paid in March 2021). The upfront payment and license option payments were reflected in *Research and development* expenses in 2018. In addition, the agreement provides for additional contingent payments from Merck to Eisai related to the successful achievement of sales-based and regulatory milestones.

Prior to 2021, Merck accrued sales-based milestone payments aggregating $1.35 billion. Of these amounts, $550 million was paid to Eisai prior to 2021 and an additional $200 million was paid in the first quarter of 2021. 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.

Prior to 2021, Lenvima received regulatory approvals triggering capitalized milestone payments of $260 million in the aggregate from Merck to Eisai. Potential future regulatory milestone payments of $125 million remain under the agreement.

The intangible asset balance related to Lenvima (which includes capitalized sales-based and regulatory milestone payments) was $1.0 billion at March 31, 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 March 31, 2021	2020
Alliance revenue - Lenvima	$ 130	$ 128
Cost of sales [1]	47	35
Selling, general and administrative	23	11
Research and development	64	64

($ in millions)	March 31, 2021	December 31, 2020
Receivables from Eisai included in *Other current assets*	$ 153	$ 157
Payables to Eisai included in *Accrued and other current liabilities* [2]	300	335
Payables to Eisai included in *Other Noncurrent Liabilities* [3]	300	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), which is approved to treat pulmonary arterial hypertension and chronic thromboembolic pulmonary hypertension. The two companies have implemented a joint development and commercialization strategy. The collaboration also includes clinical development of Bayer's Verquvo (vericiguat), which was approved by the FDA in January 2021 to reduce the risk of cardiovascular death and heart failure hospitalization following a hospitalization for heart failure or need for outpatient intravenous diuretics in adults. Verquvo is under review by regulatory authorities in other territories including the EU and Japan. Under the agreement, Bayer commercializes Adempas in the Americas, while Merck commercializes in the rest of the world. For Verquvo, Merck commercializes in the United States and Bayer will commercialize in the rest of the world. Both companies share in development costs and profits on sales. Merck records sales of Adempas and Verquvo in its marketing territories, as well as alliance revenue. Alliance revenue represents Merck's share of profits from sales in Bayer's marketing territories, which are product sales net of cost of sales and commercialization costs. In addition, the agreement provides for contingent payments from Merck to Bayer related to the successful achievement of sales-based milestones.

Prior to 2021, Merck paid $725 million of sales-based milestone payments to Bayer related to this collaboration. 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. Accordingly, Merck recorded a liability of $400 million and a corresponding increase to the intangible assets related to this collaboration in the first quarter of 2021. Merck also recognized $153 million of cumulative amortization expense related to the recognition of this milestone in the first quarter 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 $946 million at March 31, 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 $76 million at March 31, 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 March 31, 2021	2020
Alliance revenue - Adempas	$ 74	$ 53
Net sales of Adempas recorded by Merck	55	56
Total sales	$ 129	$ 109
Cost of sales [1]	189	28
Selling, general and administrative	32	15
Research and development	7	25

($ in millions)	March 31, 2021	December 31, 2020
Receivables from Bayer included in *Other current assets*	$ 68	$ 65
Payables to Bayer included in *Other Noncurrent Liabilities* [2]	400	—

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

[2] *Represents accrued milestone payment.*

4. 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 planned 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 $335 million and $168 million in the first quarter of 2021 and 2020, respectively, related to restructuring program activities. Since inception of the Restructuring Program through March 31, 2021, Merck has recorded total pretax accumulated costs of approximately $2.1 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 March 31, 2021			
($ in millions)	Separation Costs	Accelerated Depreciation	Other	Total
Cost of sales	$ —	$ 10	$ 17	$ 27
Selling, general and administrative	—	3	—	3
Research and development	—	7	—	7
Restructuring costs	229	—	69	298
	$ 229	$ 20	$ 86	$ 335

	Three Months Ended March 31, 2020			
($ in millions)	Separation Costs	Accelerated Depreciation	Other	Total
Cost of sales	$ —	$ 25	$ 43	$ 68
Selling, general and administrative	—	11	—	11
Research and development	—	17	—	17
Restructuring costs	47	—	25	72
	$ 47	$ 53	$ 68	$ 168

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 10) and share-based compensation.

The following table summarizes the charges and spending relating to restructuring program activities for the three months ended March 31, 2021:

($ in millions)	Separation Costs	Accelerated Depreciation	Other	Total
Restructuring reserves January 1, 2021	$ 567	$ —	$ 36	$ 603
Expense	229	20	86	335
(Payments) receipts, net	(155)	—	(72)	(227)
Non-cash activity	—	(20)	22	2
Restructuring reserves March 31, 2021 [(1)]	$ 641	$ —	$ 72	$ 713

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

5. Financial Instruments

Derivative Instruments and Hedging Activities

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

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

Foreign Currency Risk Management

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

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

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

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

Monetary assets and liabilities denominated in a currency other than the functional currency of a given subsidiary are remeasured at spot rates in effect on the balance sheet date with the effects of changes in spot rates reported in *Other (income) expense, net*. The forward contracts are not designated as hedges and are marked to market through *Other (income) expense, net*. Accordingly, fair value changes in the forward contracts help mitigate the changes in the value of the remeasured assets and liabilities attributable to changes in foreign currency exchange rates, except to the extent of the spot-forward differences. These differences are not significant due to the short-term nature of the contracts, which typically have average maturities at inception of less than one year.

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

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

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

	Amount of Pretax (Gain) Loss Recognized in Other Comprehensive Income [1]		Amount of Pretax (Gain) Loss Recognized in *Other (income) expense, net* for Amounts Excluded from Effectiveness Testing	
	Three Months Ended March 31,		Three Months Ended March 31,	
($ in millions)	2021	2020	2021	2020
Net Investment Hedging Relationships				
Foreign exchange contracts	$ (25)	$ (3)	$ (4)	$ (8)
Euro-denominated notes	(166)	(51)	—	—

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

Interest Rate Risk Management

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

In January 2021, five interest rate swaps with a total notional amount of $1.15 billion matured. These swaps effectively converted the Company's $1.15 billion, 3.875% fixed-rate notes due 2021 to variable rate debt. At March 31, 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.

	March 31, 2021		
($ in millions)	Par Value of Debt	Number of Interest Rate Swaps Held	Total Swap Notional Amount
2.40% notes due 2022	$ 1,000	4	$ 1,000
2.35% notes due 2022	1,250	5	1,250

The interest rate swap contracts are designated hedges of the fair value changes in the notes attributable to changes in the benchmark LIBOR swap rate. The fair value changes in the notes attributable to changes in the LIBOR swap rate are recorded in interest expense along with the offsetting fair value changes in the swap contracts. The cash flows from these contracts are reported as operating activities in the Condensed Consolidated Statement of Cash Flows.

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

	Carrying Amount of Hedged Liabilities		Cumulative Amount of Fair Value Hedging Adjustment Increase (Decrease) Included in the Carrying Amount	
($ in millions)	March 31, 2021	December 31, 2020	March 31, 2021	December 31, 2020
Loans payable and current portion of long-term debt	$ 1,265	$ 1,150	$ 16	$ —
Long-Term Debt	1,027	2,301	27	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:

		March 31, 2021			December 31, 2020		
		Fair Value of Derivative		U.S. Dollar	Fair Value of Derivative		U.S. Dollar
($ in millions)		Asset	Liability	Notional	Asset	Liability	Notional
Derivatives Designated as Hedging Instruments	*Balance Sheet Caption*						
Interest rate swap contracts	Other current assets	$ 16	$ —	$ 1,250	$ 1	$ —	$ 1,150
Interest rate swap contracts	Other Assets	28	—	1,000	54	—	2,250
Foreign exchange contracts	Other current assets	149	—	6,195	12	—	3,183
Foreign exchange contracts	Other Assets	59	—	1,610	45	—	2,030
Foreign exchange contracts	Accrued and other current liabilities	—	57	3,045	—	217	5,049
Foreign exchange contracts	Other Noncurrent Liabilities	—	1	130	—	1	52
		$ 252	$ 58	$ 13,230	$ 112	$ 218	$ 13,714
Derivatives Not Designated as Hedging Instruments							
Foreign exchange contracts	Other current assets	$ 163	$ —	$ 8,987	$ 70	$ —	$ 7,260
Foreign exchange contracts	Accrued and other current liabilities	—	223	11,778	—	307	11,810
		$ 163	$ 223	$ 20,765	$ 70	$ 307	$ 19,070
		$ 415	$ 281	$ 33,995	$ 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:

	March 31, 2021		December 31, 2020	
($ in millions)	Asset	Liability	Asset	Liability
Gross amounts recognized in the condensed consolidated balance sheet	$ 415	$ 281	$ 182	$ 525
Gross amounts subject to offset in master netting arrangements not offset in the condensed consolidated balance sheet	(213)	(213)	(156)	(156)
Cash collateral received/posted	(19)	—	—	(36)
Net amounts	$ 183	$ 68	$ 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:

	Sales		Other (income) expense, net [1]		Other comprehensive income (loss)	
	Three Months Ended March 31,		Three Months Ended March 31,		Three Months Ended March 31,	
($ in millions)	2021	2020	2021	2020	2021	2020
Financial Statement Line Items in which Effects of Fair Value or Cash Flow Hedges are Recorded	$12,080	$12,057	$ (448)	$ 71	$ 12	$ (198)
(Gain) loss on fair value hedging relationships						
Interest rate swap contracts						
Hedged items	—	—	(11)	67	—	—
Derivatives designated as hedging instruments	—	—	1	(67)	—	—
Impact of cash flow hedging relationships						
Foreign exchange contracts						
Amount of gain recognized in *OCI* on derivatives	—	—	—	—	180	178
(Decrease) increase in *Sales* as a result of *AOCI* reclassifications	(112)	46	—	—	112	(46)
Interest rate contracts						
Amount of gain recognized in *Other (income) expense, net* on derivatives	—	—	(1)	(1)	—	—
Amount of loss recognized in *OCI* on derivatives	—	—	—	—	(1)	(1)

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

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

		Amount of Derivative Pretax (Gain) Loss Recognized in Income	
		Three Months Ended March 31,	
($ in millions)		2021	2020
Derivatives Not Designated as Hedging Instruments	*Income Statement Caption*		
Foreign exchange contracts [1]	Other (income) expense, net	$ 50	$ (180)
Foreign exchange contracts [2]	Sales	(4)	(7)

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

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

At March 31, 2021, the Company estimates $72 million of pretax net unrealized losses on derivatives maturing within the next 12 months that hedge foreign currency denominated sales over that same period will be reclassified from *AOCI* to *Sales*. The amount ultimately reclassified to *Sales* may differ as foreign exchange rates change. Realized gains and losses are ultimately determined by actual exchange rates at maturity.

