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

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2020

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.)

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 ☒

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

The number of shares of common stock outstanding as of the close of business on July 31, 2020: 2,529,241,070

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Part I - Financial Information

Item 1. Financial Statements

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Sales	$ 10,872	$ 11,760	$ 22,929	$ 22,575
Costs, Expenses and Other				
Cost of sales	3,159	3,401	6,471	6,453
Selling, general and administrative	2,378	2,712	4,933	5,138
Research and development	2,123	2,189	4,331	4,119
Restructuring costs	83	59	155	212
Other (income) expense, net	(390)	140	(318)	327
	7,353	8,501	15,572	16,249
Income Before Taxes	3,519	3,259	7,357	6,326
Taxes on Income	509	615	1,128	820
Net Income	3,010	2,644	6,229	5,506
Less: Net Income (Loss) Attributable to Noncontrolling Interests	8	(26)	8	(79)
Net Income Attributable to Merck & Co., Inc.	$ 3,002	$ 2,670	$ 6,221	$ 5,585
Basic Earnings per Common Share Attributable to Merck & Co., Inc. Common Shareholders	$ 1.19	$ 1.04	$ 2.46	$ 2.17
Earnings per Common Share Assuming Dilution Attributable to Merck & Co., Inc. Common Shareholders	$ 1.18	$ 1.03	$ 2.45	$ 2.15

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Net Income Attributable to Merck & Co., Inc.	$ 3,002	$ 2,670	$ 6,221	$ 5,585
Other Comprehensive (Loss) Income Net of Taxes:				
Net unrealized loss on derivatives, net of reclassifications	(120)	(52)	(16)	(100)
Net unrealized gain (loss) on investments, net of reclassifications	—	44	(18)	126
Benefit plan net gain and prior service credit, net of amortization	39	11	99	26
Cumulative translation adjustment	79	(19)	(265)	131
	(2)	(16)	(200)	183
Comprehensive Income Attributable to Merck & Co., Inc.	$ 3,000	$ 2,654	$ 6,021	$ 5,768

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

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

	June 30, 2020	December 31, 2019
Assets		
Current Assets		
Cash and cash equivalents	$ 11,103	$ 9,676
Short-term investments	—	774
Accounts receivable (net of allowance for doubtful accounts of $90 in 2020 and $86 in 2019)	7,577	6,778
Inventories (excludes inventories of $1,921 in 2020 and $1,480 in 2019 classified in Other assets - see Note 6)	6,056	5,978
Other current assets	4,607	4,277
Total current assets	29,343	27,483
Investments	1,251	1,469
Property, Plant and Equipment, at cost, net of accumulated depreciation of $18,182 in 2020 and $17,686 in 2019	15,789	15,053
Goodwill	20,067	19,425
Other Intangibles, Net	16,566	14,196
Other Assets	7,599	6,771
	$ 90,615	$ 84,397
Liabilities and Equity		
Current Liabilities		
Loans payable and current portion of long-term debt	$ 4,718	$ 3,610
Trade accounts payable	3,448	3,738
Accrued and other current liabilities	11,182	12,549
Income taxes payable	1,266	736
Dividends payable	1,564	1,587
Total current liabilities	22,178	22,220
Long-Term Debt	26,156	22,736
Deferred Income Taxes	2,091	1,470
Other Noncurrent Liabilities	12,446	11,970
Merck & Co., Inc. Stockholders' Equity		
Common stock, $0.50 par value Authorized - 6,500,000,000 shares Issued - 3,577,103,522 shares in 2020 and 2019	1,788	1,788
Other paid-in capital	39,373	39,660
Retained earnings	49,724	46,602
Accumulated other comprehensive loss	(6,393)	(6,193)
	84,492	81,857
Less treasury stock, at cost: 1,047,935,095 shares in 2020 and 1,038,087,496 shares in 2019	56,850	55,950
Total Merck & Co., Inc. stockholders' equity	27,642	25,907
Noncontrolling Interests	102	94
Total equity	27,744	26,001
	$ 90,615	$ 84,397

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

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

	Six Months Ended June 30, 2020	Six Months Ended June 30, 2019
Cash Flows from Operating Activities		
Net income	$ 6,229	$ 5,506
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	1,869	1,871
Intangible asset impairment charges	20	252
Deferred income taxes	122	(149)
Share-based compensation	229	204
Other	(202)	114
Net changes in assets and liabilities	(4,193)	(3,378)
Net Cash Provided by Operating Activities	4,074	4,420
Cash Flows from Investing Activities		
Capital expenditures	(1,654)	(1,377)
Purchases of securities and other investments	(77)	(1,810)
Proceeds from sales of securities and other investments	1,892	4,935
Acquisition of ArQule, Inc., net of cash acquired	(2,545)	—
Acquisition of Antelliq Corporation, net of cash acquired	—	(3,620)
Other acquisitions, net of cash acquired	(321)	(270)
Other	195	85
Net Cash Used in Investing Activities	(2,510)	(2,057)
Cash Flows from Financing Activities		
Net change in short-term borrowings	1,967	(3,532)
Payments on debt	(1,952)	—
Proceeds from issuance of debt	4,445	4,958
Purchases of treasury stock	(1,281)	(2,325)
Dividends paid to stockholders	(3,128)	(2,896)
Proceeds from exercise of stock options	40	304
Other	(444)	(207)
Net Cash Used in Financing Activities	(353)	(3,698)
Effect of Exchange Rate Changes on Cash, Cash Equivalents and Restricted Cash	2	28
Net Increase (Decrease) in Cash, Cash Equivalents and Restricted Cash	1,213	(1,307)
Cash, Cash Equivalents and Restricted Cash at Beginning of Year (includes restricted cash of $258 million at January 1, 2020 included in Other Assets)	9,934	7,967
Cash, Cash Equivalents and Restricted Cash at End of Period (includes restricted cash of $44 million at June 30, 2020 included in Other Assets)	$ 11,147	$ 6,660

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 26, 2020.

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 Women's Health, Legacy Brands and Biosimilars into New Company

In February 2020, Merck announced its intention to spin-off products from its women's health, legacy brands and biosimilars 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 legacy brands included in the transaction consist of dermatology, non-opioid pain, 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 in the first half of 2021, subject to market and certain other conditions. Subsequent to the spin-off, the historical results of the women's health, legacy brands and biosimilars businesses will be reflected as discontinued operations in the Company's consolidated financial statements.

Recently Adopted Accounting Standards

In June 2016, the Financial Accounting Standards Board (FASB) issued new guidance on the accounting for credit losses on financial instruments. The new guidance introduces an expected loss model for estimating credit losses, replacing the incurred loss model. The new guidance also changes the impairment model for available-for-sale debt securities, requiring the use of an allowance to record estimated credit losses (and subsequent recoveries). The Company adopted the new guidance effective January 1, 2020. There was no impact to the Company's consolidated financial statements upon adoption.

In November 2018, the FASB issued new guidance for collaborative arrangements intended to reduce diversity in practice by clarifying whether certain transactions between collaborative arrangement participants should be accounted for under revenue recognition guidance (ASC 606). The Company adopted the new guidance effective January 1, 2020, which resulted in minor changes to the presentation of information related to the Company's collaborative arrangements.

Recently Issued Accounting Standards Not Yet Adopted

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 amended guidance is effective for interim and annual periods in 2021. Early adoption is permitted. The amendments in the new guidance are to be applied on a retrospective basis, on a modified retrospective basis through a cumulative-effect adjustment to retained earnings or prospectively, depending on the amendment. The Company is currently evaluating the impact of adoption on its consolidated financial statements.

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 new guidance is effective for interim and annual periods in 2021 and is to be applied prospectively. Early adoption is permitted. The Company is currently evaluating the impact of adoption on its consolidated financial statements.

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. The guidance provides optional expedients and exceptions for applying GAAP to contracts, hedging relationships, and other transactions affected by 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 July 2020, Merck acquired the U.S. rights to Sentinel Flavor Tabs and Sentinel Spectrum Chews from Virbac Corporation for approximately $400 million. Sentinel products provide protection against common parasites in dogs. The transaction will be accounted for as an acquisition of an asset. There are no future contingent payments associated with the acquisition.

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

In June 2020, Merck acquired privately held Themis Bioscience GmbH (Themis), a company focused on vaccines and immune-modulation therapies for infectious diseases and cancer for $366 million in cash. Merck may make additional contingent payments of up to $740 million, including up to $80 million for development milestones, up to $260 million for regulatory approval milestones, and up to $400 million for commercial milestones. Themis has a broad pipeline of vaccine candidates and immune-modulatory therapies developed using its innovative measles virus vector platform based on a vector originally developed by scientists at the Institut Pasteur and licensed exclusively to Themis for select viral indications. The acquisition builds upon an ongoing collaboration between the two companies to develop vaccine candidates using the measles virus vector platform and is expected to accelerate the development of Themis' COVID-19 vaccine candidate (V591). V591 is in preclinical development and clinical studies are planned to start in the third quarter of 2020. The transaction was accounted for as an acquisition of a business. The Company determined the fair value of the contingent consideration was $97 million at the acquisition date utilizing a probability-weighted estimated cash flow stream using an appropriate discount rate dependent on the nature and timing of the milestone payment. Merck recognized intangible assets for in-process research and development (IPR&D) of $136 million, cash of $62 million, deferred tax assets of $72 million and other net liabilities of $22 million. The excess of the consideration transferred over the fair value of net assets acquired of $215 million was recorded as goodwill that was allocated to the Pharmaceutical segment and is not deductible for tax purposes. The fair values of the identifiable intangible assets related to IPR&D were determined using an income approach. Actual cash flows are likely to be different than those assumed. In connection with the transaction, Merck has entered into a memorandum of understanding that reflects the parties' commitments to address the COVID-19 pandemic by developing, manufacturing and distributing the vaccine on a global basis and with pricing that makes the vaccine both available around the world and accessible to those who need it.

In May 2020, Merck and the International AIDS Vaccine Initiative, Inc. (IAVI), a nonprofit scientific research organization dedicated to addressing urgent, unmet global health challenges, announced a new collaboration to develop V590, an investigational vaccine against SARS-CoV-2 being studied for the prevention of COVID-19. This vaccine candidate will use the recombinant vesicular stomatitis virus (rVSV) technology that is the basis for Merck's approved Ebola Zaire virus vaccine, *Ervebo* (Ebola Zaire Vaccine, Live), which was the first rVSV vaccine approved for use in humans. Under the terms of the agreement, Merck made an upfront payment of $6.5 million and may make additional contingent payments of up to $100 million for sales-based milestones, as well as royalty payments. Merck has also signed an agreement with the Biomedical Advanced Research and Development Authority (BARDA), part of the office of the Assistant Secretary for Preparedness and Response within an agency of the United States Department of Health and Human Services, to provide initial funding support for this effort. Under the agreement, IAVI and Merck will work together to advance the development and global clinical evaluation of a SARS-CoV-2 vaccine candidate designed and engineered by IAVI scientists. The vaccine candidate is in preclinical development, and clinical studies are planned to start later in 2020. Merck will lead regulatory filings globally. Both organizations will work together to develop the vaccine and make it accessible and affordable globally, if approved.

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

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
IPR&D MK-7075 (formerly ARQ 092) *(1)*		170
Licensing arrangement for ARQ 087		80
Deferred income tax liabilities		(434)
Other assets and liabilities, net		35
Total identifiable net assets		2,276
Goodwill *(2)*		414
Consideration transferred	$	2,690

(1) *The estimated fair values of the identifiable intangible assets related to in-process research and development (IPR&D) were 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.*

On April 1, 2019, Merck acquired Antelliq Corporation (Antelliq), a leader in digital animal identification, traceability and monitoring solutions. These solutions help veterinarians, farmers and pet owners gather critical data to improve management, health and well-being of livestock and pets. Merck paid $2.3 billion to acquire all outstanding shares of Antelliq and spent $1.3 billion to repay Antelliq's debt. The transaction was accounted for as an acquisition of a business.

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

($ in millions)		April 1, 2019
Cash and cash equivalents	$	31
Accounts receivable		73
Inventories		93
Property, plant and equipment		60
Identifiable intangible assets (useful lives ranging from 18-24 years) *(1)*		2,689
Deferred income tax liabilities		(589)
Other assets and liabilities, net		(82)
Total identifiable net assets		2,275
Goodwill *(2)*		1,376
Consideration transferred	$	3,651

(1) *The estimated fair values of identifiable intangible assets relate primarily to trade names and were determined using an income approach. The future net cash flows were discounted to present value utilizing a discount rate of 11.5%. Actual cash flows are likely to be different than those assumed.*

(2) *The goodwill recognized is largely attributable to anticipated synergies expected to arise after the acquisition and was allocated to the Animal Health segment. The goodwill is not deductible for tax purposes.*

The Company's results for the second quarter of 2019 include two months of activity for Antelliq. The Company incurred $47 million of transaction costs directly related to the acquisition of Antelliq, consisting largely of advisory fees, which are reflected in *Selling, general and administrative* expenses in the first six months of 2019.

Also in April 2019, Merck acquired Immune Design, a late-stage immunotherapy company employing next-generation *in vivo* approaches to enable the body's immune system to fight disease, for $301 million in cash. The transaction was accounted for as an acquisition of a business. Merck recognized intangible assets of $156 million, cash of $83 million and other net assets of $42 million. The excess of the consideration transferred over the fair value of net assets acquired of $20 million was recorded as goodwill that was allocated to the Pharmaceutical segment and is not deductible for tax purposes. The fair values of the identifiable intangible assets related to IPR&D were determined using an income approach. Actual cash flows are likely to be different than those assumed.