Investments in Debt and Equity Securities

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

	March 31, 2021				December 31, 2020			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
($ in millions)								
U.S. government and agency securities	$ 81	$ —	$ —	$ 81	$ 84	$ —	$ —	$ 84
Foreign government bonds	2	—	—	2	5	—	—	5
Corporate notes and bonds	4	—	—	4	—	—	—	—
Total debt securities	$ 87	$ —	$ —	$ 87	$ 89	$ —	$ —	$ 89
Publicly traded equity securities [1]				1,596				1,787
Total debt and publicly traded equity securities				$ 1,683				$ 1,876

[1] *Unrealized net losses recognized in* Other (income) expense, net *on equity securities still held at March 31, 2021 were $181 million in the first quarter of 2021. Unrealized net losses recognized in* Other (income) expense, net *on equity securities still held at March 31, 2020 were $4 million in the first quarter of 2020.*

At March 31, 2021 and March 31, 2020, the Company also had $651 million and $450 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 quarter of 2021, the Company recognized unrealized gains of $33 million in *Other (income) expense, net* related to these equity investments held

at March 31, 2021. 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 March 31, 2021 were $202 million and $11 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)	March 31, 2021				December 31, 2020			
Assets								
Investments								
Foreign government bonds	$ —	$ 2	$ —	$ 2	$ —	$ 5	$ —	$ 5
Publicly traded equity securities	542	—	—	542	780	—	—	780
	542	2	—	544	780	5	—	785
Other assets [1]								
U.S. government and agency securities	81	—	—	81	84	—	—	84
Corporate notes and bonds	4	—	—	4	—	—	—	—
Publicly traded equity securities	1,054	—	—	1,054	1,007	—	—	1,007
	1,139	—	—	1,139	1,091	—	—	1,091
Derivative assets [2]								
Forward exchange contracts	—	271	—	271	—	90	—	90
Purchased currency options	—	100	—	100	—	37	—	37
Interest rate swaps	—	44	—	44	—	55	—	55
	—	415	—	415	—	182	—	182
Total assets	$ 1,681	$ 417	$ —	$ 2,098	$ 1,871	$ 187	$ —	$ 2,058
Liabilities								
Other liabilities								
Contingent consideration	$ —	$ —	$ 816	$ 816	$ —	$ —	$ 841	$ 841
Derivative liabilities [2]								
Forward exchange contracts	—	277	—	277	—	505	—	505
Written currency options	—	4	—	4	—	20	—	20
	—	281	—	281	—	525	—	525
Total liabilities	$ —	$ 281	$ 816	$ 1,097	$ —	$ 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 March 31, 2021 and December 31, 2020, *Cash and cash equivalents* included $6.0 billion and $6.8 billion of cash equivalents, respectively (which would be considered Level 2 in the fair value hierarchy).

Contingent Consideration

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

	Three Months Ended March 31,	
($ in millions)	2021	2020
Fair value January 1	$ 841	$ 767
Changes in estimated fair value [(1)]	(13)	33
Payments	—	(106)
Other	(12)	—
Fair value March 31 [(2)(3)]	$ 816	$ 694

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

[(2)] *Balance at March 31, 2021 includes $285 million recorded as a current liability for amounts expected to be paid within the next 12 months.*

[(3)] *At March 31, 2021 and December 31, 2020, $697 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 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 March 31, 2021, was $33.5 billion compared with a carrying value of $31.3 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 United States, 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 $1.8 billion and $2.3 billion of accounts receivable in the first quarter of 2021 and the fourth quarter of 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 $19 million at March 31, 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.

6. Inventories

Inventories consisted of:

($ in millions)	March 31, 2021	December 31, 2020
Finished goods	$ 2,015	$ 1,963
Raw materials and work in process	6,385	6,420
Supplies	205	206
Total (approximates current cost)	8,605	8,589
Decrease to LIFO cost	(28)	(82)
	$ 8,577	$ 8,507
Recognized as:		
Inventories	$ 6,402	$ 6,310
Other assets	2,175	2,197

Amounts recognized as *Other Assets* are comprised almost entirely of raw materials and work in process inventories. At March 31, 2021 and December 31, 2020, these amounts included $1.8 billion and $1.9 billion, respectively, of inventories not expected to be sold within one year. In addition, these amounts included $387 million and $279 million at March 31, 2021 and December 31, 2020, respectively, of inventories produced in preparation for product launches.

7. 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 United States involving *Fosamax* (*Fosamax* Litigation). As of March 31, 2021, approximately 3,485 cases are pending against Merck in either federal 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*.

All federal cases involving allegations of Femur Fractures have been or will be transferred to a multidistrict litigation in the District of New Jersey (Femur Fracture MDL). In the only bellwether case tried to date in the Femur Fracture MDL, *Glynn v. Merck*, the jury returned a verdict in Merck's favor. In addition, in June 2013, the Femur Fracture MDL court granted Merck's motion for judgment as a matter of law in the *Glynn* case and held that the plaintiff's failure to warn claim was preempted by federal law.

In August 2013, the Femur Fracture MDL court entered an order requiring plaintiffs in the Femur Fracture MDL to show cause why those cases asserting claims for a femur fracture injury that took place prior to September 14, 2010, should not be dismissed based on the court's preemption decision in the *Glynn* case. Pursuant to the show cause order, 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.

Accordingly, as of March 31, 2021, approximately 970 cases were actively pending in the Femur Fracture MDL.

As of March 31, 2021, approximately 2,235 cases alleging Femur Fractures have been filed in New Jersey state court and are pending before Judge James Hyland in Middlesex County. The parties selected an initial group of cases to be reviewed through fact discovery, and Merck has continued to select additional cases to be reviewed.

As of March 31, 2021, approximately 275 cases alleging Femur Fractures have been filed and are pending in California state court. All of the Femur Fracture cases filed in California state court have been coordinated before a single judge in Orange County, California.

Additionally, there are five Femur Fracture cases pending in other state courts.

Discovery is presently stayed in the Femur Fracture MDL and in the state court in California. Merck intends to defend against these lawsuits.

Januvia/Janumet

As previously disclosed, Merck is a defendant in product liability lawsuits in the United States involving *Januvia* and/or *Janumet*. As of March 31, 2021, Merck is aware of approximately 1,490 product users alleging that *Januvia* and/or *Janumet* caused the development of pancreatic cancer and other injuries.

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

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

As of March 31, 2021, six product users have claims pending against Merck in state courts other than California, including Illinois. In June 2017, the Illinois trial court denied Merck's motion for summary judgment based on federal preemption. Merck appealed, and the Illinois appellate court affirmed in December 2018. Merck filed a petition for leave to appeal to the Illinois Supreme Court in February 2019. In April 2019, the Illinois Supreme Court stayed consideration of the pending petition to appeal until the U.S. Supreme Court issued its opinion in *Merck Sharp & Dohme Corp. v. Albrecht* (relating to the *Fosamax* matter discussed above). Merck filed the opinion in *Albrecht* with the Illinois Supreme Court in June 2019. The petition for leave to appeal was decided in September 2019, in which the Illinois Supreme Court directed the intermediate appellate court to reconsider its earlier ruling. The Illinois Appellate Court issued a favorable decision concluding, consistent with *Albrecht*, that preemption presents a legal question to be resolved by the court. In May 2020, the Illinois Appellate Court issued a mandate to the state trial court, which, as of March 31, 2021, had not scheduled a case management conference or otherwise taken action.

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

Governmental Proceedings

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

As previously disclosed, from time to time, the Company receives inquiries and is the subject of preliminary investigation activities from competition and other governmental authorities in markets outside the United States. 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 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. The Fourth Circuit will hear argument in Defendants' appeal on May 6, 2021. Also, in August 2020, the magistrate judge recommended that the court grant the motion for class certification filed by the putative indirect purchaser class. The Merck Defendants objected to this report and recommendation and are awaiting a decision from the district court.

In August 2020, the Merck Defendants filed a motion for summary judgment and other motions, and plaintiffs filed a motion for partial summary judgment, and other motions. Those motions are now fully briefed, and the court will likely hold a hearing on the competing motions. Trial in this matter has been adjourned.

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

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

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.

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 United States beyond the expiration of all patents listed in the FDA's Orange Book. Including this exclusivity, key patent protection extends to January 2023. The Company anticipates that sales of *Januvia* and *Janumet* in the United States will decline significantly after this loss of market exclusivity. However, *Januvia*, *Janumet*, and *Janumet XR* contain sitagliptin phosphate monohydrate and the Company has another patent covering certain phosphate salt and polymorphic forms of sitagliptin, which, if determined to be valid, would preclude generic manufacturers from making sitagliptin phosphate salt and polymorphic forms before that patent, inclusive of pediatric exclusivity, expires in 2027 (2027 salt/polymorph patent). In 2019, Par Pharmaceutical filed suit against the Company in the U.S. District Court for the District of New Jersey, seeking a declaratory judgment of invalidity of the 2027 salt/polymorph patent. In response, the Company filed a patent infringement lawsuit in the U.S. District Court for the District of Delaware against Par Pharmaceutical and additional companies that also indicated an intent to market generic versions of *Januvia*, *Janumet*, and *Janumet XR* following expiration of key patent protection, but prior to the expiration of the 2027 salt/ polymorph patent, and a later granted patent owned by the Company covering the *Janumet* formulation which, inclusive of pediatric exclusivity, expires in 2029. The Company also filed a patent infringement lawsuit against Mylan in the Northern District of West Virginia. The Judicial Panel of Multidistrict Litigation entered an order transferring the Company's lawsuit against Mylan to the U.S. District Court for the District of Delaware for coordinated and consolidated pretrial proceedings with the other cases pending in that district. In February 2021, the Company amended its complaint against Apotex Inc. and Apotex Corp., additional defendants in the patent infringement lawsuits, to add infringement claims related to a patent that expires in 2025 and covers certain processes for manufacturing sitagliptin.

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

The Company has settled with ten generic companies providing that these generic companies can bring their generic versions of *Januvia* and *Janumet* to the market in May 2027 or earlier under certain circumstances, and their generic versions of *Janumet XR* to the market in July 2026 or earlier under certain circumstances.

Additionally, in 2019, Mylan filed a petition for *Inter Partes* Review (IPR) at the United States Patent and Trademark Office (USPTO) seeking invalidity of some, but not all, of the claims of the 2027 salt/polymorph patent, which other manufacturers joined. The USPTO instituted IPR proceedings in May 2020, finding a reasonable likelihood that the challenged claims are not valid. A trial was held in February 2021 and a final decision is expected in May 2021. If the challenges are successful, the unchallenged claims of the 2027 salt/polymorph patent will remain valid, subject to the court proceedings described above.

In Germany, two 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 as early as July 2022. Challenges to the *Janumet* SPC have also occurred in Portugal and Finland, and could occur in other European countries.

Nexplanon — As previously disclosed, in June 2017, Microspherix LLC (Microspherix) sued the Company in the U.S. District Court for the District of New Jersey asserting that the manufacturing, use, sale and importation of *Nexplanon* infringed several of Microspherix's patents that claim radio-opaque, implantable drug delivery devices. Microspherix is claiming damages from September 2014 until those patents expire in May 2021. The Company brought IPR proceedings in the USPTO and successfully stayed the district court action. The USPTO invalidated some, but not all, of the claims asserted against the Company. The Company appealed the decisions finding claims valid, and the Court of Appeals for the Federal Circuit affirmed the USPTO's decisions. The matter is no longer stayed in the district court, and the Company is currently litigating the invalidity and non-infringement of the remaining asserted claims.

Other Litigation

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

Legal Defense Reserves

Legal defense costs expected to be incurred in connection with a loss contingency are accrued when probable and reasonably estimable. Some of the significant factors considered in the review of these legal defense reserves are as follows: the actual costs incurred by the Company; the development of the Company's legal defense strategy and structure in light of the scope of its litigation; the number of cases being brought against the Company; the costs and outcomes of completed trials and the most current information regarding anticipated timing, progression, and related costs of pre-trial activities and trials in the associated litigation. The amount of legal defense reserves as of March 31, 2021 and December 31, 2020 of approximately $255 million and $250 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.

8. Equity

	Three Months Ended March 31,								
	Common Stock		Other		Accumulated Other	Treasury Stock		Non-	
($ and shares in millions except per share amounts)	Shares	Par Value	Paid-In Capital	Retained Earnings	Comprehensive Loss	Shares	Cost	controlling Interests	Total
Balance at January 1, 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.	—	—	—	3,219	—	—	—	—	3,219
Other comprehensive loss, net of taxes	—	—	—	—	(198)	—	—	—	(198)
Cash dividends declared on common stock ($0.61 per share)	—	—	—	(1,549)	—	—	—	—	(1,549)
Treasury stock shares purchased	—	—	—	—	—	16	(1,281)	—	(1,281)
Share-based compensation plans and other	—	—	37	—	—	(1)	70	—	107
Other changes in noncontrolling interests	—	—	—	—	—	—	—	1	1
Balance at March 31, 2020	3,577	$ 1,788	$ 39,697	$ 48,272	$ (6,391)	1,053	$ (57,161)	$ 95	$ 26,300
Balance at January 1, 2021	3,577	$ 1,788	$ 39,588	$ 47,362	$ (6,634)	1,047	$ (56,787)	$ 87	$ 25,404
Net income attributable to Merck & Co., Inc.	—	—	—	3,179	—	—	—	—	3,179
Other comprehensive income, net of taxes	—	—	—	—	12	—	—	—	12
Cash dividends declared on common stock ($0.65 per share)	—	—	—	(1,653)	—	—	—	—	(1,653)
Share-based compensation plans and other	—	—	25	—	—	(1)	65	—	90
Net income attributable to noncontrolling interests	—	—	—	—	—	—	—	7	7
Balance at March 31, 2021	3,577	$ 1,788	$ 39,613	$ 48,888	$ (6,622)	1,046	$ (56,722)	$ 94	$ 27,039

9. Share-Based Compensation Plans

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 may be granted options to purchase shares of Company common stock at the fair market value at the time of grant.

The following table provides the amounts of share-based compensation cost recorded in the Condensed Consolidated Statement of Income:

	Three Months Ended March 31,	
($ in millions)	2021	2020
Pretax share-based compensation expense	$ 120	$ 108
Income tax benefit	(17)	(15)
Total share-based compensation expense, net of taxes	$ 103	$ 93

During the first three months of 2021, the Company granted 75 thousand RSUs with a weighted-average grant date fair value of $75.04 per RSU and during the first three months of 2020 granted 58 thousand RSUs with a weighted-average grant date fair value of $85.66 per RSU. During the first three months of 2021, the Company granted 976 thousand PSUs with a weighted-average grant date fair value of $75.70 per PSU and during the first three months of 2020 granted 770 thousand PSUs with a weighted-average grant date fair value of $75.65 per PSU. The Company did not grant any stock options during the first three months of 2021 or 2020.

At March 31, 2021, there was $1.2 billion of total pretax unrecognized compensation expense related to nonvested stock options, RSU and PSU awards which will be recognized over a weighted-average period of 2.5 years. The Company typically communicates the value of annual RSU and stock option compensation awards to employees during the first quarter, but the related share amounts are not established and communicated until early May. Therefore, any RSU and stock option grants disclosed above do not reflect any amounts relating to the annual grants; however, share-based compensation costs for the first quarter of 2021 and 2020 and unrecognized compensation expense at March 31, 2021 reflect an impact relating to the awards communicated to employees. For segment reporting, share-based compensation costs are unallocated expenses.

10. Pension and Other Postretirement Benefit Plans

The Company has defined benefit pension plans covering eligible employees in the United States and in certain of its international subsidiaries. The net periodic benefit cost of such plans consisted of the following components:

	Three Months Ended March 31,			
	2021		2020	
($ in millions)	U.S.	International	U.S.	International
Service cost	$ 100	$ 93	$ 86	$ 74
Interest cost	96	29	109	34
Expected return on plan assets	(188)	(104)	(194)	(103)
Amortization of unrecognized prior service credit	(10)	(4)	(12)	(3)
Net loss amortization	85	41	75	31
Termination benefits	1	—	3	1
Curtailments	7	—	2	(1)
	$ 91	$ 55	$ 69	$ 33

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

	Three Months Ended March 31,	
($ in millions)	2021	2020
Service cost	$ 13	$ 13
Interest cost	11	14
Expected return on plan assets	(20)	(19)
Amortization of unrecognized prior service credit	(25)	(22)
	$ (21)	$ (14)

In connection with restructuring actions (see Note 4), termination charges were recorded on pension plans related to expanded eligibility for certain employees exiting Merck. Also, in connection with these restructuring actions, curtailments were recorded on pension plans as noted in the table above.

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

11. Other (Income) Expense, Net

Other (income) expense, net, consisted of:

	Three Months Ended March 31,	
($ in millions)	2021	2020
Interest income	$ (11)	$ (25)
Interest expense	200	212
Exchange losses	47	54
Income from investments in equity securities, net [(1)]	(574)	(52)
Net periodic defined benefit plan (credit) cost other than service cost	(89)	(90)
Other, net	(21)	(28)
	$ (448)	$ 71

[(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.*

Interest paid for the three months ended March 31, 2021 and 2020 was $217 million and $250 million, respectively.

12. Taxes on Income

The effective income tax rates of 8.0% and 16.1% for the first quarter of 2021 and 2020, respectively, reflect the impacts of acquisition and divestiture-related costs and restructuring costs, partially offset by the beneficial impact of foreign earnings. 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. The Company's reserves for unrecognized tax benefits for the years under examination exceeded the adjustments relating to this examination period and therefore the Company recorded a $237 million net tax benefit in the first quarter of 2021. This net benefit reflects reductions in reserves for unrecognized tax benefits and other related liabilities for tax positions relating to the years that were under examination.

13. Earnings Per Share

The calculations of earnings per share are as follows:

	Three Months Ended March 31,	
($ and shares in millions except per share amounts)	2021	2020
Net income attributable to Merck & Co., Inc.	$ 3,179	$ 3,219
Average common shares outstanding	2,531	2,533
Common shares issuable [(1)]	10	14
Average common shares outstanding assuming dilution	2,541	2,547
Basic earnings per common share attributable to Merck & Co., Inc. common shareholders	$ 1.26	$ 1.27
Earnings per common share assuming dilution attributable to Merck & Co., Inc. common shareholders	$ 1.25	$ 1.26

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

For the first quarter of 2021 and 2020, 14 million and 2 million, respectively, of common shares issuable under share-based compensation plans were excluded from the computation of earnings per common share assuming dilution because the effect would have been antidilutive.

14. Other Comprehensive Income (Loss)

Changes in *AOCI* by component are as follows:

	Three Months Ended March 31,				
($ in millions)	Derivatives	Investments	Employee Benefit Plans	Cumulative Translation Adjustment	Accumulated Other Comprehensive Income (Loss)
Balance January 1, 2020, net of taxes	$ 31	$ 18	$ (4,261)	$ (1,981)	$ (6,193)
Other comprehensive income (loss) before reclassification adjustments, pretax	178	3	—	(333)	(152)
Tax	(37)	—	5	(11)	(43)
Other comprehensive income (loss) before reclassification adjustments, net of taxes	141	3	5	(344)	(195)
Reclassification adjustments, pretax	(47) [1]	(21) [2]	69 [3]	—	1
Tax	10	—	(14)	—	(4)
Reclassification adjustments, net of taxes	(37)	(21)	55	—	(3)
Other comprehensive income (loss), net of taxes	104	(18)	60	(344)	(198)
Balance March 31, 2020, net of taxes	$ 135	$ —	$ (4,201)	$ (2,325)	$ (6,391)
Balance January 1, 2021, net of taxes	$ (266)	$ —	$ (4,540)	$ (1,828)	$ (6,634)
Other comprehensive income (loss) before reclassification adjustments, pretax	180	—	(4)	(211)	(35)
Tax	(38)	—	(1)	(88)	(127)
Other comprehensive income (loss) before reclassification adjustments, net of taxes	142	—	(5)	(299)	(162)
Reclassification adjustments, pretax	111 [1]	—	87 [3]	—	198
Tax	(23)	—	(1)	—	(24)
Reclassification adjustments, net of taxes	88	—	86	—	174
Other comprehensive income (loss), net of taxes	230	—	81	(299)	12
Balance March 31, 2021, net of taxes	$ (36)	$ —	$ (4,459)	$ (2,127)	$ (6,622)

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

[2] *Represents net realized (gains) losses on the sales of available-for-sale debt securities that were reclassified from* AOCI *to* Other (income) expense, net.

[3] *Includes net amortization of prior service cost and actuarial gains and losses included in net periodic benefit cost (see Note 10).*

15. 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 March 31,					
	2021			2020		
($ in millions)	U.S.	Int'l	Total	U.S.	Int'l	Total
Pharmaceutical:						
Oncology						
Keytruda	$ 2,181	$ 1,718	$ 3,899	$ 1,906	$ 1,378	$ 3,284
Alliance revenue - Lynparza [(1)]	118	110	228	85	60	145
Alliance revenue - Lenvima [(1)]	85	44	130	90	38	128
Vaccines						
Gardasil/Gardasil 9	313	604	917	461	636	1,097
ProQuad/M-M-R II/*Varivax*	333	117	449	333	102	435
Pneumovax 23	73	99	171	182	75	256
RotaTeq	118	41	158	140	82	222
Vaqta	25	9	34	30	30	60
Hospital Acute Care						
Bridion	167	173	340	143	157	299
Prevymis	35	47	82	26	33	60
Noxafil	15	52	67	8	87	94
Primaxin	—	65	65	—	51	51
Cancidas	3	55	57	3	52	55
Invanz	4	52	57	6	59	64
Zerbaxa	(2)	(6)	(8)	20	16	37
Immunology						
Simponi	—	214	214	—	215	215
Remicade	—	85	85	—	88	88
Neuroscience						
Belsomra	18	61	79	27	53	79
Virology						
Isentress/Isentress HD	71	138	209	75	170	245
Cardiovascular						
Zetia	2	90	92	(2)	147	145
Vytorin	2	38	41	3	50	53
Atozet	—	112	112	—	122	122
Alliance revenue - Adempas [(2)]	68	6	74	49	5	53
Adempas	—	55	55	—	56	56
Diabetes						
Januvia	348	461	809	355	419	774
Janumet	84	401	486	113	390	503
Women's Health						
Implanon/Nexplanon	141	42	183	149	45	195
NuvaRing	21	24	45	26	37	63
Diversified Brands						
Singulair	4	102	107	5	151	155
Cozaar/Hyzaar	3	87	90	7	95	102
Arcoxia	—	56	56	—	70	70
Follistim AQ	25	27	52	21	21	41
Nasonex	2	41	43	6	65	71
Other pharmaceutical [(3)]	384	814	1,197	447	886	1,338
Total Pharmaceutical segment sales	4,641	6,034	10,675	4,714	5,941	10,655
Animal Health:						
Livestock	157	662	819	162	577	739
Companion Animals	280	319	599	222	253	475
Total Animal Health segment sales	437	981	1,418	384	830	1,214
Other segment sales [(4)]	—	—	—	23	—	23
Total segment sales	5,078	7,015	12,093	5,121	6,771	11,892
Other [(5)]	58	(72)	(13)	16	149	165
	$ 5,136	$ 6,943	$12,080	$ 5,137	$ 6,920	$12,057

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 3).