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 July 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* (pembrolizumab) and Imfinzi. The companies will also jointly develop and commercialize AstraZeneca's Koselugo (selumetinib), an oral, selective inhibitor of MEK, part of the mitogen-activated protein kinase (MAPK) pathway, currently being developed for multiple indications. In April 2020, Koselugo was approved by the U.S. Food and Drug Administration (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 of $1.6 billion in 2017 and made payments of $750 million 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.

In the second quarter of 2020, Merck determined it was probable that sales of Lynparza in the future would trigger $400 million of sales-based milestone payments from Merck to AstraZeneca. Accordingly, Merck recorded a $400 million liability and a corresponding increase to the intangible asset related to Lynparza. Prior to 2020, Merck accrued sales-based milestone payments aggregating $1.0 billion related to Lynparza, of which $200 million and $250 million was paid to AstraZeneca in 2019 and 2018, respectively, and $250 million was paid in the first six months of 2020. 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.

In the second quarter of 2020, Lynparza received regulatory approvals triggering capitalized milestone payments of $135 million from Merck to AstraZeneca. In 2019 and 2018, Lynparza received regulatory approvals triggering capitalized milestone payments of $60 million and $140 million, respectively, 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 $1.3 billion at June 30, 2020 and is included in *Other Intangibles, Net* on the Consolidated Balance Sheet. The amount is being amortized over its estimated useful life through 2028 as supported by projected future cash flows, subject to impairment testing.

Summarized financial information related to this collaboration is as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
($ in millions)	2020	2019	2020	2019
Alliance revenue - Lynparza	$ 178	$ 111	$ 323	$ 190
Cost of sales [(1)]	137	73	164	92
Selling, general and administrative	39	33	72	59
Research and development	37	33	73	78

($ in millions)	June 30, 2020	December 31, 2019
Receivables from AstraZeneca included in *Other current assets*	$ 168	$ 128
Payables to AstraZeneca included in *Accrued and other current liabilities* [(2)]	324	577
Payables to AstraZeneca included in *Other Noncurrent Liabilities* [(2)]	400	—

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

[(2)] *Includes accrued milestone payments.*

Eisai

In March 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 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, including for studies evaluating Lenvima as monotherapy, are shared equally by the two companies and reflected in *Research and development* expenses.

Under the agreement, Merck made an upfront payment to Eisai of $750 million 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 is expected to be paid in March 2021). In addition, the agreement provides for additional contingent payments from Merck to Eisai related to the successful achievement of sales-based and regulatory milestones.

In the second quarter of 2020, Merck determined it was probable that sales of Lenvima in the future would trigger sales-based milestone payments aggregating $370 million from Merck to Eisai. Accordingly, Merck recorded a $370 million liability and a corresponding increase to the intangible asset related to Lenvima. Prior to 2020, Merck accrued sales-based milestone payments aggregating $950 million. Of these amounts, $50 million was paid to Eisai in 2019 and an additional $500 million was paid in the first six months of 2020. 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.

In 2018, Lenvima received regulatory approvals triggering capitalized milestone payments of $250 million in the aggregate from Merck to Eisai. Potential future regulatory milestone payments of $135 million remain under the agreement.

The intangible asset balance related to Lenvima (which includes capitalized sales-based and regulatory milestone payments) was $1.2 billion at June 30, 2020 and is included in *Other Intangibles, Net* on the Consolidated Balance Sheet. The amount is being amortized over its estimated useful life through 2026 as supported by projected future cash flows, subject to impairment testing.

Summarized financial information related to this collaboration is as follows:

($ in millions)	Three Months Ended June 30, 2020	Three Months Ended June 30, 2019	Six Months Ended June 30, 2020	Six Months Ended June 30, 2019
Alliance revenue - Lenvima	$ 151	$ 97	$ 279	$ 171
Cost of sales [(1)]	135	23	170	74
Selling, general and administrative	19	19	31	38
Research and development	56	62	120	109

($ in millions)	June 30, 2020	December 31, 2019
Receivables from Eisai included in *Other current assets*	$ 173	$ 150
Payables to Eisai included in *Accrued and other current liabilities* [(2)]	325	700
Payables to Eisai included in *Other Noncurrent Liabilities* [(3)]	570	525

[(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 vericiguat, which is in development for the potential treatment of worsening heart failure. Vericiguat is currently under review by the FDA. Under the agreement, Bayer leads commercialization of Adempas in the Americas, while Merck leads commercialization in the rest of the world. For vericiguat, if approved, Bayer will lead commercialization in the rest of world and Merck will lead in the Americas. Both companies share in development costs and profits on sales and have the right to co-promote in territories where they are not the lead. Merck records sales of Adempas in its marketing territories, as well as alliance revenue, which is Merck's share of profits from the sale of Adempas in Bayer's marketing territories. In addition, the agreement provides for additional contingent payments from Merck to Bayer related to the successful achievement of sales-based milestones.

Prior to 2020, Merck accrued $725 million of sales-based milestone payments for this collaboration, of which $350 million was paid to Bayer in 2018. There is an additional $400 million potential future sales-based milestone payment that has not yet been accrued as it is not deemed by the Company to be probable at this time.

The intangible asset balance related to this collaboration (which includes the acquired intangible asset balance, as well as capitalized sales-based milestone payments) was $832 million at June 30, 2020 and is included in *Other Intangibles, Net* on the Consolidated Balance Sheet. The amount is being amortized over its estimated useful life through 2027 as supported by projected future cash flows, subject to impairment testing.

Summarized financial information related to this collaboration is as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
($ in millions)	2020	2019	2020	2019
Alliance revenue - Adempas	$ 79	$ 51	$ 133	$ 94
Net sales of Adempas recorded by Merck	57	53	113	100
Total sales	$ 136	$ 104	$ 246	$ 194
Cost of sales [(1)]	28	29	57	58
Selling, general and administrative	17	11	28	20
Research and development	16	32	41	62

($ in millions)	June 30, 2020	December 31, 2019
Receivables from Bayer included in *Other current assets*	$ 62	$ 49
Payables to Bayer included in *Other Noncurrent Liabilities* [(2)]	375	375

[(1)] *Includes amortization of intangible assets.*

[(2)] *Represents accrued milestone payment.*

4. Restructuring

In early 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 $2.5 billion. The Company estimates that approximately 60% of the cumulative pretax costs will result in cash outlays, primarily related to employee separation expense and facility shut-down costs. Approximately 40% of the cumulative pretax costs will be non-cash, relating primarily to the accelerated depreciation of facilities to be closed or divested. The Company expects to record charges of approximately $800 million in 2020 related to the Restructuring Program. Actions under previous global restructuring programs have been substantially completed.

The Company recorded total pretax costs of $150 million and $159 million in the second quarter of 2020 and 2019, respectively, and $318 million and $346 million for the first six months of 2020 and 2019, respectively, related to restructuring program activities. Since inception of the Restructuring Program through June 30, 2020, Merck has recorded total pretax accumulated costs of approximately $1.2 billion. For segment reporting, restructuring charges are unallocated expenses.

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

	Three Months Ended June 30, 2020				Six Months Ended June 30, 2020			
($ in millions)	Separation Costs	Accelerated Depreciation	Other	Total	Separation Costs	Accelerated Depreciation	Other	Total
Cost of sales	$ —	$ 31	$ (6)	$ 25	$ —	$ 56	$ 37	$ 93
Selling, general and administrative	—	11	—	11	—	22	—	22
Research and development	—	31	—	31	—	48	—	48
Restructuring costs	35	—	48	83	82	—	73	155
	$ 35	$ 73	$ 42	$ 150	$ 82	$ 126	$ 110	$ 318

	Three Months Ended June 30, 2019				Six Months Ended June 30, 2019			
($ in millions)	Separation Costs	Accelerated Depreciation	Other	Total	Separation Costs	Accelerated Depreciation	Other	Total
Cost of sales	$ —	$ 64	$ 1	$ 65	$ —	$ 98	$ 1	$ 99
Selling, general and administrative	—	32	—	32	—	32	—	32
Research and development	—	2	1	3	—	2	1	3
Restructuring costs	25	—	34	59	153	—	59	212
	$ 25	$ 98	$ 36	$ 159	$ 153	$ 132	$ 61	$ 346

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 2020 and 2019 includes asset abandonment, facility shut-down and other related costs, as well as pretax gains and losses resulting from the sales of facilities and related assets. Additionally, other activity includes certain employee-related costs associated with pension and other postretirement benefit plans (see Note 11) and share-based compensation.

The following table summarizes the charges and spending relating to restructuring program activities for the six months ended June 30, 2020:

($ in millions)	Separation Costs	Accelerated Depreciation	Other	Total
Restructuring reserves January 1, 2020	$ 690	$ —	$ 69	$ 759
Expense	82	126	110	318
(Payments) receipts, net	(328)	—	(163)	(491)
Non-cash activity	—	(126)	34	(92)
Restructuring reserves June 30, 2020 [(1)]	$ 444	$ —	$ 50	$ 494

[(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 June 30,		Six Months Ended June 30,		Three Months Ended June 30,		Six Months Ended June 30,	
($ in millions)	2020	2019	2020	2019	2020	2019	2020	2019
Net Investment Hedging Relationships								
Foreign exchange contracts	$ 8	$ 17	$ 5	$ 7	$ (4)	$ (8)	$ (11)	$ (15)
Euro-denominated notes	72	28	21	(2)	—	—	—	—

[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 February 2020, five interest rate swaps with notional amounts of $250 million each matured. These swaps effectively converted the Company's $1.25 billion, 1.85% fixed-rate notes due 2020 to variable rate debt. At June 30, 2020, the Company was a party to 14 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.

	June 30, 2020		
($ in millions)	Par Value of Debt	Number of Interest Rate Swaps Held	Total Swap Notional Amount
3.875% notes due 2021	$ 1,150	5	$ 1,150
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 London Interbank Offered Rate (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 Consolidated Balance Sheet related to cumulative basis adjustments for fair value hedges:

	Carrying Amount of Hedged Liabilities		Cumulative Amount of Fair Value Hedging Adjustment Increase (Decrease) Included in the Carrying Amount	
($ in millions)	June 30, 2020	December 31, 2019	June 30, 2020	December 31, 2019
Balance Sheet Line Item in which Hedged Item is Included				
Loans payable and current portion of long-term debt	$ 1,160	$ 1,249	$ 10	$ (1)
Long-Term Debt	2,318	3,409	71	14

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

		June 30, 2020			December 31, 2019		
		Fair Value of Derivative			Fair Value of Derivative		
($ in millions)	Balance Sheet Caption	Asset	Liability	U.S. Dollar Notional	Asset	Liability	U.S. Dollar Notional
Derivatives Designated as Hedging Instruments							
Interest rate swap contracts	Other current assets	$ 10	$ —	$ 1,150	$ —	$ —	$ —
Interest rate swap contracts	Other Assets	72	—	2,250	15	—	3,400
Interest rate swap contracts	Accrued and other current liabilities	—	—	—	—	1	1,250
Foreign exchange contracts	Other current assets	83	—	4,959	152	—	6,117
Foreign exchange contracts	Other Assets	70	—	1,993	55	—	2,160
Foreign exchange contracts	Accrued and other current liabilities	—	27	1,884	—	22	1,748
Foreign exchange contracts	Other Noncurrent Liabilities	—	1	11	—	1	53
		$ 235	$ 28	$ 12,247	$ 222	$ 24	$ 14,728
Derivatives Not Designated as Hedging Instruments							
Foreign exchange contracts	Other current assets	$ 93	$ —	$ 5,324	$ 66	$ —	$ 7,245
Foreign exchange contracts	Accrued and other current liabilities	—	103	5,865	—	73	8,693
		$ 93	$ 103	$ 11,189	$ 66	$ 73	$ 15,938
		$ 328	$ 131	$ 23,436	$ 288	$ 97	$ 30,666

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

	June 30, 2020		December 31, 2019	
($ in millions)	Asset	Liability	Asset	Liability
Gross amounts recognized in the condensed consolidated balance sheet	$ 328	$ 131	$ 288	$ 97
Gross amounts subject to offset in master netting arrangements not offset in the condensed consolidated balance sheet	(115)	(115)	(84)	(84)
Cash collateral received	(38)	—	(34)	—
Net amounts	$ 175	$ 16	$ 170	$ 13

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)		Sales		Other (income) expense, net (1)		Other comprehensive income (loss)	
	Three Months Ended June 30,		Three Months Ended June 30,		Three Months Ended June 30,		Six Months Ended June 30,		Six Months Ended June 30,		Six Months Ended June 30,	
($ in millions)	2020	2019	2020	2019	2020	2019	2020	2019	2020	2019	2020	2019
Financial Statement Line Items in which Effects of Fair Value or Cash Flow Hedges are Recorded	$10,872	$11,760	$ (390)	$ 140	$ (2)	$ (16)	$22,929	$22,575	$ (318)	$ 327	$ (200)	$ 183
(Gain) loss on fair value hedging relationships												
Interest rate swap contracts												
Hedged items	—	—	1	55	—	—	—	—	68	88	—	—
Derivatives designated as hedging instruments	—	—	(8)	(45)	—	—	—	—	(76)	(68)	—	—
Impact of cash flow hedging relationships												
Foreign exchange contracts												
Amount of (loss) gain recognized in *OCI* on derivatives	—	—	—	—	(109)	10	—	—	—	—	69	(2)
Increase (decrease) in *Sales* as a result of *AOCI* reclassifications	42	75	—	—	(42)	(75)	88	119	—	—	(88)	(119)
Interest rate contracts												
Amount of gain recognized in *Other (income) expense, net* on derivatives	—	—	(1)	(1)	—	—	—	—	(2)	(2)	—	—
Amount of loss recognized in *OCI* on derivatives	—	—	—	—	(1)	(1)	—	—	—	—	(2)	(5)

(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 June 30,		Six Months Ended June 30,	
($ in millions)	Income Statement Caption	2020	2019	2020	2019
Derivatives Not Designated as Hedging Instruments					
Foreign exchange contracts (1)	Other (income) expense, net	$ 49	$ 2	$ (131)	$ 120
Foreign exchange contracts (2)	Sales	4	(6)	(3)	4
Interest rate contracts (3)	Other (income) expense, net	9	—	9	—

(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.*

(3) *These derivatives serve as economic hedges against rising treasury rates.*

At June 30, 2020, the Company estimates $9 million of pretax net unrealized gains on derivatives maturing within the next 12 months that hedge foreign currency denominated sales over that same period will be reclassified from *AOCI* to *Sales*. The amount ultimately reclassified to *Sales* may differ as foreign exchange rates change. Realized gains and losses are ultimately determined by actual exchange rates at maturity.

Investments in Debt and Equity Securities

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

	June 30, 2020				December 31, 2019			
	Amortized Cost	Gross Unrealized		Fair Value	Amortized Cost	Gross Unrealized		Fair Value
($ in millions)		Gains	Losses			Gains	Losses	
U.S. government and agency securities	$ 74	$ —	$ —	$ 74	$ 266	$ 3	$ —	$ 269
Foreign government bonds	2	—	—	2	—	—	—	—
Commercial paper	—	—	—	—	668	—	—	668
Corporate notes and bonds	—	—	—	—	608	13	—	621
Asset-backed securities	—	—	—	—	226	1	—	227
Total debt securities	$ 76	$ —	$ —	$ 76	$ 1,768	$ 17	$ —	$ 1,785
Publicly traded equity securities [(1)]				1,307				838
Total debt and publicly traded equity securities				$ 1,383				$ 2,623

[(1)] *Unrealized net (gains) losses recognized in* Other (income) expense, net *on equity securities still held at June 30, 2020 were $(464) million and $(469) million in the second quarter and first six months of 2020, respectively. Unrealized net losses (gains) recognized in* Other (income) expense, net *on equity securities still held at June 30, 2019 were $39 million and $(75) million in the second quarter and first six months of 2019, respectively.*

At June 30, 2020 and June 30, 2019, the Company also had $487 million and $465 million, respectively, of equity investments without readily determinable fair values included in *Other Assets*. The Company recognizes unrealized gains on these equity investments based on favorable observable price changes from transactions involving similar investments of the same investee and recognizes unrealized losses based on unfavorable observable price changes. During the first six months of 2020, the Company recognized unrealized gains of $18 million and unrealized losses of $3 million in *Other (income) expense, net* related to these equity investments held at June 30, 2020. During the first six months of 2019, the Company recognized unrealized gains of $4 million and unrealized losses of $10 million in *Other (income) expense, net* related to these investments held at June 30, 2019. Cumulative unrealized gains and cumulative unrealized losses based on observable prices changes for investments in equity investments without readily determinable fair values still held at June 30, 2020 were $127 million and $24 million, respectively.

Fair Value Measurements

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. The Company uses a fair value hierarchy which maximizes the use of observable inputs and minimizes the use of unobservable inputs when measuring fair value. There are three levels of inputs used to measure fair value with Level 1 having the highest priority and Level 3 having the lowest: *Level 1* - Quoted prices (unadjusted) in active markets for identical assets or liabilities; *Level 2* - Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities; *Level 3* - Unobservable inputs that are supported by little or no market activity. Level 3 assets or liabilities are those whose values are determined using pricing models, discounted cash flow methodologies, or similar techniques with significant unobservable inputs, as well as assets or liabilities for which the determination of fair value requires significant judgment or estimation. If the inputs used to measure the financial assets and liabilities fall within more than one level described above, the categorization is based on the lowest level input that is significant to the fair value measurement of the instrument.

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

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

	Fair Value Measurements Using				Fair Value Measurements Using			
	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3	Total
($ in millions)	June 30, 2020				December 31, 2019			
Assets								
Investments								
Foreign government bonds	$ —	$ 2	$ —	$ 2	$ —	$ —	$ —	$ —
Commercial paper	—	—	—	—	—	668	—	668
Corporate notes and bonds	—	—	—	—	—	621	—	621
Asset-backed securities (1)	—	—	—	—	—	227	—	227
U.S. government and agency securities	—	—	—	—	—	209	—	209
Publicly traded equity securities	1,249	—	—	1,249	518	—	—	518
	1,249	2	—	1,251	518	1,725	—	2,243
Other assets (2)								
U.S. government and agency securities	74	—	—	74	60	—	—	60
Publicly traded equity securities	58	—	—	58	320	—	—	320
	132	—	—	132	380	—	—	380
Derivative assets (3)								
Forward exchange contracts	—	142	—	142	—	169	—	169
Purchased currency options	—	104	—	104	—	104	—	104
Interest rate swaps	—	82	—	82	—	15	—	15
	—	328	—	328	—	288	—	288
Total assets	$ 1,381	$ 330	$ —	$ 1,711	$ 898	$ 2,013	$ —	$ 2,911
Liabilities								
Other liabilities								
Contingent consideration	$ —	$ —	$ 798	$ 798	$ —	$ —	$ 767	$ 767
Derivative liabilities (3)								
Forward exchange contracts	—	128	—	128	—	95	—	95
Written currency options	—	3	—	3	—	1	—	1
Interest rate swaps	—	—	—	—	—	1	—	1
	—	131	—	131	—	97	—	97
Total liabilities	$ —	$ 131	$ 798	$ 929	$ —	$ 97	$ 767	$ 864

(1) *Primarily all of the asset-backed securities were highly rated (Standard & Poor's rating of AAA and Moody's Investors Service rating of Aaa), secured primarily by auto loan, credit card and student loan receivables, with weighted-average lives of primarily 5 years or less.*

(2) *Investments included in other assets are restricted as to use, including for the payment of benefits under employee benefit plans.*

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

As of June 30, 2020 and December 31, 2019, *Cash and cash equivalents* included $10.4 billion and $8.9 billion of cash equivalents, respectively (which would be considered Level 2 in the fair value hierarchy).

Contingent Consideration

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

	Six Months Ended June 30,	
($ in millions)	2020	2019
Fair value January 1	$ 767	$ 788
Additions	97	—
Changes in estimated fair value [(1)]	40	50
Payments	(106)	(85)
Fair value June 30 [(2)(3)]	$ 798	$ 753

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

[(2)] *Balance at June 30, 2020 includes $138 million recorded as a current liability for amounts expected to be paid within the next 12 months.*

[(3)] *At June 30, 2020 and December 31, 2019, $608 million and $625 million, respectively, of the liabilities relate to the termination of the Sanofi-Pasteur MSD joint venture in 2016. As part of the termination, Merck recorded a liability for contingent future royalty payments of 11.5% on net sales of all Merck products that were previously sold by the joint venture through December 31, 2024. The fair value of this liability is determined utilizing the estimated amount and timing of projected cash flows using a risk-adjusted discount rate of 8% to present value the cash flows.*

The additions to contingent consideration in 2020 relate to the acquisition of Themis (see Note 2). The payments of contingent consideration in both periods relate to liabilities recorded in connection with the termination of the Sanofi-Pasteur MSD joint venture in 2016.

Other Fair Value Measurements

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

The estimated fair value of loans payable and long-term debt (including current portion) at June 30, 2020, was $34.5 billion compared with a carrying value of $30.9 billion and at December 31, 2019, was $28.8 billion compared with a carrying value of $26.3 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 $1.9 billion and $2.7 billion of accounts receivable in the second quarter of 2020 and the fourth quarter of 2019, 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 $38 million and $34 million at June 30, 2020 and December 31, 2019, respectively. The obligation to return such collateral is recorded in *Accrued and other current liabilities*. No cash collateral was advanced by the Company to counterparties as of June 30, 2020 or December 31, 2019.

6. Inventories

Inventories consisted of:

($ in millions)	June 30, 2020	December 31, 2019
Finished goods	$ 2,032	$ 1,772
Raw materials and work in process	5,874	5,650
Supplies	190	207
Total (approximates current cost)	8,096	7,629
Decrease to LIFO cost	(119)	(171)
	$ 7,977	$ 7,458
Recognized as:		
Inventories	$ 6,056	$ 5,978
Other assets	1,921	1,480

Amounts recognized as *Other Assets* are comprised almost entirely of raw materials and work in process inventories. At June 30, 2020 and December 31, 2019, these amounts included $1.7 billion and $1.3 billion, respectively, of inventories not expected to be sold within one year. In addition, these amounts included $266 million and $168 million at June 30, 2020 and December 31, 2019, respectively, of inventories produced in preparation for product launches.

7. Long-Term Debt

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 intends to use 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.

8. Contingencies

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

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

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

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

Product Liability Litigation

Fosamax

As previously disclosed, Merck is a defendant in product liability lawsuits in the United States involving *Fosamax* (*Fosamax* Litigation). As of June 30, 2020, approximately 3,590 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 June 30, 2020, approximately 970 cases were actively pending in the Femur Fracture MDL.

As of June 30, 2020, approximately 2,345 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 June 30, 2020, 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 four 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 June 30, 2020, Merck is aware of approximately 1,440 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). 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).

In November 2015, the MDL and California State Court–in separate opinions–granted summary judgment to defendants on grounds of federal preemption.

Plaintiffs appealed in both forums. In November 2017, the U.S. Court of Appeals for the Ninth Circuit vacated the judgment and remanded for further discovery. In November 2018, the California state appellate court reversed and remanded on similar grounds. In March 2019, the parties in the MDL and the California coordinated proceedings agreed to coordinate and adopt a schedule for completing discovery on general causation and preemption issues and for renewing summary judgment and *Daubert* motions. Under the stipulated case management schedule, the hearings for *Daubert* and summary judgment motions are expected to take place in the second half of 2020.

As of June 30, 2020, 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 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 these lawsuits.

Vioxx

As previously disclosed, Merck is a defendant in a lawsuit brought by the Attorney General of Utah alleging that Merck misrepresented the safety of *Vioxx*. The lawsuit is pending in Utah state court. Utah seeks damages and penalties under the Utah False Claims Act. A bench trial in this matter has been rescheduled for April 6, 2021.

Governmental Proceedings

On June 17, 2020, Merck received a Civil Investigative Demand (CID) from the U.S. Department of Justice. The CID requests answers to interrogatories, as well as various documents, regarding temperature excursions at a third-party storage facility containing certain Merck products. Merck is cooperating with the government's investigation and intends to produce information and/or documents as necessary in response to the CID.

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. The Merck Defendants moved to dismiss the new allegations in both complaints. In October 2019, the magistrate judge issued a report and recommendation recommending that the district judge grant the motions in their entirety. In December 2019, the district court adopted this report and recommendation in part. 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. On June 18, 2020, the magistrate judge issued a report and recommendation recommending that the district judge grant in part the direct purchasers' motion for class certification and certify a class of 35 direct purchasers. On July 2, 2020, defendants objected to the report and recommendation. The indirect purchasers' class certification motion is still pending before the magistrate judge. Trial in this matter has been rescheduled to begin on February 23, 2021.

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 March 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 and April 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. 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. No schedule for the cases has been set by the courts.

Januvia, Janumet, Janumet XR — In February 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 a patent owned by the Company covering certain salt and polymorphic forms of sitagliptin that expires in 2026. 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 in 2022, but prior to the expiration of the later-granted patent owned by the Company covering certain salt and polymorphic forms of sitagliptin that expires in 2026, and a later granted patent owned by the Company covering the *Janumet* formulation which expires in 2028. Par Pharmaceutical dismissed its case in the U.S. District Court for the District of New Jersey against the Company and will litigate the action in the U.S. District Court for the District of Delaware. The Company filed a patent infringement lawsuit against Mylan Pharmaceuticals Inc. and Mylan Inc. (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. The U.S. District Court for the District of Delaware has scheduled the lawsuits for a single 3-day trial on invalidity issues in October 2021. The Court will schedule separate 1-day trials on infringement issues if 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. In February 2020, the Company amended its complaint against one defendant, Teva Pharmaceuticals USA, Inc., to add patent infringement claims related to a patent that expires in 2025 and covers certain processes for manufacturing sitagliptin.

The Company has settled with five generic companies such that these generic companies can bring their products to the market in November 2026 or earlier under certain circumstances.

In October 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 2026 patent. The USPTO instituted IPR proceedings in May 2020, finding a reasonable likelihood that the challenged claims are not valid. A trial is scheduled for February 2021 and a final decision is expected in May 2021. After institution, three additional IPR petitions were filed by Teva Pharmaceuticals USA, Inc., Dr. Reddy's Laboratories, Inc., and Sun Pharmaceutical Industries Ltd., as well as related entities, which requested joinder with Mylan's IPR proceedings. If the challenges are successful, the unchallenged claims of the 2026 patent will remain valid, subject to the Court proceedings described above.