(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 3).

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

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

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

Product sales are recorded net of the provision for discounts, including chargebacks, which are customer discounts that occur when a contracted customer purchases through an intermediary wholesale purchaser, and rebates that are owed based upon definitive contractual agreements or legal requirements with private sector and public sector (Medicaid and Medicare Part D) benefit providers, after the final dispensing of the product by a pharmacy to a benefit plan participant. These discounts, in the aggregate, reduced U.S. sales by $3.3 billion and $3.2 billion for the three months ended March 31, 2021 and 2020, respectively.

Consolidated sales by geographic area where derived are as follows:

	Three Months Ended March 31,	
($ in millions)	2021	2020
United States	$ 5,136	$ 5,137
Europe, Middle East and Africa	3,729	3,534
China	927	864
Asia Pacific (other than China and Japan)	751	728
Japan	730	811
Latin America	569	556
Other	238	427
	$ 12,080	$ 12,057

A reconciliation of segment profits to *Income before taxes* is as follows:

	Three Months Ended March 31,	
($ in millions)	2021	2020
Segment profits:		
Pharmaceutical segment	$ 7,555	$ 7,582
Animal Health segment	572	479
Other segment	—	1
Total segment profits	8,127	8,062
Other profits	(34)	139
Unallocated:		
Interest income	11	25
Interest expense	(200)	(212)
Amortization	(534)	(410)
Depreciation	(358)	(377)
Research and development	(2,358)	(2,097)
Restructuring costs	(298)	(72)
Other unallocated, net	(894)	(1,220)
	$ 3,462	$ 3,838

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.

Planned Spin-Off of Organon

In February 2020, Merck announced its intention to spin-off 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 consist of dermatology, non-opioid pain management, respiratory, and select cardiovascular products including *Zetia* (ezetimibe) and *Vytorin* (ezetimibe and simvastatin), as well as the rest of Merck's diversified brands franchise. Merck's existing research pipeline programs will continue to be owned and developed within Merck as planned. Organon will have development capabilities initially focused on late-stage development and life-cycle management and is expected over time to develop research capabilities in selected therapeutic areas. The spin-off is expected to be completed on June 2, 2021, subject to market and certain other conditions. Subsequent to the spin-off, the historical results of the women's health, biosimilars and established brands businesses will be reflected as discontinued operations in the Company's consolidated financial statements.

In March 2021, Merck and Alydia Health entered into a definitive agreement pursuant to which, after the spin-off, Organon will acquire Alydia Health for up to $240 million in total consideration, subject to customary purchase price adjustments. Total consideration includes a $215 million upfront payment plus a $25 million contingent sales-based milestone payment. Alydia Health is a commercial-stage medical device company focused on preventing maternal morbidity and mortality caused by postpartum hemorrhage or abnormal postpartum uterine bleeding. Of the $215 million upfront payment, $50 million was paid by Merck and the remaining $165 million will be paid by Organon upon the close of the acquisition, which remains subject to customary closing conditions and completion of the spin-off of Organon from Merck. The $25 million contingent milestone payment will be paid by Organon upon achievement of the milestone. Pursuant to the agreement, in the event the spin-off of Organon is not completed, Alydia is entitled to retain the initial $50 million payment.

In April 2021, Organon Finance 1 LLC, a subsidiary of Merck, issued €1.25 billion aggregate principal amount of 2.875% senior secured notes due 2028, $2.1 billion aggregate principal amount of 4.125% senior secured notes due 2028 and $2.0 billion aggregate principal amount of 5.125% senior unsecured notes due 2031 (collectively, the notes), in connection with the spin-off of Organon. As part of the spin-off, the notes will be assumed by Organon and a Dutch private limited company, a wholly owned subsidiary of Organon, which will act as co-issuer of the notes. The proceeds of the notes offering will be held in escrow until satisfaction of the conditions precedent to the spin-off and certain other escrow release conditions. Also in connection with the spin-off, Organon expects to enter into a credit agreement providing for a U.S. dollar denominated senior secured term loan in the amount of $3.0 billion due 2028 and a Euro denominated senior secured term loan in the amount of €750 million due 2028. Organon is expected to distribute approximately $9.0 billion of the approximately $9.5 billion of proceeds received from the issuance of this debt to Merck in connection with the spin-off. In addition, Organon expects to enter into an unsecured, unsubordinated 5-year revolving credit facility that provides for the availability of $1.0 billion of borrowings.

Recent Developments

Management

In March 2021, Merck announced that Caroline Litchfield has been appointed executive vice president and chief financial officer (CFO), effective April 1, 2021. Litchfield succeeds Robert M. Davis; as previously announced, Davis, Merck's previous CFO, became president of Merck, effective April 1, 2021, and will become chief executive officer on July 1, 2021.

Also in March 2021, Merck announced that effective immediately, Frank Clyburn, chief commercial officer, Human Health was named president, Human Health and will lead Human Health marketing and commercial operations. Michael T. Nally, chief marketing officer, Human Health, left the Company at the end of March.

Business Developments

Below is a summary of significant business development activity thus far in 2021. See Note 2 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 quarter of 2021, for license and other rights for the first two collaboration targets and agreed to make another upfront payment of $15 million for license and other rights for the third collaboration target

when it is selected by Merck and accepted by Artiva. In addition, Artiva is eligible to receive future contingent milestone payments 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 an approximate total equity value of $1.85 billion. Pandion is advancing a pipeline of precision immune modulators targeting critical immune control nodes.

Coronavirus Disease 2019 (COVID-19) Update

Overall, in response to the COVID-19 pandemic, Merck is focused on protecting the safety of its employees, ensuring that its supply of medicines and vaccines reaches its patients, contributing its scientific expertise to the development of an antiviral approach, 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 first quarter of 2021, Merck continues to experience strong global underlying demand across its business.

In the first quarter of 2021, the estimated negative impact of the COVID-19 pandemic to Merck's Pharmaceutical sales was approximately $600 million. The impact to Animal Health sales was immaterial. Roughly two-thirds 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. Reduced access to health care providers combined with the prioritization of COVID-19 vaccines and public health guidance on co-administration with other vaccines has resulted in reduced administration of many of the Company's human health products, notably vaccines in the United States, which the Company anticipates will continue while pandemic-related access measures remain in place.

In April 2021, Merck announced it was discontinuing development of MK-7110 (formerly known as CD24Fc) for the treatment of hospitalized patients with COVID-19. This decision resulted in a charge of $170 million to *Cost of sales* in the first quarter of 2021.

Merck also announced a Phase 2/3 trial of molnupiravir (MK-4482/EIDD-2801), an investigational oral antiviral agent being developed in collaboration with Ridgeback Biotherapeutics LP (Ridgeback Bio), for the treatment of outpatients diagnosed with COVID-19 will proceed to Phase 3. See "Research and Development Update" below. In April 2021, Merck entered into non-exclusive voluntary licensing agreements for molnupiravir with five established Indian generics manufacturers to accelerate availability of molnupiravir in India and in other low- and middle-income countries following approvals or emergency authorization by local regulatory agencies. Under the agreements, Merck will provide licenses to these manufacturers to supply molnupiravir to India and more than 100 low- and middle-income countries. Merck is also in discussions with the Medicines Patent Pool to explore the potential for additional licenses. The Medicines Patent Pool is a United Nations-backed public health organization working to increase access to, and facilitate the development of, life-saving medicines for low- and middle-income countries.

Operating expenses reflect a minor positive effect in the first quarter of 2021 from the COVID-19 pandemic 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.

Merck continues to believe that global health systems and patients have largely adapted to the impacts of the COVID-19 pandemic, but that negative impacts will persist, particularly during the first half of 2021 and most notably with respect to vaccine sales in the United States. For the full year of 2021, Merck assumes a net unfavorable impact to sales of approximately 3% due to the COVID-19 pandemic, all of which relates to the Pharmaceutical segment. In addition, for the full year of 2021, Merck expects a negligible impact to operating expenses, as spending on the development of its COVID-19-related research programs is expected to largely offset the favorable impact of lower spending in other areas due to the COVID-19 pandemic.

In March 2021, Merck announced it has 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 of up to $268.8 million 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 with Janssen Pharmaceuticals, Inc., one of the Janssen Pharmaceutical Companies of Johnson & Johnson, to support the manufacturing and supply of Johnson & Johnson's SARS-CoV-2/COVID-19 vaccine. Merck will use its facilities in the United States 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 three months of 2021 was negatively affected by other cost-reduction measures taken by governments and other third-parties to lower health care costs. The Company anticipates all of these actions and additional actions in the future will continue to negatively affect sales performance.

Operating Results

Sales

($ in millions)	Three Months Ended March 31, 2021	2020	% Change	% Change Excluding Foreign Exchange
United States	$ 5,136	$ 5,137	— %	— %
International	6,943	6,920	— %	(2)%
Total	$ 12,080	$ 12,057	— %	(1)%

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

Worldwide sales were $12.1 billion for the first quarter of 2021, comparable to sales in the first quarter of 2020. Revenue performance reflects higher sales in the oncology franchise reflecting strong growth of *Keytruda* (pembrolizumab) and increased alliance revenue from Lynparza (olaparib), as well as higher sales of certain hospital acute care products, including *Bridion* (sugammadex) Injection and *Prevymis* (letermovir). Higher sales of Animal Health products also contributed to revenue performance in the first quarter of 2021.

Sales in the quarter were unfavorably affected by lower sales of certain vaccines including *Gardasil* (Human Papillomavirus Quadrivalent [Types 6,11,16 and 18] Vaccine, Recombinant)*/Gardasil* 9 (Human Papillomavirus 9-valent Vaccine, Recombinant), *Pneumovax* 23 (pneumococcal vaccine polyvalent), *RotaTeq* (Rotavirus Vaccine, Live Oral, Pentavalent) and *Vaqta* (hepatitis A vaccine, inactivated), as well as generic competition for cardiovascular product *Zetia* (ezetimibe), hospital acute care product *Noxafil* (posaconazole), and certain products within the diversified brands franchise. The diversified brands franchise includes certain products that are approaching the expiration of their marketing exclusivity or that are no longer protected by patents in developed markets. The decline in sales of hospital acute care product *Zerbaxa* (ceftolozane and tazobactam) for injection and lower sales of virology products *Isentress/Isentress HD* (raltegravir) also negatively affected revenue in the first quarter of 2021. As discussed above, the COVID-19 pandemic unfavorably affected sales in the first quarter of 2021.

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

Pharmaceutical Segment

Oncology

($ in millions)	Three Months Ended March 31, 2021	2020	% Change	% Change Excluding Foreign Exchange
Keytruda	$ 3,899	$ 3,284	19 %	16 %
Alliance Revenue - Lynparza [(1)]	228	145	57 %	51 %
Alliance Revenue - Lenvima [(1)]	130	128	1 %	(1)%

[(1)] *Alliance revenue represents Merck's share of profits, which are product sales net of cost of sales and commercialization costs (see Note 3 to the condensed consolidated financial statements).*

Keytruda is an anti-PD-1 (programmed death receptor-1) therapy that has been approved as monotherapy for the treatment of certain patients with cervical cancer, classical Hodgkin lymphoma (cHL), cutaneous squamous cell carcinoma (cSCC), esophageal cancer, gastric or gastroesophageal junction adenocarcinoma, head and neck squamous cell carcinoma

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

Global sales of *Keytruda* grew 19% in the first quarter of 2021. Sales growth 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 due to a decline in the number of new patients starting treatment. Sales in the United States continue to build across the multiple approved indications, in particular for the treatment of advanced NSCLC as monotherapy, and in combination with chemotherapy for both nonsquamous and squamous metastatic NSCLC, along with uptake in the RCC, adjuvant melanoma, HNSCC, bladder cancer and endometrial carcinoma indications. Uptake of the every six weeks (Q6W) adult dosing regimen in the United States benefited sales in the first quarter of 2021. *Keytruda* sales growth in international markets was driven by continued uptake in approved indications, particularly in the European Union (EU). Sales growth in the first quarter of 2021 was partially offset by pricing declines in the EU and in Japan.

In March 2021, the U.S. Food and Drug Administration (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 platinum- and fluoropyrimidine-based chemotherapy. The approval is based on the results of the KEYNOTE-590 trial.

In May 2021, the FDA approved *Keytruda*, in combination with trastuzumab, fluoropyrimidine- and platinum-containing chemotherapy, for the first-line treatment of patients with locally advanced unresectable or metastatic human epidermal growth factor receptor 2 (HER2) positive gastric or 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.

Also in March 2021, Merck announced it was voluntarily withdrawing the U.S. indication for *Keytruda* for the treatment of patients with metastatic small-cell lung cancer 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 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 trial and supportive data from an updated analysis of the KEYNOTE-087 trial. This is the first pediatric approval for *Keytruda* in the EU.

Lynparza, an oral poly (ADP-ribose) polymerase (PARP) inhibitor being developed as part of a collaboration with AstraZeneca PLC (AstraZeneca) (see Note 3 to the condensed consolidated financial statements), is approved for the treatment of certain types of advanced ovarian, breast, pancreatic and prostate cancers. Alliance revenue related to Lynparza increased 57% in the first quarter of 2021. Sales growth was largely driven by continued uptake across the multiple approved indications in the United States, the EU and China.

Lenvima (lenvatinib), an oral receptor tyrosine kinase inhibitor being developed as part of a collaboration with Eisai Co., Ltd. (Eisai) (see Note 3 to the condensed consolidated financial statements), is approved for the treatment of certain types of thyroid cancer, HCC, in combination with everolimus for certain patients with RCC, and in combination with *Keytruda* for the treatment of certain patients with endometrial carcinoma. Alliance revenue related to Lenvima was nearly flat in the first quarter of 2021 driven in part by increased competition for the treatment of HCC.

Vaccines

($ in millions)	Three Months Ended March 31, 2021	2020	% Change	% Change Excluding Foreign Exchange
Gardasil/Gardasil 9	$ 917	$ 1,097	(16)%	(20)%
ProQuad	165	157	5 %	4 %
M-M-R II	80	100	(20)%	(21)%
Varivax	204	179	14 %	14 %
Pneumovax 23	171	256	(33)%	(36)%
RotaTeq	158	222	(29)%	(29)%
Vaqta	34	60	(43)%	(44)%

Worldwide sales of *Gardasil/Gardasil* 9, vaccines to help prevent certain cancers and other diseases caused by certain types of human papillomavirus (HPV), declined 16% in the first quarter of 2021. The sales decline was primarily due to buying patterns in the United States and the timing of shipments in China, which in total negatively affected the year over year *Gardasil/Gardasil* 9 sales comparison by approximately $230 million. The COVID-19 pandemic also negatively affected sales of *Gardasil/Gardasil* 9, particularly in the United States and the EU.

Global sales of *ProQuad* (Measles, Mumps, Rubella and Varicella Virus Vaccine Live), a pediatric combination vaccine to help protect against measles, mumps, rubella and varicella, grew 5% in the first quarter of 2021 primarily due to higher pricing and demand in the United States, partially offset by lower demand in the EU.

Worldwide sales of *M-M-R* II (Measles, Mumps and Rubella Virus Vaccine Live), a vaccine to help protect against measles, mumps and rubella, declined 20% in the first quarter of 2021 primarily due to lower demand in the United States and the EU, partially offset by higher pricing in the United States.

Global sales of *Varivax* (Varicella Virus Vaccine Live), a vaccine to help prevent chickenpox (varicella), grew 14% in the first quarter of 2021 driven by the timing of government tenders in Brazil.

Worldwide sales of *Pneumovax* 23, a vaccine to help prevent pneumococcal disease, declined 33% in the first quarter of 2021 primarily driven by lower demand in the United States attributable to the COVID-19 pandemic, partially offset by higher volumes in the Asia Pacific region, due in part to the timing of sales in China.

Global sales of *RotaTeq*, a vaccine to help protect against rotavirus gastroenteritis in infants and children, declined 29% in the first quarter of 2021 largely due to the timing of shipments in China and lower demand in the United States.

Worldwide sales of *Vaqta*, a vaccine indicated for the prevention of disease caused by hepatitis A virus, declined 43% in the first quarter of 2021 primarily reflecting lower demand attributable to the COVID-19 pandemic and lower government tenders in Turkey.

Hospital Acute Care

($ in millions)	Three Months Ended March 31, 2021	2020	% Change	% Change Excluding Foreign Exchange
Bridion	$ 340	$ 299	14 %	11 %
Prevymis	82	60	37 %	31 %
Noxafil	67	94	(29)%	(32)%
Zerbaxa	(8)	37	(121)%	(120)%

Worldwide sales of *Bridion*, for the reversal of two types of neuromuscular blocking agents used during surgery, grew 14% in the first quarter of 2021 largely attributable to higher demand globally, particularly in the United States.

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 37% in the first quarter of 2021, due to continued uptake since launch in the United States and the EU. *Prevymis* was approved by the FDA in November 2017 and by the EC in January 2018.

Global sales of *Noxafil*, an antifungal agent for the prevention of certain invasive fungal infections, declined 29% in the first quarter of 2021 primarily due to generic competition in the EU, 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 volume and pricing declines in *Noxafil* sales in these markets as a result of generic competition and expects the declines to continue.

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

Immunology

($ in millions)	Three Months Ended March 31, 2021	2020	% Change	% Change Excluding Foreign Exchange
Simponi	$ 214	$ 215	— %	(8)%
Remicade	85	88	(3)%	(9)%

Sales of *Simponi* (golimumab), a once-monthly subcutaneous treatment for certain inflammatory diseases (marketed by the Company in Europe, Russia and Turkey), were essentially flat in the first quarter of 2021. Excluding the favorable effect of foreign exchange, sales performance reflects lower demand in the EU. 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*.

Sales of *Remicade* (infliximab), a treatment for certain inflammatory diseases (marketed by the Company in Europe, Russia and Turkey), declined 3% in the first quarter of 2021 driven by ongoing biosimilar competition in the Company's marketing territories in Europe. The Company lost market exclusivity for *Remicade* in major European markets in 2015 and no longer has market exclusivity in any of its marketing territories. The Company is experiencing pricing and volume declines in these markets as a result of biosimilar competition and expects the declines to continue.

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

Virology

($ in millions)	Three Months Ended March 31, 2021	2020	% Change	% Change Excluding Foreign Exchange
Isentress/Isentress HD	209	245	(15)%	(15)%

Global combined sales of *Isentress/Isentress HD*, an HIV integrase inhibitor for use in combination with other antiretroviral agents for the treatment of HIV-1 infection, declined 15% in the first quarter of 2021 due to competitive pressure in most markets, particularly in the EU and the United States. The Company expects competitive pressure for *Isentress/ Isentress HD* to continue.

Cardiovascular

($ in millions)	Three Months Ended March 31, 2021	2020	% Change	% Change Excluding Foreign Exchange
Zetia/Vytorin	$ 133	$ 198	(33)%	(37)%
Atozet	112	122	(9)%	(16)%
Rosuzet	15	32	(52)%	(54)%
Alliance Revenue - Adempas [(1)]	74	53	38 %	38 %
Adempas	55	56	(2)%	(10)%

[(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 3 to the condensed consolidated financial statements).*

Combined global sales of *Zetia* (marketed in most countries outside the United States as *Ezetrol*) and *Vytorin* (ezetimibe/simvastatin) (marketed outside the United States as *Inegy*), medicines for lowering LDL cholesterol, declined 33% in the first quarter of 2021, primarily due to lower sales of *Ezetrol* in Japan. The patent that provided market exclusivity for *Ezetrol* in Japan expired in September 2019 and generic competition began in June 2020. Accordingly, the Company is experiencing sales declines in Japan as a result of generic competition and expects the decline to continue. Higher demand for *Ezetrol* in China partially offset the sales decline in the quarter.

Sales of *Atozet* (ezetimibe and atorvastatin) (marketed outside of the United States), a medicine for lowering LDL cholesterol, declined 9% in the first quarter of 2021 due to lower demand in the EU, partially offset by higher demand in the Asia Pacific region.

Sales of *Rosuzet* (ezetimibe and rosuvastatin) (marketed outside of the United States), a medicine for lowering LDL cholesterol, declined 52% in the first quarter of 2021 due to the expiration of a distribution agreement in Korea.