In Germany, a generic company has sought the revocation of the Supplementary Protection Certificate (SPC) for *Janumet*. If the generic company is successful, *Janumet* could lose market exclusivity in Germany as early as July 2022. It is possible that challenges to the *Janumet* SPC could occur in other European countries.

Other Litigation

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

Legal Defense Reserves

Legal defense costs expected to be incurred in connection with a loss contingency are accrued when probable and reasonably estimable. Some of the significant factors considered in the review of these legal defense reserves are as follows: the actual costs incurred by the Company; the development of the Company's legal defense strategy and structure in light of the scope of its litigation; the number of cases being brought against the Company; the costs and outcomes of completed trials and the most current information regarding anticipated timing, progression, and related costs of pre-trial activities and trials in the associated litigation. The amount of legal defense reserves as of June 30, 2020 and December 31, 2019 of approximately $265 million and $240 million, respectively, represents the Company's best estimate of the minimum amount of defense costs to be incurred in connection with its outstanding litigation; however, events such as additional trials and other events that could arise in the course of its litigation could affect the ultimate amount of legal defense costs to be incurred by the Company. The Company will continue to monitor its legal defense costs and review the adequacy of the associated reserves and may determine to increase the reserves at any time in the future if, based upon the factors set forth, it believes it would be appropriate to do so.

9. Equity

	Three Months Ended June 30,								
	Common Stock					Treasury Stock			
($ and shares in millions except per share amounts)	Shares	Par Value	Other Paid-In Capital	Retained Earnings	Accumulated Other Comprehensive Loss	Shares	Cost	Non-controlling Interests	Total
Balance at April 1, 2019	3,577	$ 1,788	$ 38,768	$ 44,065	$ (5,346)	994	$ (51,736)	$ 131	$ 27,670
Net income attributable to Merck & Co., Inc.	—	—	—	2,670	—	—	—	—	2,670
Other comprehensive loss, net of taxes	—	—	—	—	(16)	—	—	—	(16)
Cash dividends declared on common stock ($0.55 per share)	—	—	—	(1,440)	—	—	—	—	(1,440)
Treasury stock shares purchased	—	—	1,000	—	—	24	(2,235)	—	(1,235)
Share-based compensation plans and other	—	—	(284)	—	—	(8)	401	—	117
Net loss attributable to noncontrolling interests	—	—	—	—	—	—	—	(26)	(26)
Other changes in noncontrolling interests	—	—	—	—	—	—	—	(3)	(3)
Balance at June 30, 2019	3,577	$ 1,788	$ 39,484	$ 45,295	$ (5,362)	1,010	$ (53,570)	$ 102	$ 27,737
Balance at April 1, 2020	3,577	$ 1,788	$ 39,697	$ 48,272	$ (6,391)	1,053	$ (57,161)	$ 95	$ 26,300
Net income attributable to Merck & Co., Inc.	—	—	—	3,002	—	—	—	—	3,002
Other comprehensive loss, net of taxes	—	—	—	—	(2)	—	—	—	(2)
Cash dividends declared on common stock ($0.61 per share)	—	—	—	(1,550)	—	—	—	—	(1,550)
Share-based compensation plans and other	—	—	(324)	—	—	(5)	311	—	(13)
Net income attributable to noncontrolling interests	—	—	—	—	—	—	—	8	8
Distributions attributable to noncontrolling interests	—	—	—	—	—	—	—	(1)	(1)
Balance at June 30, 2020	3,577	$ 1,788	$ 39,373	$ 49,724	$ (6,393)	1,048	$ (56,850)	$ 102	$ 27,744

	Six Months Ended June 30,								
	Common Stock					Treasury Stock			
($ and shares in millions except per share amounts)	Shares	Par Value	Other Paid-In Capital	Retained Earnings	Accumulated Other Comprehensive Loss	Shares	Cost	Non-controlling Interests	Total
Balance at January 1, 2019	3,577	$ 1,788	$ 38,808	$ 42,579	$ (5,545)	985	$ (50,929)	$ 181	$ 26,882
Net income attributable to Merck & Co., Inc.	—	—	—	5,585	—	—	—	—	5,585
Other comprehensive income, net of taxes	—	—	—	—	183	—	—	—	183
Cash dividends declared on common stock ($1.10 per share)	—	—	—	(2,869)	—	—	—	—	(2,869)
Treasury stock shares purchased	—	—	1,000	—	—	38	(3,325)	—	(2,325)
Share-based compensation plans and other	—	—	(324)	—	—	(13)	684	—	360
Net loss attributable to noncontrolling interests	—	—	—	—	—	—	—	(79)	(79)
Balance at June 30, 2019	3,577	$ 1,788	$ 39,484	$ 45,295	$ (5,362)	1,010	$ (53,570)	$ 102	$ 27,737
Balance at January 1, 2020	3,577	$ 1,788	$ 39,660	$ 46,602	$ (6,193)	1,038	$ (55,950)	$ 94	$ 26,001
Net income attributable to Merck & Co., Inc.	—	—	—	6,221	—	—	—	—	6,221
Other comprehensive loss, net of taxes	—	—	—	—	(200)	—	—	—	(200)
Cash dividends declared on common stock ($1.22 per share)	—	—	—	(3,099)	—	—	—	—	(3,099)
Treasury stock shares purchased	—	—	—	—	—	16	(1,281)	—	(1,281)
Share-based compensation plans and other	—	—	(287)	—	—	(6)	381	—	94
Net income attributable to noncontrolling interests	—	—	—	—	—	—	—	8	8
Balance at June 30, 2020	3,577	$ 1,788	$ 39,373	$ 49,724	$ (6,393)	1,048	$ (56,850)	$ 102	$ 27,744

10. 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:

($ in millions)	Three Months Ended June 30, 2020	Three Months Ended June 30, 2019	Six Months Ended June 30, 2020	Six Months Ended June 30, 2019
Pretax share-based compensation expense	$ 121	$ 111	$ 229	$ 204
Income tax benefit	(16)	(15)	(31)	(28)
Total share-based compensation expense, net of taxes	$ 105	$ 96	$ 198	$ 176

During the first six months of 2020, the Company granted 6 million RSUs with a weighted-average grant date fair value of $77.74 per RSU and during the first six months of 2019 granted 6 million RSUs with a weighted-average grant date fair value of $76.31 per RSU. During the first six months of 2020, the Company granted 773 thousand PSUs with a weighted-average grant date fair value of $75.22 per PSU and during the first six months of 2019 granted 609 thousand PSUs with a weighted-average grant date fair value of $90.50 per PSU.

During the first six months of 2020, the Company granted 4 million stock options with a weighted-average exercise price of $77.67 per option and during the first six months of 2019 granted 3 million stock options with a weighted-average exercise price of $80.00 per option. The weighted-average fair value of options granted during the first six months of 2020 and 2019 was $9.93 and $10.63 per option, respectively, and was determined using the following assumptions:

	Six Months Ended June 30, 2020	Six Months Ended June 30, 2019
Expected dividend yield	3.1%	3.2%
Risk-free interest rate	0.4%	2.4%
Expected volatility	22.1%	18.7%
Expected life (years)	5.8	5.9

At June 30, 2020, there was $908 million 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 2.2 years. For segment reporting, share-based compensation costs are unallocated expenses.

11. 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 June 30,				Six Months Ended June 30,			
	2020		2019		2020		2019	
($ in millions)	U.S.	International	U.S.	International	U.S.	International	U.S.	International
Service cost	$ 88	$ 74	$ 74	$ 60	$ 175	$ 148	$ 144	$ 120
Interest cost	109	33	113	44	217	68	228	89
Expected return on plan assets	(195)	(101)	(205)	(107)	(388)	(205)	(411)	(214)
Amortization of unrecognized prior service credit	(12)	(3)	(12)	(3)	(25)	(6)	(25)	(6)
Net loss amortization	76	31	35	16	152	62	70	31
Termination benefits	1	—	3	1	4	1	5	1
Curtailments	—	—	—	—	2	(1)	1	—
Settlements	9	2	—	—	9	2	—	—
	$ 76	$ 36	$ 8	$ 11	$ 146	$ 69	$ 12	$ 21

The Company now anticipates contributing approximately $220 million to its U.S. pension plans in 2020, of which $170 million was contributed in the first half of the year.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
($ in millions)	2020	2019	2020	2019
Service cost	$ 13	$ 12	$ 26	$ 24
Interest cost	14	18	29	35
Expected return on plan assets	(19)	(18)	(37)	(36)
Amortization of unrecognized prior service credit	(22)	(21)	(45)	(43)
Curtailments	—	(1)	(1)	(1)
	$ (14)	$ (10)	$ (28)	$ (21)

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 and other postretirement benefit plans and settlements were recorded on certain U.S. and international pension plans as reflected in the tables above.

The components of net periodic benefit cost (credit) other than the service cost component are included in *Other (income) expense, net* (see Note 12), with the exception of certain amounts for termination benefits, curtailments and settlements, which are recorded in *Restructuring costs* if the event giving rise to the termination benefits, curtailment or settlement is related to restructuring actions as noted above.

12. Other (Income) Expense, Net

Other (income) expense, net, consisted of:

	Three Months Ended June 30,		Six Months Ended June 30,	
($ in millions)	2020	2019	2020	2019
Interest income	$ (14)	$ (75)	$ (39)	$ (164)
Interest expense	209	233	421	442
Exchange losses	24	27	78	128
Income from investments in equity securities, net [(1)]	(551)	(58)	(603)	(32)
Net periodic defined benefit plan (credit) cost other than service cost	(80)	(140)	(170)	(281)
Other, net	22	153	(5)	234
	$ (390)	$ 140	$ (318)	$ 327

[(1)] *Includes net realized and unrealized gains and losses from investments in equity securities either owned directly or through ownership interests in investment funds. Unrealized gains and losses from investments that are directly owned are determined at the end of the reporting period, while ownership interests in investment funds are accounted for on a one quarter lag. The Company estimates that gains of approximately $300 million will be recognized in the third quarter of 2020 from ownership interests in investment funds.*

The decline in interest income in the second quarter and first six months of 2020 reflects lower investments and lower interest rates. The lower exchange losses in the first six months of 2020 reflect losses on forward exchange contracts in 2019 related to the acquisition of Antelliq. The increase in income from investments in equity securities, net, in both the second quarter and first six months of 2020 was driven primarily by the recognition of unrealized gains on certain investments, most of which relate to Moderna, Inc., as well as NGM Biopharmaceuticals, Inc.

Other, net (as reflected in the table above) in the second quarter and first six months of 2019 includes $78 million and $162 million, respectively, of goodwill impairment charges related to certain businesses in the Healthcare Services segment.

Interest paid for the six months ended June 30, 2020 and 2019 was $387 million and $356 million, respectively.

13. Taxes on Income

The effective income tax rates of 14.5% and 18.9% for the second quarter of 2020 and 2019, respectively, and 15.3% and 13.0% for the first six months of 2020 and 2019, respectively, reflect the impacts of acquisition and divestiture-related costs and restructuring costs, partially offset by the beneficial impact of foreign earnings. In addition, the effective income tax rate for the first six months of 2019 reflects the favorable impact of a $360 million net tax benefit related to the settlement of certain federal income tax matters.

In the first quarter of 2019, the Internal Revenue Service (IRS) concluded its examinations of Merck's 2012-2014 U.S. federal income tax returns. As a result, the Company was required to make a payment of $107 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 $360 million net tax benefit in the first six months of 2019. This net benefit reflects reductions in reserves for unrecognized tax benefits for tax positions relating to the years that were under examination, partially offset by additional reserves for tax positions not previously reserved for.

14. Earnings Per Share

The calculations of earnings per share are as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
($ and shares in millions except per share amounts)	2020	2019	2020	2019
Net income attributable to Merck & Co., Inc.	$ 3,002	$ 2,670	$ 6,221	$ 5,585
Average common shares outstanding	2,527	2,574	2,531	2,579
Common shares issuable [(1)]	9	14	11	17
Average common shares outstanding assuming dilution	2,536	2,588	2,542	2,596
Basic earnings per common share attributable to Merck & Co., Inc. common shareholders	$ 1.19	$ 1.04	$ 2.46	$ 2.17
Earnings per common share assuming dilution attributable to Merck & Co., Inc. common shareholders	$ 1.18	$ 1.03	$ 2.45	$ 2.15

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

For the second quarter of 2020 and 2019, 8 million and 3 million, respectively, and for both the first six months of 2020 and 2019, 4 million of common shares issuable under share-based compensation plans were excluded from the computation of earnings per common share assuming dilution because the effect would have been antidilutive.