Zetia, *Vytorin*, *Atozet* and *Rosuze*t will be contributed to Organon in connection with the spin-off (see Note 1 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 3 to the condensed consolidated financial statements). Revenue from Adempas includes Merck's share of profits from the sale of Adempas in Bayer's marketing territories (alliance revenue), which grew 38% in the first quarter of 2021, as well as sales in Merck's marketing territories, which declined 2% in the first quarter of 2021.

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. The approval was based on the results of the VICTORIA trial and follows a priority regulatory review. Verquvo is part of the same worldwide clinical development collaboration with Bayer that includes Adempas referenced above.

Diabetes

	Three Months Ended March 31,			% Change Excluding Foreign
($ in millions)	2021	2020	% Change	Exchange
Januvia/Janumet	$ 1,295	$ 1,277	1 %	(2)%

Worldwide combined sales of *Januvia* (sitagliptin) and *Janumet* (sitagliptin/metformin HCl), medicines that help lower blood sugar levels in adults with type 2 diabetes, increased 1% in the first quarter of 2021. Excluding the favorable effect of foreign exchange, sales performance reflects lower demand in the United States and Europe, partially offset by higher demand in China. The Company has historically experienced U.S. pricing pressure on *Januvia* and *Janumet* and expects this pricing pressure to continue in future periods. *Januvia* and *Janumet* will lose market exclusivity in the United States 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.

Women's Health

	Three Months Ended March 31,			% Change Excluding Foreign
($ in millions)	2021	2020	% Change	Exchange
Implanon/Nexplanon	$ 183	$ 195	(6)%	(7)%
NuvaRing	45	63	(28)%	(30)%

Global sales of *Implanon/Nexplanon* (etonogestrel implant), a single-rod subdermal contraceptive implant, declined 6% in the first quarter of 2021 primarily due to lower demand in the United States resulting from the COVID-19 pandemic.

Worldwide sales of *NuvaRing* (etonogestrel/ethinyl estradiol vaginal ring), a vaginal contraceptive product, declined 28% in the first quarter of 2021 due to generic competition in most markets, particularly in the EU and the United States. The Company expects sales to continue to decline as a result of generic competition.

Implanon/Nexplanon and *NuvaRing* will be contributed to Organon in connection with the spin-off (see Note 1 to the condensed consolidated financial statements).

Biosimilars

	Three Months Ended March 31,			% Change Excluding Foreign
($ in millions)	2021	2020	% Change	Exchange
Biosimilars	$ 81	$ 68	19 %	13 %

Biosimilar products are marketed by the Company pursuant to an agreement with Samsung Bioepis Co., Ltd. (Samsung) to develop and commercialize multiple pre-specified biosimilar candidates. Currently, the Company markets Renflexis (infliximab-abda), a biosimilar to Remicade (infliximab) for the treatment of certain inflammatory diseases; Ontruzant (trastuzumab-dttb), a biosimilar to Herceptin (trastuzumab) for the treatment of HER2-positive breast cancer and HER2 overexpressing gastric cancer; Brenzys (etanercept biosimilar), a biosimilar to Enbrel for the treatment of certain inflammatory diseases; and Aybintio (bevacizumab) for the treatment of certain types of cancer. Merck's commercialization territories under the agreement vary by product. Sales of biosimilars grew 19% in the first quarter of 2021 primarily due to continued post-launch uptake of Renflexis in the United States and the launch of Aybintio in the EU, partially offset by the timing of Brenzys shipments in Brazil.

The above biosimilar products will be contributed to Organon in connection with the spin-off (see Note 1 to the condensed consolidated financial statements).

Animal Health Segment

($ in millions)	Three Months Ended March 31, 2021	2020	% Change	% Change Excluding Foreign Exchange
Livestock	$ 819	$ 739	11 %	9 %
Companion Animal	599	475	26 %	24 %

Sales of livestock products grew 11% in the first quarter of 2021 primarily due to higher demand in international markets for ruminant, poultry and swine products, as well as higher demand globally for animal health intelligence solutions for animal identification, monitoring and traceability. Sales of companion animal products grew 26% in the first quarter of 2021 primarily due to higher demand for parasiticides, including the *Bravecto* (fluralaner) line of products, as well as higher demand for companion animal vaccines.

Costs, Expenses and Other

($ in millions)	Three Months Ended March 31, 2021	2020	% Change
Cost of sales	$ 3,670	$ 3,312	11 %
Selling, general and administrative	2,633	2,555	3 %
Research and development	2,465	2,209	12 %
Restructuring costs	298	72	*
Other (income) expense, net	(448)	71	*
	$ 8,618	$ 8,219	5 %

** Greater than 100%.*

Cost of Sales

Cost of sales increased 11% in the first quarter of 2021. Cost of sales includes the amortization of intangible assets recorded in connection with acquisitions, collaborations, and licensing arrangements, which totaled $495 million and $403 million in the first quarter of 2021 and 2020, respectively. Costs in the first quarter of 2021 also include a charge of $188 million related to the discontinuation of COVID-19 development programs. Also included in cost of sales are expenses associated with restructuring activities which amounted to $27 million and $68 million in the first quarter 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 69.6% in the first quarter of 2021 compared with 72.5% in the first quarter of 2020. The gross margin decline reflects higher costs associated with COVID-19 development programs, including a charge related to the discontinuation of certain COVID-19 development programs, as well as higher amortization of intangible assets (noted above) and the unfavorable effect of pricing pressure, partially offset by the favorable effects of product mix and lower restructuring costs.

Selling, General and Administrative

Selling, general and administrative (SG&A) expenses increased 3% in the first quarter of 2021 primarily due to higher promotion and administrative costs, the unfavorable effect of foreign exchange and higher costs related to the Company's planned spin-off of Organon, partially offset by $95 million of costs in the prior year related to the acquisition of

ArQule, Inc. (ArQule), as well as lower selling costs due in part to the COVID-19 pandemic. SG&A expenses include $208 million and $165 million of costs related to the planned spin-off of Organon in the first quarter of 2021 and 2020, respectively.

Research and Development

Research and development (R&D) expenses grew 12% in the first quarter of 2021 primarily due to higher clinical development spending, including investment in COVID-19 development programs, as well as increased investment in discovery research and early drug development, partially offset by lower licensing costs.

R&D expenses are comprised of the costs directly incurred by MRL, the Company's research and development division that focuses on human health-related activities, which were $1.8 billion and $1.5 billion in the first quarter 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 $680 million and $625 million for the first quarter of 2021 and 2020, respectively. In addition, R&D expenses include expense or income related to changes in the estimated fair value measurement of liabilities for contingent consideration recorded in connection with business acquisitions. The Company recorded net expenses of $33 million in the first quarter of 2020 related to the changes in these estimates.

Restructuring Costs

In 2019, Merck approved a new global restructuring program (Restructuring Program) as part of a worldwide initiative focused on further optimizing the Company's manufacturing and supply network, as well as reducing its global real estate footprint. This program is a continuation of the Company's plant rationalization, builds on prior restructuring programs and does not include any actions associated with the planned spin-off of Organon. As the Company continues to evaluate its global footprint and overall operating model, it subsequently identified additional actions under the Restructuring Program, and could identify further actions over time. The actions currently contemplated under the Restructuring Program are expected to be substantially completed by the end of 2023, with the cumulative pretax costs to be incurred by the Company to implement the program estimated to be approximately $3.0 billion. The Company expects to record charges of approximately $700 million in 2021 related to the Restructuring Program. The Company anticipates the actions under the Restructuring Program to result in annual net cost savings of approximately $900 million by the end of 2023.

Restructuring costs, primarily representing separation and other related costs associated with these restructuring activities, were $298 million and $72 million for the first quarter 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 $335 million and $168 million in the first quarter of 2021 and 2020, respectively, related to restructuring program activities (see Note 4 to the condensed consolidated financial statements).

Other (Income) Expense, Net

Other (income) expense, net, was $448 million of income in the first quarter of 2021 compared with $71 million of expense in the first quarter of 2020 primarily due to higher income from investments in equity securities, net, largely related to the disposition of the Company's ownership interest in Preventice Solutions Inc. (Preventice) as a result of the acquisition of Preventice by Boston Scientific. For details on the components of Other (income) expense, net, see Note 11 to the condensed consolidated financial statements.

Segment Profits

	Three Months Ended March 31,	
($ in millions)	2021	2020
Pharmaceutical segment profits	$ 7,555	$ 7,582
Animal Health segment profits	572	479
Other non-reportable segment profits	—	1
Other	(4,665)	(4,224)
Income before taxes	$ 3,462	$ 3,838

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

Pharmaceutical segment profits in the first quarter of 2021 were comparable to the first quarter of 2020 reflecting higher promotional costs, offset by the favorable effects of foreign exchange, product mix, and lower selling costs. Animal Health segment profits grew 19% in the first quarter of 2021 reflecting higher sales, partially offset by higher R&D costs, higher administrative costs and the unfavorable effect of foreign exchange.

Taxes on Income

The effective income tax rates of 8.0% and 16.1% for the first quarter of 2021 and 2020, respectively, reflect the impacts of acquisition and divestiture-related costs and restructuring costs, partially offset by the beneficial impact of foreign earnings, including product mix.

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. The Company's reserves for unrecognized tax benefits for the years under examination exceeded the adjustments relating to this examination period and therefore the Company recorded a $237 million net tax benefit in the first quarter of 2021. 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.

Net Income and Earnings per Common Share

Net income attributable to Merck & Co., Inc. was $3.2 billion in both the first quarter of 2021 and 2020. Earnings per common share assuming dilution attributable to Merck & Co., Inc. common shareholders (EPS) for the first quarter of 2021 were $1.25 compared with $1.26 in the first quarter of 2020.

Non-GAAP Income and Non-GAAP EPS

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 United States (GAAP).

In 2021, the Company changed the treatment of certain items for purposes of its non-GAAP reporting. Historically, Merck's non-GAAP results excluded the amortization of intangible assets recognized in connection with business acquisitions but did not exclude the amortization of intangible assets originating from collaborations, asset acquisitions or licensing arrangements. Beginning in 2021, Merck's non-GAAP results no longer differentiate between the nature of intangible assets being amortized and exclude all amortization of intangible assets. Also, beginning in 2021, Merck's non-GAAP results exclude income and losses from investments in equity securities. Non-GAAP results for the comparable periods of 2020 have been recast to conform to the new presentation.