15. Other Comprehensive Income (Loss)

Changes in *AOCI* by component are as follows:

	Three Months Ended June 30,				
($ in millions)	Derivatives	Investments	Employee Benefit Plans	Cumulative Translation Adjustment	Accumulated Other Comprehensive Income (Loss)
Balance April 1, 2019, net of taxes	$ 118	$ 4	$ (3,541)	$ (1,927)	$ (5,346)
Other comprehensive income (loss) before reclassification adjustments, pretax	10	55	—	(25)	40
Tax	(2)	—	—	6	4
Other comprehensive income (loss) before reclassification adjustments, net of taxes	8	55	—	(19)	44
Reclassification adjustments, pretax	(76) [(1)]	(11) [(2)]	14 [(3)]	—	(73)
Tax	16	—	(3)	—	13
Reclassification adjustments, net of taxes	(60)	(11)	11	—	(60)
Other comprehensive income (loss), net of taxes	(52)	44	11	(19)	(16)
Balance June 30, 2019, net of taxes	$ 66	$ 48	$ (3,530)	$ (1,946)	$ (5,362)
Balance April 1, 2020, net of taxes	$ 135	$ —	$ (4,201)	$ (2,325)	$ (6,391)
Other comprehensive income (loss) before reclassification adjustments, pretax	(110)	—	(21)	63	(68)
Tax	23	—	6	16	45
Other comprehensive income (loss) before reclassification adjustments, net of taxes	(87)	—	(15)	79	(23)
Reclassification adjustments, pretax	(42) [(1)]	—	69 [(3)]	—	27
Tax	9	—	(15)	—	(6)
Reclassification adjustments, net of taxes	(33)	—	54	—	21
Other comprehensive income (loss), net of taxes	(120)	—	39	79	(2)
Balance June 30, 2020, net of taxes	$ 15	$ —	$ (4,162)	$ (2,246)	$ (6,393)

	Six Months Ended June 30,				
($ in millions)	Derivatives	Investments	Employee Benefit Plans	Cumulative Translation Adjustment	Accumulated Other Comprehensive Income (Loss)
Balance January 1, 2019, net of taxes	$ 166	$ (78)	$ (3,556)	$ (2,077)	$ (5,545)
Other comprehensive income (loss) before reclassification adjustments, pretax	(3)	131	(1)	131	258
Tax	1	—	6	—	7
Other comprehensive income (loss) before reclassification adjustments, net of taxes	(2)	131	5	131	265
Reclassification adjustments, pretax	(124) (1)	(5) (2)	28 (3)	—	(101)
Tax	26	—	(7)	—	19
Reclassification adjustments, net of taxes	(98)	(5)	21	—	(82)
Other comprehensive income (loss), net of taxes	(100)	126	26	131	183
Balance June 30, 2019, net of taxes	$ 66	$ 48	$ (3,530)	$ (1,946)	$ (5,362)
Balance January 1, 2020, net of taxes	$ 31	$ 18	$ (4,261)	$ (1,981)	$ (6,193)
Other comprehensive income (loss) before reclassification adjustments, pretax	68	3	(21)	(270)	(220)
Tax	(14)	—	11	5	2
Other comprehensive income (loss) before reclassification adjustments, net of taxes	54	3	(10)	(265)	(218)
Reclassification adjustments, pretax	(89) (1)	(21) (2)	138 (3)	—	28
Tax	19	—	(29)	—	(10)
Reclassification adjustments, net of taxes	(70)	(21)	109	—	18
Other comprehensive income (loss), net of taxes	(16)	(18)	99	(265)	(200)
Balance June 30, 2020, net of taxes	$ 15	$ —	$ (4,162)	$ (2,246)	$ (6,393)

(1) *Relates to foreign currency cash flow hedges that were reclassified from* AOCI *to* Sales*.*

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

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

16. Segment Reporting

The Company's operations are principally managed on a products basis and include three operating segments, which are the Pharmaceutical, Animal Health and Healthcare Services segments. The Pharmaceutical and Animal Health segments are the only 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 Healthcare Services segment provided services and solutions that focus on engagement, health analytics and clinical services to improve the value of care delivered to patients. The Company has been in the process of divesting the businesses in the Healthcare Services segment. The remaining businesses were divested during the first quarter of 2020.

Sales of the Company’s products were as follows:

	Three Months Ended June 30,						Six Months Ended June 30,					
	2020			2019			2020			2019		
($ in millions)	U.S.	Int’l	Total	U.S.	Int’l	Total	U.S.	Int’l	Total	U.S.	Int’l	Total
Pharmaceutical:												
Oncology												
Keytruda	$2,043	$ 1,345	$ 3,388	$1,498	$ 1,136	$ 2,634	$ 3,949	$ 2,722	$ 6,672	$ 2,782	$ 2,121	$ 4,903
Alliance revenue - Lynparza [(1)]	105	73	178	66	45	111	190	133	323	116	74	190
Alliance revenue - Lenvima [(1)]	98	53	151	54	43	97	188	91	279	104	67	171
Emend	6	27	33	67	54	121	11	65	76	130	107	237
Vaccines												
Gardasil/Gardasil 9	168	488	656	456	430	886	629	1,124	1,753	818	906	1,724
ProQuad/M-M-R II/*Varivax*	263	115	378	500	174	675	596	217	813	843	328	1,171
RotaTeq	100	68	168	104	68	172	241	150	391	258	125	383
Pneumovax 23	21	96	117	123	47	170	203	170	373	248	107	355
Vaqta	17	11	28	38	20	58	47	41	88	67	39	105
Hospital Acute Care												
Bridion	107	117	224	129	149	278	250	274	524	248	285	533
Noxafil	6	67	73	100	93	193	14	154	168	191	192	383
Prevymis	28	35	63	19	18	38	55	68	123	37	33	70
Primaxin	1	63	64	—	70	71	1	114	115	1	129	130
Invanz	—	43	43	18	60	78	6	102	108	31	118	150
Cancidas	(2)	45	43	3	64	67	1	98	98	4	125	129
Cubicin	10	21	32	22	45	67	25	53	78	64	91	155
Zerbaxa	17	15	32	13	14	27	37	32	69	25	28	53
Immunology												
Simponi	—	191	191	—	214	214	—	406	406	—	422	422
Remicade	—	73	73	—	98	98	—	160	160	—	221	221
Neuroscience												
Belsomra	22	61	84	21	55	76	49	114	163	45	98	143
Virology												
Isentress/Isentress HD	76	120	196	94	153	247	151	290	441	202	300	502
Zepatier	15	24	39	39	68	108	33	62	94	72	149	221
Cardiovascular												
Zetia	(1)	138	137	6	150	156	(4)	285	282	6	290	296
Vytorin	2	37	39	3	73	76	5	86	92	6	167	174
Atozet	—	115	115	—	92	92	—	238	238	—	186	186
Alliance revenue - Adempas [(2)]	73	6	79	49	2	51	122	11	133	89	5	94
Adempas	—	57	57	—	53	53	—	113	113	—	100	100
Diabetes												
Januvia	413	441	854	471	437	908	768	860	1,628	855	877	1,732
Janumet	143	348	490	166	366	533	256	737	993	333	730	1,063
Women’s Health												
Implanon/Nexplanon	87	44	132	136	48	183	237	90	326	285	98	382
NuvaRing	35	28	63	206	34	240	61	65	126	391	68	459
Diversified Brands												
Singulair	4	96	100	8	153	160	9	246	255	13	338	352
Cozaar/Hyzaar	4	94	98	6	103	109	12	189	200	10	202	213
Arcoxia	—	65	65	—	75	75	—	135	135	—	149	149
Nasonex	4	45	49	(1)	73	72	10	110	120	(2)	170	168
Follistim AQ	20	24	44	24	39	63	40	45	85	53	67	121
Other pharmaceutical [(3)]	385	720	1,103	369	837	1,203	792	1,500	2,293	697	1,589	2,283
Total Pharmaceutical segment sales	4,270	5,409	9,679	4,807	5,653	10,460	8,984	11,350	20,334	9,022	11,101	20,123
Animal Health:												
Livestock	122	526	648	145	526	671	284	1,102	1,386	261	1,021	1,282
Companion Animals	220	233	453	190	263	453	442	486	928	367	500	867
Total Animal Health segment sales	342	759	1,101	335	789	1,124	726	1,588	2,314	628	1,521	2,149
Other segment sales [(4)]	—	—	—	47	—	48	23	—	23	86	—	87
Total segment sales	4,612	6,168	10,780	5,189	6,442	11,632	9,733	12,938	22,671	9,736	12,622	22,359
Other [(5)]	22	70	92	4	125	128	38	220	258	12	206	216
	$4,634	$ 6,238	$ 10,872	$5,193	$ 6,567	$ 11,760	$ 9,771	$13,158	$ 22,929	$ 9,748	$12,828	$ 22,575

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 divested as of March 31, 2020.*

[(5)] *Other is primarily comprised of miscellaneous corporate revenues, including revenue hedging activities, as well as third-party manufacturing sales. Other in the first six months of 2020 and 2019 also includes approximately $85 million and $15 million, respectively, related to the sale of the marketing rights for certain products.*

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 $3.0 billion and $2.9 billion for the three months ended June 30, 2020 and 2019, respectively, and $6.2 billion and $5.5 billion for the six months ended June 30, 2020 and 2019, respectively.

Consolidated sales by geographic area where derived are as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
($ in millions)	2020	2019	2020	2019
United States	$ 4,634	$ 5,193	$ 9,771	$ 9,748
Europe, Middle East and Africa	3,071	3,163	6,605	6,265
China	834	763	1,699	1,509
Japan	867	921	1,678	1,720
Asia Pacific (other than China and Japan)	666	716	1,394	1,461
Latin America	510	658	1,066	1,219
Other	290	346	716	653
	$ 10,872	$ 11,760	$ 22,929	$ 22,575

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

	Three Months Ended June 30,		Six Months Ended June 30,	
($ in millions)	2020	2019	2020	2019
Segment profits:				
Pharmaceutical segment	$ 6,560	$ 7,115	$ 14,036	$ 13,690
Animal Health segment	407	405	885	820
Other segment	—	(2)	2	—
Total segment profits	6,967	7,518	14,923	14,510
Other profits	61	94	200	124
Unallocated:				
Interest income	14	75	39	164
Interest expense	(209)	(233)	(421)	(442)
Depreciation and amortization	(390)	(427)	(772)	(786)
Research and development	(1,994)	(2,093)	(4,092)	(3,935)
Amortization of purchase accounting adjustments	(299)	(378)	(594)	(775)
Restructuring costs	(83)	(59)	(155)	(212)
Other unallocated, net	(548)	(1,238)	(1,771)	(2,322)
	$ 3,519	$ 3,259	$ 7,357	$ 6,326

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 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.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

Planned Spin-Off of Women's Health, Legacy Brands and Biosimilars into New Company

In February 2020, Merck announced its intention to spin-off products from its women's health, legacy brands and biosimilars 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 legacy brands included in the transaction consist of dermatology, non-opioid pain, 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 in the first half of 2021, subject to market and certain other conditions. Subsequent to the spin-off, the historical results of the women's health, legacy brands and biosimilars businesses will be reflected as discontinued operations in the Company's consolidated financial statements.

Recent Developments

Business Developments

Below is a summary of significant business development activity in the first six months of 2020. See Note 2 to the condensed consolidated financial statements for additional information.

In July 2020, Merck acquired the U.S. rights to Sentinel Flavor Tabs and Sentinel Spectrum Chews from Virbac Corporation for approximately $400 million. Sentinel products provide protection against common parasites in dogs.

Also, in July 2020, Merck and Ridgeback Biotherapeutics LP (Ridgeback Bio), a closely held biotechnology company, closed a collaboration agreement to develop MK-4482 (formerly known as EIDD-2801), an orally available antiviral candidate currently in clinical development for the treatment of patients with COVID-19. Merck gained exclusive worldwide rights to develop and commercialize MK-4482 and related molecules. Under the terms of the agreement, Ridgeback Bio received an upfront payment and also is eligible to receive future contingent payments dependent upon the achievement of certain developmental and regulatory approval milestones, as well as a share of the net profits of MK-4482 and related molecules, if approved.

In June 2020, Merck acquired privately held Themis Bioscience GmbH (Themis), a company focused on vaccines and immune-modulation therapies for infectious diseases and cancer for $366 million in cash. Merck may make additional contingent payments dependent upon the achievement of certain developmental, regulatory approval and commercial milestones. The acquisition builds upon an ongoing collaboration between the two companies to develop vaccine candidates using the measles virus vector platform and is expected to accelerate the development of Themis' COVID-19 vaccine candidate (V591).

In May 2020, Merck and the International AIDS Vaccine Initiative, Inc. (IAVI), a nonprofit scientific research organization dedicated to addressing urgent, unmet global health challenges, announced a new collaboration to develop V590, an investigational vaccine against SARS-CoV-2 being studied for the prevention of COVID-19. Under the terms of the agreement, Merck made an upfront payment of $6.5 million and may make additional contingent payments dependent upon the achievement of certain sales-based milestones, as well as royalties.

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, for $2.7 billion. 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.

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 vaccine and antiviral approaches, and supporting health care providers and Merck's communities. Although COVID-19-related disruptions to patients' ability to access health care providers negatively affected second quarter results, Merck remains confident in the fundamental underlying demand for its products and its prospects for long-term growth.

In the second quarter of 2020, the negative impact of the COVID-19 pandemic to Merck's sales was estimated to be $1.6 billion, including approximately $1.5 billion for Pharmaceutical revenue and approximately $100 million for Animal Health revenue. The impact to sales in the first quarter of 2020 was immaterial. For the full-year 2020, Merck expects an unfavorable impact to sales of approximately $1.95 billion (excluding the impact of foreign exchange) due to the COVID-19 pandemic, comprised of approximately $1.8 billion for Pharmaceutical revenue and approximately $150 million for Animal Health revenue. These estimates include the impacts for the first half of the year.

Roughly two-thirds of Merck's Pharmaceutical revenue is comprised of physician-administered products, which, despite strong underlying demand, were affected by social distancing measures, fewer well visits and delays in elective surgeries due to the COVID-19 pandemic. These impacts, as well as the prioritization of COVID-19 patients at health care providers, have resulted in reduced administration of many of the Company's human health products, in particular for its vaccines as well as for *Keytruda* (pembrolizumab) and *Implanon/Nexplanon* (etonogestrel implant). The Company anticipates reduced demand for its physician-administered products while pandemic-related access measures remain in place. In addition, declines in medical visits and elective surgeries also negatively affected the demand for certain products, including *Bridion* (sugammadex) Injection. In Merck's Animal Health business, reduced veterinary visits and lower demand for protein and milk due to restaurant and school closures have negatively affected sales.

While the Company expects to rely on governmental authorities to determine when operations can return to normal, and is cognizant that the duration, spread and severity of the outbreak will be critical determinants for the purposes of the full-year estimates provided above, Merck has assumed that the majority of the negative impact occurred in the second quarter of 2020, with a gradual recovery having commenced in the second quarter and extending through the third quarter, with a return to normal operating levels in the fourth quarter of 2020.

Operating expenses were positively affected in the second quarter and first six months of 2020 by approximately $325 million and $425 million, respectively, primarily driven by lower promotional and selling costs, as well as lower research and development expenses due to the COVID-19 pandemic. For the full-year 2020, Merck continues to expect a net favorable impact to operating expenses of approximately $400 million including both the favorable impact of lower spending, largely reflected in the first half of 2020, partially offset by anticipated spending on recently initiated COVID-19-related vaccine and antiviral research programs.

Pricing

Global efforts toward health care cost containment continue to exert pressure on product pricing and market access worldwide. In the United States, pricing pressure continues on many of the Company's products. 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 revenue performance in the first six months of 2020 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 revenue performance.

Operating Results

Sales

	Three Months Ended June 30,			% Change Excluding Foreign Exchange	Six Months Ended June 30,			% Change Excluding Foreign Exchange
($ in millions)	2020	2019	% Change		2020	2019	% Change	
United States	$ 4,634	$ 5,193	(11)%	(11)%	$ 9,771	$ 9,748	—%	—%
International	6,238	6,567	(5)%	— %	13,158	12,828	3%	6%
Total	$ 10,872	$ 11,760	(8)%	(5)%	$ 22,929	$ 22,575	2%	4%

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

Worldwide sales were $10.9 billion for the second quarter of 2020, a decline of 8% compared with the second quarter of 2019, reflecting an unfavorable impact from the COVID-19 pandemic as discussed above. The sales decline reflects lower sales of vaccines, including human papillomavirus (HPV) vaccines *Gardasil* (Human Papillomavirus Quadrivalent [Types 6,11,16 and 18] Vaccine, Recombinant)/*Gardasil* 9 (Human Papillomavirus 9-valent Vaccine, Recombinant) and lower sales of pediatric vaccines *ProQuad* (Measles, Mumps, Rubella and Varicella Virus Vaccine Live), *M-M-R* II (Measles, Mumps and Rubella Virus Vaccine Live) and *Varivax* (Varicella Virus Vaccine Live). The sales decline was also attributable to the ongoing effects of generic competition for women's health product *NuvaRing* (etonogestrel/ethinyl estradiol vaginal ring), hospital acute care products *Noxafil* (posaconazole) and *Cubicin* (daptomycin for injection), oncology products *Emend* (aprepitant)/*Emend* (fosaprepitant dimeglumine) for Injection, cardiovascular products *Zetia* (ezetimibe) and *Vytorin* (ezetimibe/simvastatin), as well as 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. Lower sales of diabetes products *Januvia* (sitagliptin) and *Janumet* (sitagliptin/metformin HCl) and virology product *Zepatier* (elbasvir and grazoprevir) also contributed to the revenue decline in the quarter. The sales decline was partially offset by higher sales in the oncology franchise reflecting strong growth of *Keytruda*, as well as increased alliance revenue from Lynparza (olaparib) and Lenvima (lenvatinib).

Global sales were $22.9 billion for the first six months of 2020, growth of 2% compared with the same period of 2019. Sales growth was largely due to higher sales in the oncology franchise and higher sales of animal health products, partially offset by ongoing generic competition for certain brands, and an unfavorable impact from the COVID-19 pandemic that resulted in lower demand for certain products.

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

Pharmaceutical Segment

Oncology

	Three Months Ended June 30,			% Change Excluding Foreign Exchange	Six Months Ended June 30,			% Change Excluding Foreign Exchange
($ in millions)	2020	2019	% Change		2020	2019	% Change	
Keytruda	$ 3,388	$ 2,634	29 %	31 %	$ 6,672	$ 4,903	36 %	38 %
Alliance Revenue - Lynparza [(1)]	178	111	61 %	62 %	323	190	70 %	72 %
Alliance Revenue - Lenvima [(1)]	151	97	57 %	57 %	279	171	63 %	64 %
Emend	33	121	(72)%	(71)%	76	237	(68)%	(67)%

[(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), small-cell lung cancer (SCLC), melanoma, Merkel cell carcinoma, microsatellite instability-high (MSI-H) or mismatch repair deficient cancer, primary mediastinal large B-cell lymphoma (PMBCL), and urothelial carcinoma. *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 HNSCC, 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" below).

In January 2020, the U.S. Food and Drug Administration (FDA) approved *Keytruda* as monotherapy for the treatment of certain patients with Bacillus Calmette-Guerin (BCG)-unresponsive, high-risk, non-muscle invasive bladder cancer (NMIBC) based on the results of the KEYNOTE-057 trial.

In April 2020, the FDA granted accelerated approval for an additional recommended dosage of 400 mg every six weeks (Q6W) for *Keytruda* across all adult indications, including monotherapy and combination therapy. This new dosage option will be available in addition to the current dose of 200 mg every three weeks (Q3W).

In June 2020, the FDA granted accelerated approval for *Keytruda* as monotherapy for the treatment of adult and pediatric patients with unresectable or metastatic tumor mutational burden-high (TMB-H) (≥10 mutations/megabase) solid tumors, as determined by an FDA-approved test, that have progressed following prior treatment and who have no satisfactory alternative treatment options based in part on the results of the KEYNOTE-158 trial.

Also in June 2020, the FDA approved *Keytruda* as monotherapy both for the treatment of patients with recurrent or metastatic cSCC that is not curable by surgery or radiation based on data from the Phase 2 KEYNOTE-629 trial and for the first-line treatment of patients with unresectable or metastatic MSI-H or mismatch repair deficient colorectal cancer based on results from the Phase 3 KEYNOTE-177 trial.

In addition, in June 2020, *Keytruda* was approved by the National Medical Products Administration (NMPA) in China as monotherapy for the second-line treatment of patients with locally advanced or metastatic esophageal squamous cell carcinoma whose tumors express PD-L1 (Combined Positive Score [CPS] ≥10). This indication was granted based on the Phase 3 KEYNOTE-181 trial, including data from an extension of the global study in Chinese patients.

Global sales of *Keytruda* grew 29% and 36% in the second quarter and first six months of 2020, respectively. Sales growth in both periods was driven by higher demand as the Company continues to launch *Keytruda* with multiple new indications globally, although the COVID-19 pandemic had a dampening effect on growing demand. Sales in the United States continue to build across the multiple approved indications, in particular for the treatment of NSCLC as monotherapy, and in combination with chemotherapy for both nonsquamous and squamous metastatic NSCLC, along with uptake in the adjuvant melanoma and RCC indications. Other indications contributing to U.S. sales growth include HNSCC, bladder cancer, melanoma, and MSI-H cancer. *Keytruda* sales growth in international markets was driven by continued uptake in approved indications, particularly in the European Union (EU).

Pursuant to a re-pricing rule, the Japanese government reduced the price of *Keytruda* by 17.5% effective February 2020. Additionally, *Keytruda* was subject to another price reduction of 20.9% in April 2020 under a provision of the Japanese pricing rules.

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 61% and 70% in the second quarter and first six months of 2020, respectively. Sales growth in both periods was largely driven by continued uptake across the multiple approved indications in the United States and in the EU. In May 2020, the FDA approved Lynparza in combination with bevacizumab as a first-line maintenance treatment of certain adult patients with advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy based on the results from the Phase 3 PAOLA-1 trial. Also in May 2020, the FDA approved Lynparza for the treatment of adult patients with deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer (mCRPC) who have progressed following prior treatment with enzalutamide or abiraterone based on positive results from the Phase 3 PROfound trial. In July 2020, Lynparza was approved in the EU as a monotherapy for the maintenance treatment of adult patients with germline *BRCA*1/2 mutations who have metastatic adenocarcinoma of the pancreas and have not progressed after a minimum of 16 weeks of platinum treatment within a first-line chemotherapy regimen based on the results from the Phase 3 POLO trial.

Lenvima, 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 grew 57% and 63% in the second quarter and first six months of 2020, respectively. Sales growth in both periods was primarily due to higher demand in the United States, the EU and China.

Global sales of *Emend*, for the prevention of chemotherapy-induced nausea and vomiting, declined 72% and 68% in the second quarter and first six months of 2020, respectively. The sales declines were primarily driven by lower demand and pricing in the United States due to generic competition, including recent generic competition for *Emend* for Injection following U.S. patent expiry in September 2019. Also contributing to the sales declines in the second quarter and first six months of 2020 was lower demand in the EU as a result of generic competition for the oral formulation of *Emend* following loss of market exclusivity in May of 2019. U.S. market exclusivity for the oral formulation of *Emend* previously expired in 2015. *Emend* for Injection will lose market exclusivity in major European markets in August 2020. The Company anticipates that sales of *Emend* for Injection in these markets will decline significantly thereafter.

In April 2020, the FDA approved Koselugo (selumetinib) for the treatment of pediatric patients two years of age and older with neurofibromatosis type 1 (NF1) who have symptomatic, inoperable plexiform neurofibromas (PN). The FDA approval is based on positive results from the National Cancer Institute (NCI) Cancer Therapy Evaluation Program (CTEP)-sponsored Phase 2 SPRINT Stratum 1 trial coordinated by the NCI's Center for Cancer Research, Pediatric Oncology Branch. This is the first regulatory approval of a medicine for the treatment of NF1 PN, a rare and debilitating genetic condition. Koselugo is being jointly developed and commercialized with AstraZeneca globally (see Note 3 to the condensed consolidated financial statements).

Vaccines

	Three Months Ended June 30,			% Change Excluding Foreign Exchange	Six Months Ended June 30,			% Change Excluding Foreign Exchange
($ in millions)	2020	2019	% Change		2020	2019	% Change	
Gardasil/Gardasil 9	$ 656	$ 886	(26)%	(24)%	$ 1,753	$ 1,724	2 %	4 %
ProQuad	133	204	(35)%	(35)%	290	356	(19)%	(18)%
M-M-R II	72	199	(64)%	(64)%	172	322	(47)%	(46)%
Varivax	173	271	(36)%	(35)%	352	492	(29)%	(28)%
Pneumovax 23	117	170	(31)%	(29)%	373	355	5 %	7 %

Worldwide sales of *Gardasil/Gardasil* 9, vaccines to help prevent certain cancers and other diseases caused by certain types of HPV, declined 26% in the second quarter of 2020 primarily due to lower demand in the United States and Hong Kong, SAR, PRC attributable to the COVID-19 pandemic, partially offset by higher demand in China. Worldwide sales of *Gardasil/Gardasil* 9 grew 2% in the first six months of 2020 driven by higher demand in China and in the EU, partially offset by the unfavorable effects of the COVID-19 pandemic, particularly in the United States and Hong Kong, SAR, PRC.

In June 2020, the FDA approved an expanded indication for *Gardasil* 9 for the prevention of oropharyngeal and other head and neck cancers caused by HPV Types 16, 18, 31, 33, 45, 52, and 58. The oropharyngeal and head and neck cancer indication is approved under accelerated approval based on effectiveness in preventing HPV-related anogenital disease.

In July 2020, *Silgard* 9 aqueous suspension for intramuscular injection syringes (recombinant adsorbed 9-valent Human Papillomavirus virus-like particles vaccine) were approved for use in women and girls by the Ministry of Health, Labor and Welfare in Japan.

Global sales of *ProQuad*, a pediatric combination vaccine to help protect against measles, mumps, rubella and varicella, declined 35% and 19% in the second quarter and first six months of 2020, respectively, primarily due to lower demand in the United States resulting from the COVID-19 pandemic.

Worldwide sales of *M-M-R* II, a vaccine to help protect against measles, mumps and rubella, declined 64% and 47% in the second quarter and first six months of 2020, respectively, primarily driven by lower demand in the United States resulting from fewer measles outbreaks in 2020, coupled with the unfavorable impact of the COVID-19 pandemic. Private sector buy-in during the second quarter of 2019 also contributed to the U.S. *M-M-R* II sales declines in the second quarter and first six months of 2020. Additionally, the sales decline in the first six months of 2020 reflects lower demand in Brazil.

Global sales of *Varivax*, a vaccine to help prevent chickenpox (varicella), declined 36% and 29% in the second quarter and first six months of 2020, respectively. The sales declines reflect lower government tenders in Brazil, as well as lower demand in the United States resulting from the COVID-19 pandemic.

Worldwide sales of *Pneumovax* 23 (pneumococcal vaccine polyvalent), a vaccine to help prevent pneumococcal disease, declined 31% in the second quarter of 2020 primarily due to lower demand in the United States related to the COVID-19 pandemic, partially offset by higher volumes in the EU attributable in part to increased demand for pneumococcal vaccination during the COVID-19 pandemic. Global sales of *Pneumovax* 23 grew 5% in first six months of 2020 largely due to higher demand in the EU, partially offset by lower demand in the United States and the timing of shipments in China.