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

($ in millions except per share amounts)	Three Months Ended March 31, 2021	2020
Income before taxes as reported under GAAP	$ 3,462	$ 3,838
Increase (decrease) for excluded items:		
Acquisition and divestiture-related costs	725	714
Restructuring costs	335	168
Income from investments in equity securities, net	(561)	(87)
Other items:		
Charge for the discontinuation of COVID-19 development programs	188	—
Non-GAAP income before taxes	4,149	4,633
Taxes on income as reported under GAAP	276	619
Estimated tax benefit on excluded items [(1)]	73	163
Net tax benefit from the settlement of certain federal income tax matters	237	—
Non-GAAP taxes on income	586	782
Non-GAAP net income	$ 3,563	$ 3,851
EPS assuming dilution as reported under GAAP	$ 1.25	$ 1.26
EPS difference	0.15	0.25
Non-GAAP EPS assuming dilution	$ 1.40	$ 1.51

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

Acquisition and Divestiture-Related Costs

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

Restructuring Costs

Non-GAAP income and non-GAAP EPS exclude costs related to restructuring actions (see Note 4 to the condensed consolidated financial statements). These amounts include employee separation costs and accelerated depreciation associated with facilities to be closed or divested. Accelerated depreciation costs represent the difference between the depreciation expense to be recognized over the revised useful life of the asset, based upon the anticipated date the site will be closed or divested or the equipment disposed of, and depreciation expense as determined utilizing the useful life prior to the restructuring actions. Restructuring costs also include asset abandonment, facility shut-down and other related costs, as well as employee-related costs such as curtailment, settlement and termination charges associated with pension and other postretirement benefit plans and share-based compensation costs.

Income and Losses from Investments in Equity Securities

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

Certain Other Items

Non-GAAP income and non-GAAP EPS exclude certain other items. These items are adjusted for after evaluating them on an individual basis, considering their quantitative and qualitative aspects. Typically, these consist of items that are unusual in nature, significant to the results of a particular period or not indicative of future operating results. Excluded from non-GAAP income and non-GAAP EPS in 2021 is a charge related to the discontinuation of COVID-19 development programs (see Note 2 to the condensed consolidated financial statements) and a net tax benefit related to the settlement of certain federal income tax matters (see Note 12 to the condensed consolidated financial statements).

Research and Development Update

MK-7655A is a combination of relebactum, a beta-lactamase inhibitor, and imipenem/cilastatin (a carbapenem antibiotic) under review in Japan for the treatment of bacterial infection. MK-7655A was approved by the FDA in 2019 and is marketed in the United States as *Recarbrio*.

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, and will be discussed at an upcoming advisory committee meeting. No date has been set yet. The FDA set a Prescription Drug User Fee Act (PDUFA), or target action, date of December 21, 2021. Gefapixant is also under review in Japan.

MK-1242, vericiguat, is an orally administered sGC stimulator under review in the EU and in Japan to reduce the risk of cardiovascular death and heart failure hospitalization following a worsening heart failure event in patients with symptomatic chronic heart failure with reduced ejection fraction, in combination with other heart failure therapies. The applications are based on results from the Phase 3 VICTORIA trial. Vericiguat was approved by the FDA in January 2021 and is being marketed in the United States as Verquvo. Vericiguat is being jointly developed with Bayer (see Note 3 to the condensed consolidated financial statements). Bayer will commercialize vericiguat in territories outside the United States, if approved.

MK-5618, selumetinib, received a positive opinion from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) for the treatment of pediatric patients two years of age and older with neurofibromatosis type 1 who have symptomatic, inoperable plexiform neurofibromas based on positive results from the National Cancer Institute Cancer Therapy Evaluation Program-sponsored Phase 2 SPRINT Stratum 1 trial. Selumetinib was approved by the FDA in April 2020 and is marketed in the United States as Koselugo. Selumetinib is being jointly developed and commercialized with AstraZeneca globally (see Note 3 to the condensed consolidated financial statements).

V114 is an investigational 15-valent pneumococcal conjugate vaccine under priority review by the FDA for the prevention of invasive pneumococcal disease in adults 18 years of age and older. The FDA set a PDUFA date of July 18, 2021. The EMA is also reviewing an application for licensure of V114 in adults. Additionally, the Company has several ongoing Phase 3 trials evaluating V114 in pediatric patients. 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 and adults 18 years of age and older. The Company is involved in litigation challenging the validity of several Pfizer Inc. patents that relate to pneumococcal vaccine technology in the United States and several foreign jurisdictions.

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

Keytruda is an anti-PD-1 therapy approved for the treatment of many cancers that is in clinical development for expanded indications. These approvals were the result of a broad clinical development program that currently consists of more than 1,450 clinical trials, including more than 1,050 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 in combination with chemotherapy is under review in the EU for the treatment of locally recurrent unresectable or metastatic TNBC in adults whose tumors express PD-L1 with a Combined Positive Score (CPS) ≥ 10 and who have not received prior chemotherapy for metastatic disease based on the results of the KEYNOTE-355 trial. *Keytruda* was approved for this indication under accelerated approval based on PFS by the FDA in November 2020. *Keytruda* in combination with chemotherapy is also under review in Japan for the treatment of patients with locally recurrent unresectable or metastatic TNBC based on data from the KEYNOTE-355 trial.

In March 2021, Merck received a Complete Response Letter (CRL) from the FDA regarding Merck's supplemental Biologics License Application (BLA) seeking approval for *Keytruda* for the treatment of patients with high-risk early-stage TNBC, in combination with chemotherapy as neoadjuvant (pre-operative) treatment, then continuing as a single agent as adjuvant (post-operative) treatment after surgery. Merck is reviewing the letter and will discuss next steps with the FDA. The application was based on pCR data and early interim event-free survival (EFS) findings from the Phase 3 KEYNOTE-522 trial, which is continuing to evaluate for EFS. Ahead of the PDUFA action date for the application, the FDA's Oncologic Drugs Advisory Committee (ODAC) voted 10-0 that a regulatory decision should be deferred until further data are available

from KEYNOTE-522. The next interim analysis is calendar-driven and will occur in the third quarter of 2021. This CRL does not impact any current approved indications for *Keytruda*.

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

In January 2021, the FDA accepted a supplemental BLA seeking use of *Keytruda* for the treatment of patients with locally advanced cSCC that is not curable by surgery or radiation based on the results of the KEYNOTE-629 trial. The FDA set a PDUFA date of September 9, 2021.

In December 2020, the CHMP of the EMA announced the start of a procedure to extend the indication for *Keytruda* to include in combination with chemotherapy, first-line treatment of locally advanced unresectable or metastatic carcinoma of the esophagus or HER-2 negative gastroesophageal junction adenocarcinoma in adults, based on the results from the KEYNOTE-590 trial. These data were presented at the European Society of Medical Oncology Virtual Congress 2020. *Keytruda* is also under review for this indication in Japan.

Keytruda is also under review in Japan for treatment of adult and pediatric patients with unresectable or metastatic TMB-H solid tumors that have progressed following prior treatment and who have no satisfactory alternative treatment options.

In April 2021, the CHMP of the EMA adopted a positive opinion recommending the addition of the 400 mg Q6W dosing regimen to indications where *Keytruda* is administered in combination with other anticancer agents.

In March 2021, the CHMP of the EMA adopted a positive opinion recommending that the European label for *Keytruda* be updated to include data from KEYNOTE-361, an open-label trial that evaluated *Keytruda* as a monotherapy and in combination with chemotherapy for the first-line treatment of certain patients with advanced or metastatic urothelial carcinoma. In Europe, *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 with a CPS ≥10. This approval was based on a single-arm study, KEYNOTE-052; KEYNOTE-361 was conducted as part of a post-marketing commitment following the initial approval of *Keytruda* for these patients. As previously announced, KEYNOTE-361 did not meet its primary endpoints of PFS and overall survival OS for the combination of *Keytruda* plus chemotherapy. However, the CHMP concluded that the benefit-risk profile remains positive and that including data from KEYNOTE-361 in the label allows physicians to evaluate the potential benefit-risk of *Keytruda* on an individual basis.

In April 2021, the FDA's ODAC discussed three U.S. indications for *Keytruda* as part of the FDA's industry-wide evaluation of indications based on accelerated approvals that have not met their post-marketing requirements. The ODAC voted in favor of maintaining accelerated approval of *Keytruda* for the treatment of patients with locally advanced or metastatic urothelial carcinoma who are not eligible for cisplatin-containing chemotherapy and whose tumors express PD-L1 (CPS ≥10), or in patients who are not eligible for any platinum-containing chemotherapy regardless of PD-L1 status. The ODAC also voted in favor of maintaining accelerated approval of *Keytruda* for the treatment of patients with HCC who have been previously treated with sorafenib. The ODAC voted against maintaining accelerated approval of *Keytruda* for the third-line treatment of certain patients with gastric cancer. *Keytruda* is currently approved for the treatment of patients with recurrent locally advanced or metastatic gastric or gastroesophageal junction adenocarcinoma whose tumors express PD-L1 (CPS≥1), with disease progression on or after two or more prior lines of therapy including fluoropyrimidine- and platinum-containing chemotherapy and if appropriate, HER2/neu-targeted therapy. These indications are approved under accelerated approval based on tumor response rate and durability of response. Continued approval for these indications may be contingent upon verification and description of clinical benefit in confirmatory trials. Merck is conducting multiple ongoing Phase 3 trials to gather confirmatory evidence for all accelerated approval indications. The FDA is not bound by the committee's recommendations. Merck will discuss next steps with the FDA.

Also in April 2021, Merck announced that the pivotal Phase 3 KEYNOTE-564 trial evaluating *Keytruda* met its primary endpoint of disease-free survival (DFS) for the potential adjuvant treatment of patients with RCC following nephrectomy (surgical removal of a kidney) or following nephrectomy and resection of metastatic lesions. Based on an interim analysis conducted by an independent Data Monitoring Committee, *Keytruda* monotherapy demonstrated a statistically significant and clinically meaningfully improvement in DFS compared with placebo. The trial will continue to evaluate OS, a key secondary endpoint. Results will be presented at an upcoming medical meeting and will be submitted to regulatory authorities.

Keytruda has also received Breakthrough Therapy designation from the FDA in February 2020 for the combination of *Keytruda* with Padcev (enfortumab vedotin-ejfv), in the first-line setting for the treatment of patients with unresectable locally advanced or metastatic urothelial cancer who are not eligible for cisplatin-containing chemotherapy. The FDA's Breakthrough Therapy designation is intended to expedite the development and review of a candidate that is planned for use,

alone or in combination, to treat a serious or life-threatening disease or condition when preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints.

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

Also in April 2021, the FDA accepted and granted priority review for a supplemental BLA for the combination of *Keytruda* plus Lenvima for the treatment of certain patients with advanced, metastatic or recurrent endometrial cancer following one prior platinum-based regimen in any setting. The supplemental BLA is based on data from the Phase 3 KEYNOTE-775/Study 309 trial, which met the dual primary endpoints of PFS and OS as well as the secondary efficacy endpoint of objective response rate. KEYNOTE-775/Study 309 is the confirmatory trial for KEYNOTE-146/Study 111, which supported accelerated approval by the FDA in 2019 of the *Keytruda* plus Lenvima combination for the treatment of patients with advanced endometrial carcinoma that is not MSI-H or dMMR, who have disease progression following prior systemic therapy and are not candidates for curative surgery or radiation. In April 2021, the CHMP of the EMA announced the start of a procedure to extend the indication to include *Keytruda* in combination with lenvatinib for the treatment of advanced endometrial carcinoma in adults who have disease progression following prior systemic therapy in any setting and who are not candidates for curative surgery or radiation, based on the KEYNOTE-775 trial. *Keytruda* is also under review for this indication in Japan.