Hospital Acute Care

($ in millions)	Three Months Ended June 30, 2020	Three Months Ended June 30, 2019	% Change	% Change Excluding Foreign Exchange	Six Months Ended June 30, 2020	Six Months Ended June 30, 2019	% Change	% Change Excluding Foreign Exchange
Bridion	$ 224	$ 278	(19)%	(18)%	$ 524	$ 533	(2)%	— %
Noxafil	73	193	(62)%	(60)%	168	383	(56)%	(55)%
Prevymis	63	38	66 %	67 %	123	70	76 %	78 %
Cubicin	32	67	(53)%	(51)%	78	155	(50)%	(48)%

Worldwide sales of *Bridion*, for the reversal of two types of neuromuscular blocking agents used during surgery, declined 19% in the second quarter of 2020 primarily attributable to lower demand resulting from fewer elective surgeries due to the COVID-19 pandemic. Excluding the impact of foreign exchange, global sales of *Bridion* in the first six months of 2020 were flat as higher demand in the first quarter was offset by lower demand in the second quarter resulting from the COVID-19 pandemic.

Global sales of *Noxafil*, for the prevention of invasive fungal infections, declined 62% and 56% in the second quarter and first six months of 2020, respectively, primarily due to generic competition in the United States and in the EU. The patents that provided U.S. market exclusivity for certain forms of *Noxafil* representing the majority of U.S. *Noxafil* sales expired in July 2019. Additionally, the patent for *Noxafil* expired in a number of major European markets in December 2019. Accordingly, 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.

Worldwide sales of *Prevymis* (letermovir), a medicine for prophylaxis (prevention) of cytomegalovirus (CMV) infection and disease in adult CMV-seropositive recipients of an allogenic hematopoietic stem cell transplant, grew 66% and 76% in the second quarter and first six months of 2020, respectively, due to continued uptake since launch in the EU and in the United States.

Global sales of *Cubicin*, an I.V. antibiotic for complicated skin and skin structure infections or bacteremia when caused by designated susceptible organisms, declined 53% and 50% in the second quarter and first six months of 2020, respectively, due in part to ongoing generic competition in the United States and in the EU.

In June 2020, the FDA approved a supplemental New Drug Application (sNDA) for *Recarbrio* (imipenem, cilastatin, and relebactam) for the treatment of patients 18 years of age and older with hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP), caused by certain susceptible Gram-negative microorganisms.

Immunology

($ in millions)	Three Months Ended June 30, 2020	Three Months Ended June 30, 2019	% Change	% Change Excluding Foreign Exchange	Six Months Ended June 30, 2020	Six Months Ended June 30, 2019	% Change	% Change Excluding Foreign Exchange
Simponi	$ 191	$ 214	(11)%	(8)%	$ 406	$ 422	(4)%	(1)%
Remicade	73	98	(26)%	(25)%	160	221	(28)%	(26)%

Sales of *Simponi* (golimumab), a once-monthly subcutaneous treatment for certain inflammatory diseases (marketed by the Company in Europe, Russia and Turkey), declined 11% and 4% in the second quarter and first six month of 2020, respectively, primarily driven by lower demand in the EU due to the uptake of biosimilars for a competing product. Higher volumes in Russia partially offset the decline in the first six months of 2020.

Sales of *Remicade* (infliximab), a treatment for inflammatory diseases (marketed by the Company in Europe, Russia and Turkey), declined 26% and 28% in the second quarter and first six months of 2020, respectively, 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.

Virology

($ in millions)	Three Months Ended June 30, 2020	Three Months Ended June 30, 2019	% Change	% Change Excluding Foreign Exchange	Six Months Ended June 30, 2020	Six Months Ended June 30, 2019	% Change	% Change Excluding Foreign Exchange
Isentress/Isentress HD	$ 196	$ 247	(21)%	(17)%	$ 441	$ 502	(12)%	(9)%
Zepatier	39	108	(63)%	(62)%	94	221	(57)%	(56)%

Global combined sales of *Isentress/Isentress HD* (raltegravir), an HIV integrase inhibitor for use in combination with other antiretroviral agents for the treatment of HIV-1 infection, declined 21% in the second quarter of 2020 primarily driven by competitive pressure in the United States and in the EU, as well as the timing of shipments in Russia. Worldwide sales declined 12% in the first six months of 2020 primarily due to lower sales in the United States and in the EU, partially offset by higher volumes in Russia.

Global sales of *Zepatier*, a treatment for adult patients with chronic hepatitis C virus genotype (GT) 1 or GT4 infection, declined 63% and 57% in the second quarter and first six months of 2020, respectively, primarily driven by lower demand in the EU, the United States, and the Asia Pacific region due to competition and declining patient volumes, coupled with the impact of the COVID-19 pandemic.

Cardiovascular

($ in millions)	Three Months Ended June 30, 2020	Three Months Ended June 30, 2019	% Change	% Change Excluding Foreign Exchange	Six Months Ended June 30, 2020	Six Months Ended June 30, 2019	% Change	% Change Excluding Foreign Exchange
Zetia/Vytorin	$ 175	$ 232	(24)%	(23)%	$ 374	$ 470	(20)%	(19)%
Atozet	115	92	25 %	28 %	238	186	28 %	31 %
Rosuzet	31	52	(41)%	(40)%	63	66	(5)%	(2)%
Alliance Revenue - Adempas [(1)]	79	51	54 %	54 %	133	94	41 %	41 %
Adempas	57	53	8 %	9 %	113	100	12 %	14 %

[(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* (marketed outside the United States as *Inegy*), medicines for lowering LDL cholesterol, declined 24% and 20% in the second quarter and first six months of 2020, respectively, primarily due to generic competition for *Ezetrol* and *Inegy* in the EU. The EU patents for *Ezetrol* and *Inegy* expired in April 2018 and April 2019, respectively. The Company expects the sales declines in these markets to continue. The sales decline was also attributable to loss of exclusivity in Australia. The patent that provided market exclusivity for *Ezetrol* in Japan expired in September 2019 and generic competition began in the second quarter of 2020. These declines were partially offset by higher demand for *Ezetrol* in China.

Sales of *Atozet* (ezetimibe and atorvastatin) (marketed outside of the United States), a medicine for lowering LDL cholesterol, grew 25% and 28% in the second quarter and first six months of 2020, respectively, primarily due to higher demand in most markets, particularly in the EU and in Japan.

Sales of *Rosuzet* (ezetimibe and rosuvastatin) (marketed outside of the United States), a medicine for lowering LDL cholesterol, declined 41% and 5% in the second quarter and first six months of 2020, respectively, due to prior year launch buy-in in Japan. In the first six months of 2020, the decline was partially offset by higher demand in Korea.

Adempas (riociguat), a cardiovascular drug for the treatment of pulmonary arterial hypertension, is part of a worldwide clinical development 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, which grew 54% and 41% in the second quarter and first six months of 2020, respectively, as well as sales in Merck's marketing territories, which grew 8% and 12% in the second quarter and first six months of 2020, respectively.

Diabetes

($ in millions)	Three Months Ended June 30, 2020	Three Months Ended June 30, 2019	% Change	% Change Excluding Foreign Exchange	Six Months Ended June 30, 2020	Six Months Ended June 30, 2019	% Change	% Change Excluding Foreign Exchange
Januvia/Janumet	$ 1,344	$ 1,441	(7)%	(5)%	$ 2,621	$ 2,795	(6)%	(5)%

Worldwide combined sales of *Januvia* and *Janumet*, medicines that help lower blood sugar levels in adults with type 2 diabetes, declined 7% and 6% in the second quarter and first six months of 2020, respectively. The declines were primarily due to continued pricing pressure in the United States and lower demand in certain markets resulting from the COVID-19 pandemic, partially offset by higher demand in China. The Company expects U.S. pricing pressure to continue. The patents that provide market exclusivity for *Januvia* and *Janumet* in the United States expire in July 2022 (although six-month pediatric exclusivity may extend this date). The patent that provides market exclusivity for *Januvia* in the EU expires in July 2022 (although pediatric exclusivity has recently been granted which may extend this date to September 2022 and the Company is applying in individual countries for the extensions). The supplementary patent certificate that provides market exclusivity for *Janumet* in the EU expires in April 2023. The Company anticipates sales of *Januvia* and *Janumet* in these markets will decline substantially after these patent expiries.

Women's Health

($ in millions)	Three Months Ended June 30, 2020	Three Months Ended June 30, 2019	% Change	% Change Excluding Foreign Exchange	Six Months Ended June 30, 2020	Six Months Ended June 30, 2019	% Change	% Change Excluding Foreign Exchange
Implanon/Nexplanon	$ 132	$ 183	(28)%	(26)%	$ 326	$ 382	(15)%	(13)%
NuvaRing	63	240	(74)%	(73)%	126	459	(73)%	(72)%

Global sales of *Implanon/Nexplanon*, a single-rod subdermal contraceptive implant, declined 28% and 15% in the second quarter and first six months of 2020, respectively, primarily due to lower demand in the United States and in the EU resulting from the COVID-19 pandemic, partially offset by higher demand in Latin America.

Worldwide sales of *NuvaRing*, a vaginal contraceptive product, declined 74% and 73% in the second quarter and first six months of 2020, respectively, due to generic competition in the United States. The patent that provided U.S. market exclusivity for *NuvaRing* expired in April 2018 and generic competition began in December 2019. Accordingly, the Company is experiencing a rapid and substantial decline in U.S. *NuvaRing* sales and expects the decline to continue.

Biosimilars

($ in millions)	Three Months Ended June 30, 2020	Three Months Ended June 30, 2019	% Change	% Change Excluding Foreign Exchange	Six Months Ended June 30, 2020	Six Months Ended June 30, 2019	% Change	% Change Excluding Foreign Exchange
Biosimilars	$ 60	$ 78	(23)%	(21)%	$ 128	$ 121	6%	7%

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 human epidermal growth factor receptor 2 (HER2)-positive breast cancer and HER2 overexpressing gastric cancer; and Brenzys (etanercept biosimilar), a biosimilar to Enbrel for the treatment of certain inflammatory diseases. Merck's commercialization territories under the agreement vary by product. Sales of biosimilars declined 23% in the second quarter of 2020 primarily due to lower volumes for Brenzys in Brazil due in part to the timing of shipments. Sales of biosimilars grew 6% in the first six months of 2020 driven by continued post-launch uptake of Renflexis in United States and Canada and Ontruzant in the EU, partially offset by lower sales of Brenzys in Brazil.

In April 2020, Merck announced the U.S. launch of Ontruzant, which was approved by the FDA in January 2019.

Animal Health Segment

	Three Months Ended June 30,			% Change Excluding Foreign Exchange	Six Months Ended June 30,			% Change Excluding Foreign Exchange
($ in millions)	2020	2019	% Change		2020	2019	% Change	
Livestock	$ 648	$ 671	(3)%	3%	$ 1,386	$ 1,282	8%	13%
Companion Animal	453	453	— %	3%	928	867	7%	9%

Sales of livestock products declined 3% in the second quarter of 2020 primarily driven by lower demand attributable to the COVID-19 pandemic and the unfavorable effect of foreign exchange, partially offset by an additional month of sales in 2020 related to the April 2019 acquisition of Antelliq Corporation (Antelliq) (see Note 2 to the condensed consolidated financial statements). Sales of livestock products grew 8% in the first six months of 2020 largely driven by the Antelliq acquisition. Sales of companion animal products were flat in the second quarter of 2020 as higher demand for the *Bravecto* (fluralaner) line of products for parasitic control was offset by lower demand for companion animal vaccines due to reduced veterinary access resulting from the COVID-19 pandemic. Companion animal sales grew 7% in the first six months of 2020 primarily driven by higher sales of the *Bravecto* line of products, partially offset by lower demand for other companion animal products attributable to the COVID-19 pandemic.

Costs, Expenses and Other

	Three Months Ended June 30,			Six Months Ended June 30,		
($ in millions)	2020	2019	% Change	2020	2019	% Change
Cost of sales	$ 3,159	$ 3,401	(7)%	$ 6,471	$ 6,453	— %
Selling, general and administrative	2,378	2,712	(12)%	4,933	5,138	(4)%
Research and development	2,123	2,189	(3)%	4,331	4,119	5 %
Restructuring costs	83	59	41 %	155	212	(27)%
Other (income) expense, net	(390)	140	*	(318)	327	*
	$ 7,353	$ 8,501	(14)%	15,572	16,249	(4)%

** Greater than 100%.*

Cost of Sales

Cost of sales declined 7% in the second quarter of 2020 and were essentially flat in the first six months of 2020. Cost of sales includes the amortization of intangible assets recorded in connection with business acquisitions, which totaled $281 million and $371 million in the second quarter of 2020 and 2019, respectively, and $573 million and $768 million in the first six months of 2020 and 2019, respectively. Cost of sales also includes the amortization of amounts capitalized in connection with collaborations of $298 million and $124 million in the second quarter of 2020 and 2019, respectively, and $388 million and $222 million in the first six months of 2020 and 2019, respectively. Additionally, costs include intangible asset impairment charges of $69 million and $81 million in the second quarter and first six months of 2019 related to marketed products recorded in connection with business acquisitions. The Company may recognize additional impairment charges in the future related to intangible assets that were measured at fair value and capitalized in connection with business acquisitions and such charges could be material. Also included in cost of sales are expenses associated with restructuring activities which amounted to $25 million and $65 million in the second quarter of 2020 and 2019, respectively, and $93 million and $99 million in the first six months of 2020 and 2019, 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 70.9% in the second quarter of 2020 compared with 71.1% in the second quarter of 2019. The gross margin decline reflects higher amortization of unfavorable manufacturing variances and intangible assets (noted above), largely offset by the favorable effects of foreign exchange, product mix and lower restructuring costs. Gross margin was 71.8% in the first six months of 2020 compared with 71.4% in the first six months of 2019. The gross margin improvement was primarily driven by favorable product mix, partially offset by the unfavorable effects of pricing pressure, manufacturing variances, royalties, and inventory write-offs.