Additionally, in April 2021, Merck and Ridgeback Bio provided an update on the clinical development program for molnupiravir (MK-4482/ EIDD-2801), an investigational orally available antiviral therapeutic. Based on a planned interim analysis of data from the Phase 2, dose-finding portion (Part 1) of two ongoing placebo-controlled Phase 2/3 trials evaluating molnupiravir administered twice a day for five days in outpatients (MOVe-OUT) and hospitalized patients (MOVe-IN) with COVID-19, and from a previously completed Phase 2a dose-ranging study in outpatients, the decision has been made to proceed with the Phase 3 portion (Part 2) of MOVe-OUT in outpatients with COVID-19, evaluating the 800 mg dose of molnupiravir twice daily. Data from MOVe-IN indicate that molnupiravir is unlikely to demonstrate a clinical benefit in hospitalized patients, who generally had a longer duration of symptoms prior to study entry; therefore, the decision has been made not to proceed to Phase 3.

In April 2021, Merck also announced the discontinuation of development of MK-7110 (formerly known as CD24Fc) for the treatment of hospitalized patients with COVID-19. Merck acquired MK-7110 in December 2020 through its acquisition of OncoImmune, a privately held clinical-stage biopharmaceutical company. In 2021, Merck received feedback from the FDA that additional data would be needed to support a potential Emergency Use Authorization application and therefore the Company did not expect MK-7110 would become available until the first half of 2022. Given this timeline and the technical, clinical and regulatory uncertainties, the availability of a number of medicines for patients hospitalized with COVID-19, and the need to concentrate Merck's resources on accelerating the development and manufacture of the most viable therapeutics and vaccines, Merck decided to discontinue development of MK-7110 for the treatment of COVID-19. Due to the discontinuation, the Company recorded a charge of $170 million in the first quarter of 2021, which was reflected in *Cost of sales* and related to fixed-asset and materials write-offs, as well as the recognition of liabilities for purchase commitments.

The chart below reflects the Company's research pipeline as of May 5, 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
Antiviral COVID-19 MK-4482 (molnupiravir)[1] **Cancer** MK-1026 Hematological Malignancies MK-1308 (quavonlimab)[2] Advanced Solid Tumors Hepatocellular Carcinoma Melanoma Non-Small-Cell Lung MK-2140 Advanced Solid Tumors MK-3475 *Keytruda* Advanced Solid Tumors MK-4280[2] Hematological Malignancies Non-Small-Cell Lung MK-4830 Non-Small-Cell Lung MK-5890[2] Non-Small-Cell Lung MK-6440 (ladiratuzumab vedotin)[1][3] Advanced Solid Tumors Breast MK-7119 Tukysa[1] Advanced Solid Tumors Colorectal Gastric MK-7339 Lynparza[1][3] Advanced Solid Tumors MK-7684 (vibostolimab)[2] Melanoma MK-7902 Lenvima[1][2] Advanced Solid Tumors Biliary Tract Glioblastoma Pancreatic V937 Breast Cutaneous Squamous Cell Head and Neck Melanoma Solid Tumors **Chikungunya Virus Vaccine** V184 **Cytomegalovirus** V160 **HIV-1 Infection** MK-8591B (islatravir/MK-8507) **Nonalcoholic Steatohepatitis (NASH)** MK-3655 **Overgrowth Syndrome** MK-7075 (miransertib) **Pneumococcal Vaccine Adult** V116 **Respiratory Syncytial Virus** MK-1654 **Schizophrenia** MK-8189	**Acute Graft Versus Host Disease** MK-7110 **Cancer** MK-1308A (pembrolizumab/quavonlimab) 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) MK-6482 (belzutifan) Renal Cell (February 2020) MK-7119 Tukysa[1] Breast (October 2019) MK-7339 Lynparza[1][2] Colorectal[1] (August 2020) Non-Small-Cell Lung[2] (June 2019) Small-Cell Lung[2] (December 2020) MK-7684A (pembrolizumab/vibostolimab) Non-Small-Cell Lung (April 2021) MK-7902 Lenvima[1][2] Bladder (May 2019) Colorectal (April 2021) Gastric (December 2020) Head and Neck (February 2020) Melanoma (March 2019) Non-Small-Cell Lung (March 2019) **HIV-1 Infection** MK-8591A (doravirine/islatravir) (February 2020) **HIV-1 Prevention** MK-8591 (islatravir) (February 2021)	**New Molecular Entities/Vaccines** **Bacterial Infection** MK-7655A (relebactam+imipenem/cilastatin) (JPN) **Cough** MK-7264 (gefapixant) (U.S.) (JPN) **Heart Failure** MK-1242 (vericiguat)[1] (EU) (JPN) **Pediatric Neurofibromatosis Type 1** MK-5618 (selumetinib)[1] (EU) **Pneumococcal Vaccine Adult** V114 (U.S.) (EU) **Von Hippel-Lindau Disease-Associated Renal Cell Carcinoma** MK-6482 (belzutifan) (U.S.) **Certain Supplemental Filings** **Cancer** MK-3475 *Keytruda* • Metastatic Triple-Negative Breast Cancer (KEYNOTE-355) (EU) (JPN) • High-Risk Early-Stage Triple-Negative Breast Cancer (KEYNOTE-522) (U.S.)[4] • Unresectable or Metastatic MSI-H or dMMR Colorectal Cancer (KEYNOTE-177) (JPN) • Locally Advanced Cutaneous Squamous Cell Cancer (KEYNOTE-629) (U.S.) • Advanced Unresectable Metastatic Esophageal Cancer (KEYNOTE-590) (EU) (JPN) • Tumor Mutational Burden-High (KEYNOTE-158) (JPN) • Alternative Dosing Regimen (Q6W) For Combination Therapy (EU) MK-7902 Lenvima[1][2] • First-Line Metastatic Hepatocellular Carcinoma (KEYNOTE-524) (U.S.)[5] • Advanced Unresectable Renal Cell Carcinoma (KEYNOTE-581) (U.S.) (EU) (JPN) • Advanced Endometrial Cancer (KEYNOTE-775) (U.S.) (EU) (JPN)
		Footnotes: [1] Being developed in a collaboration. [2] Being developed in combination with *Keytruda*. [3] Being developed as monotherapy and in combination with *Keytruda*. [4] In March 2021, the FDA issued a CRL for Merck's application. Merck is reviewing the letter and will discuss next steps with the FDA. [5] In July 2020, the FDA issued a CRL for Merck's and Eisai's applications. Merck and Eisai intend to submit additional data when available to the FDA.

Liquidity and Capital Resources

($ in millions)	March 31, 2021	December 31, 2020
Cash and investments	$ 7,525	$ 8,847
Working capital	548	437
Total debt to total liabilities and equity	34.4 %	34.7 %

Cash provided by operating activities was $1.8 billion in the first three months of 2021 compared with $707 million in the first three months of 2020. Cash provided by operating activities in the first three months of 2021 includes $325 million of payments related to collaborations compared with $750 million in the first three months of 2020. Cash provided by operating activities 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 was $738 million in the first three months of 2021 compared with $1.6 billion in the first three months of 2020. The lower use of cash in investing activities was driven primarily by the 2020 acquisition of Arqule, partially offset by lower proceeds from sales of securities and other investments and higher capital expenditures.

Cash used in financing activities was $2.1 billion in the first three months of 2021 compared with $1.5 billion in the first three months of 2020. The higher use of cash in financing activities was primarily due to a lower increase in net short-term borrowings and higher dividends paid to shareholders, partially offset by purchases of treasury stock in 2020 and lower payments on debt.

Capital expenditures totaled $1.1 billion and $1.0 billion for the first three 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 $1.8 billion and $2.3 billion of accounts receivable in the first quarter of 2021 and the fourth quarter of 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 $1.6 billion for both the first three months of 2021 and 2020. In January 2021, the Board of Directors declared a quarterly dividend of $0.65 per share on the Company's common stock for the second quarter that was paid in April 2021.

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

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

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

In 2018, Merck's Board of Directors authorized purchases of up to $10 billion of Merck's common stock for its treasury. The treasury stock purchase authorization has no time limit and will be made over time in open-market transactions, block transactions on or off an exchange, or in privately negotiated transactions. In March 2020, the Company temporarily suspended its share repurchase program and therefore did not purchase any of its common stock for its treasury under this share repurchase program in the first three months of 2021. As of March 31, 2021, the Company's remaining share repurchase authorization was $5.9 billion.

The Company has a $6.0 billion credit facility that matures in June 2024. 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 March 31, 2021, the Company's disclosure controls and procedures are effective. For the first 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, as filed on February 25, 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 7 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, but that negative impacts will persist, particularly during the first half of 2021 and most notably with respect to vaccine sales in the United States. For the full year of 2021, Merck assumes a net unfavorable impact to sales of approximately 3% due to the COVID-19 pandemic, all of which relates to the Pharmaceutical segment. In addition, for the full year of 2021, Merck expects a negligible impact to operating expenses, as spending on the development of its COVID-19-related research programs is expected to largely offset the favorable impact of lower spending in other areas due to the COVID-19 pandemic. To the extent these assumptions prove to be incorrect, the Company's results may differ materially from the estimates set forth herein.

Thus far in 2021, the COVID-19 pandemic has impacted the Company's business and the Company continues to expect that it will impact the business in numerous ways, including but not limited to those outlined below:

In the first quarter of 2021, the estimated negative impact of the COVID-19 pandemic to Merck's Pharmaceutical sales was approximately $600 million. The impact to Animal Health sales was immaterial. Roughly two-thirds 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. Reduced access to health care providers combined with the prioritization of COVID-19 vaccines and public health guidance on co-administration with other vaccines has resulted in reduced administration of many of the Company's human health products, notably vaccines in the United States, which the Company anticipates will continue while pandemic-related access measures remain in place.

Operating expenses reflect a minor positive effect in the first quarter of 2021 from the COVID-19 pandemic 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 March 31, 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)]
January 1 - January 31	—	$0.00	$5,888
February 1 - February 28	—	$0.00	$5,888
March 1 - March 31	—	$0.00	$5,888
Total	—	$0.00	$5,888

[(1)] *The Company did not purchase any shares during the three months ended March 31, 2021 under the plan approved by the Board of Directors in October 2018 to purchase up to $10 billion of Merck's common stock for its treasury.*

Item 6. Exhibits

Number		Description
3.1	—	Restated Certificate of Incorporation of Merck & Co., Inc. (November 3, 2009) – Incorporated by reference to Current Report on Form 8-K filed on November 4, 2009 (No. 1-6571)
3.2	—	By-Laws of Merck & Co., Inc. (effective 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: May 5, 2021

/s/ Jennifer Zachary

JENNIFER ZACHARY

Executive Vice President, General Counsel and Corporate Secretary

Date: May 5, 2021

/s/ Rita A. Karachun

RITA A. KARACHUN

Senior Vice President Finance - Global Controller