Selling, General and Administrative

Selling, general and administrative (SG&A) expenses declined 12% and 4% in the second quarter and first six months of 2020, respectively, primarily due to lower promotional, selling, and administrative costs, including reduced travel and fewer meetings, due in part to the COVID-19 pandemic, and the favorable effect of foreign exchange, partially offset by costs related to the planned spin-off of Organon. Transaction costs related to the acquisition of ArQule also contributed to the increase in SG&A expenses in the first six months of 2020 (see Note 2 to the condensed consolidated financial statements).

Research and Development

Research and development (R&D) expenses declined 3% in the second quarter of 2020 reflecting a decrease in the estimated fair value measurement of liabilities for contingent consideration, as well as lower laboratory supply costs, reduced travel and fewer meetings due to the COVID-19 pandemic, partially offset by higher expenses related to clinical development and increased investment in discovery research and early drug development. R&D expenses increased 5% in the first six months of 2020 primarily driven by higher clinical development and discovery research spending, as well as higher licensing and restructuring costs, partially offset by lower costs associated with the COVID-19 pandemic and the favorable effect of foreign exchange.

R&D expenses are comprised of the costs directly incurred by Merck Research Laboratories (MRL), the Company's research and development division that focuses on human health-related activities, which were $1.5 billion in both the second quarter of 2020 and 2019, and $3.0 billion and $2.9 billion in the first six months of 2020 and 2019, 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 $645 million and $715 million for the second quarter of 2020 and 2019, respectively, and $1.3 billion in both the first six months of 2020 and 2019. In addition, R&D expenses include expense or income related to changes in the estimated fair value measurement of liabilities for contingent consideration recorded in connection with business acquisitions. The Company recorded a net reduction in expenses of $82 million in the second quarter of 2020 and $49 million and $38 million in the first six months of 2020 and 2019, respectively, related to the changes in these estimates. R&D expenses also reflect $31 million and $48 million of accelerated depreciation costs in connection with restructuring activities in the second quarter and first six months of 2020, respectively.

Restructuring Costs

In early 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 $2.5 billion. The Company expects to record charges of approximately $800 million in 2020 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. Actions under previous global restructuring programs have been substantially completed.

Restructuring costs, primarily representing separation and other related costs associated with these restructuring activities, were $83 million and $59 million for the second quarter of 2020 and 2019, respectively, and $155 million and $212 million in the first six months of 2020 and 2019, 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 $150 million and $159 million in the second quarter of 2020 and 2019, respectively, and $318 million and $346 million in the first six months of 2020 and 2019, respectively, related to restructuring program activities (see Note 4 to the condensed consolidated financial statements).

Other (Income) Expense, Net

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

Segment Profits

($ in millions)	Three Months Ended June 30, 2020	Three Months Ended June 30, 2019	Six Months Ended June 30, 2020	Six Months Ended June 30, 2019
Pharmaceutical segment profits	$ 6,560	$ 7,115	$ 14,036	$ 13,690
Animal Health segment profits	407	405	885	820
Other non-reportable segment profits	—	(2)	2	—
Other	(3,448)	(4,259)	(7,566)	(8,184)
Income before taxes	$ 3,519	$ 3,259	$ 7,357	$ 6,326

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 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 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 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 declined 8% in the second quarter of 2020 largely due to lower sales and the unfavorable effect of foreign exchange, partially offset by lower selling and promotional costs. Pharmaceutical segment profits grew 3% in the first six months of 2020 driven primarily by higher sales, as well as lower selling and promotional costs, partially offset by the unfavorable effect of foreign exchange. Animal Health segment profits grew 1% in the second quarter of 2020 reflecting lower selling and promotional costs, largely offset by lower sales and the unfavorable effect of foreign exchange. Animal Health segment profits grew 8% in the first six months of 2020 reflecting higher sales driven by the Antelliq acquisition, partially offset by higher research costs and the unfavorable effect of foreign exchange.

Taxes on Income

The effective income tax rates of 14.5% and 18.9% for the second quarter of 2020 and 2019, respectively, and 15.3% and 13.0% for the first six months of 2020 and 2019, respectively, reflect the impacts of acquisition and divestiture-related costs and restructuring costs, partially offset by the beneficial impact of foreign earnings. In addition, the effective income tax rate for the first six months of 2019 reflects the favorable impact of a $360 million net tax benefit related to the settlement of certain federal income tax matters.

In the first quarter of 2019, the Internal Revenue Service (IRS) concluded its examinations of Merck's 2012-2014 U.S. federal income tax returns. As a result, the Company was required to make a payment of $107 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 $360 million net tax benefit in the first six months of 2019. This net benefit reflects reductions in reserves for unrecognized tax benefits for tax positions relating to the years that were under examination, partially offset by additional reserves for tax positions not previously reserved for.

Net Loss Attributable to Noncontrolling Interests

Net loss attributable to noncontrolling interests of $26 million for the second quarter of 2019 and $79 million for the first six months of 2019 includes the portion of goodwill impairment charges related to certain businesses in the Healthcare Services segment that are attributable to noncontrolling interests.

Net Income and Earnings per Common Share

Net income attributable to Merck & Co., Inc. was $3.0 billion for the second quarter of 2020 compared with $2.7 billion for the second quarter of 2019 and was $6.2 billion for the first six months of 2020 compared with $5.6 billion for the first six months of 2019. Earnings per common share assuming dilution attributable to Merck & Co., Inc. common shareholders (EPS) for the second quarter of 2020 were $1.18 compared with $1.03 in the second quarter of 2019 and were $2.45 for the first six months of 2020 compared with $2.15 for the first six months of 2019.

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 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).

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

	Three Months Ended June 30,		Six Months Ended June 30,	
($ in millions except per share amounts)	2020	2019	2020	2019
Income before taxes as reported under GAAP	$ 3,519	$ 3,259	$ 7,357	$ 6,326
Increase (decrease) for excluded items:				
Acquisition and divestiture-related costs	443	660	1,043	1,208
Restructuring costs	150	159	318	346
Other	(16)	48	(16)	48
Non-GAAP income before taxes	4,096	4,126	8,702	7,928
Taxes on income as reported under GAAP	509	615	1,128	820
Estimated tax benefit on excluded items [(1)]	95	145	260	274
Net tax benefit from the settlement of certain federal income tax matters	—	—	—	360
Tax charge related to finalization of treasury regulations for the Tax Cuts and Job Act of 2017	—	—	—	(67)
Non-GAAP taxes on income	604	760	1,388	1,387
Non-GAAP net income	3,492	3,366	7,314	6,541
Less: Net income (loss) attributable to noncontrolling interests as reported under GAAP	8	(26)	8	(79)
Acquisition and divestiture-related costs attributable to noncontrolling interests	—	36	—	89
Non-GAAP net income attributable to noncontrolling interests	8	10	8	10
Non-GAAP net income attributable to Merck & Co., Inc.	$ 3,484	$ 3,356	$ 7,306	$ 6,531
EPS assuming dilution as reported under GAAP	$ 1.18	$ 1.03	$ 2.45	$ 2.15
EPS difference	0.19	0.27	0.42	0.37
Non-GAAP EPS assuming dilution	$ 1.37	$ 1.30	$ 2.87	$ 2.52

[(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 business 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 business acquisitions and divestitures.

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.

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 2019 is a net tax benefit related to the settlement of certain federal income tax matters (see Note 13 to the condensed consolidated financial statements) and a tax charge related to the finalization of U.S. treasury regulations related to the Tax Cuts and Jobs Act of 2017.

Research and Development Update

In July 2020, the FDA accepted for priority review the New Drug Application (NDA) for vericiguat, an orally administered sGC stimulator, 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 FDA set a Prescription Drug User Fee Act (PDUFA), or target action, date of January 20, 2021. Vericiguat is being jointly developed with Bayer (see Note 3 to the condensed consolidated financial statements). The application is based on results from the Phase 3 VICTORIA trial, which is the first contemporary outcomes study focused exclusively on a population with worsening chronic heart failure who are at high risk for cardiovascular mortality and repeated heart failure hospitalizations. Data from VICTORIA were presented at the virtual American College of Cardiology's 69th Annual Scientific Session together with World Congress of Cardiology and published in *The New England Journal of Medicine*. Vericiguat is also under review in the EU and in Japan. Merck and Bayer plan to share VICTORIA data with regulatory authorities worldwide.

Koselugo (selumetinib) is under review in the EU for the treatment of pediatric patients two years of age and older with NF1 who have symptomatic, inoperable PN based on positive results from the NCI CTEP-sponsored Phase 2 SPRINT Stratum 1 trial. Koselugo was approved by the FDA in April 2020. Koselugo is being jointly developed and commercialized with AstraZeneca globally (see Note 3 to the condensed consolidated financial statements).

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 1,200 clinical trials, including more than 850 trials that combine *Keytruda* with other cancer treatments. These studies encompass more than 30 cancer types including: biliary tract, cervical, colorectal, cutaneous squamous cell, endometrial, gastric, glioblastoma, head and neck, hepatocellular, Hodgkin lymphoma, non-Hodgkin lymphoma, melanoma, mesothelioma, nasopharyngeal, non-small-cell lung, ovarian, PMBCL, prostate, renal, small-cell lung, triple-negative breast and urothelial, many of which are currently in Phase 3 clinical development. Further trials are being planned for other cancers.

In July 2020, the FDA accepted and granted Priority Review for a supplemental Biologics License Application (BLA) seeking accelerated approval for *Keytruda* in combination with chemotherapy for the treatment of patients with locally recurrent unresectable or metastatic triple-negative breast cancer (TNBC) whose tumors express PD-L1 (CPS ≥10). The application was based on data from the KEYNOTE-355 trial in which *Keytruda* plus chemotherapy demonstrated a statistically significant and clinically meaningful improvement in progression-free survival (PFS) compared with chemotherapy alone in patients whose tumors expressed PD-L1 at CPS ≥10. In patients whose tumors expressed PD-L1 with CPS ≥1, *Keytruda* plus chemotherapy improved PFS versus chemotherapy alone, however these results did not meet statistical significance. These data were presented at the virtual scientific program of the 2020 American Society of Clinical Oncology (ASCO) Annual Meeting. As previously announced, the trial will continue without changes to evaluate the other dual primary endpoint of overall survival (OS). The FDA set a PDUFA date of November 28, 2020.

Also in July 2020, the FDA accepted for standard review a supplemental BLA for *Keytruda* for the treatment of patients with high-risk, early-stage TNBC, in combination with chemotherapy as neoadjuvant treatment, and then as a single agent as adjuvant treatment after surgery. The application was based on data from the KEYNOTE-522 trial in which neoadjuvant *Keytruda* plus chemotherapy resulted in a statistically significant increase in pathologic complete response in patients with early-stage TNBC, regardless of PD-L1 expression. The *Keytruda* regimen also demonstrated a favorable trend for the other dual primary endpoint of event-free survival. An interim analysis for this study was conducted by the Independent Data Monitoring Committee (DMC). Based on the recommendation of the DMC, the study continues to evaluate event-free survival. Data from the KEYNOTE-522 trial were presented at the European Society for Medical Oncology 2019 Congress. As previously announced, *Keytruda* plus chemotherapy was granted Breakthrough Therapy designation by the FDA in September 2019 for the neoadjuvant treatment of patients with high-risk, early-stage TNBC. The PDUFA date for this application is March 29, 2021.

Additionally in July 2020, the FDA accepted and granted Priority Review for a new supplemental BLA for *Keytruda* as monotherapy for the second-line treatment of adult patients with relapsed or refractory cHL based on data from the pivotal

Phase 3 KEYNOTE-204 trial, in which *Keytruda* demonstrated a significant improvement in PFS compared to brentuximab vedotin (BV), a current standard of care in this patient population. The FDA set a PDUFA date of October 30, 2020. KEYNOTE-204 also serves as the confirmatory trial for the *Keytruda* accelerated approval hematology indications and as previously announced the Company plans to submit these data to global regulatory authorities this year. The Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) announced the start of a procedure to extend the currently approved therapeutic indication for the treatment of relapsed or refractory cHL in adults to an earlier line of therapy and to include pediatric patients based on KEYNOTE-204. Data from KEYNOTE-204 were presented during the virtual scientific program of the 2020 ASCO Annual Meeting.

Keytruda is under review in Japan as monotherapy for the second-line treatment of advanced or metastatic esophageal or esophagogastric junction carcinoma based on the results of the Phase 3 KEYNOTE-181 trial. The *Keytruda* review in Japan for both monotherapy and in combination with chemotherapy for the first-line treatment of advanced gastric or gastroesophageal junction adenocarcinoma based on results from the pivotal Phase 3 KEYNOTE-062 trial was withdrawn in June 2020.

Keytruda is also under review in the EU for the first-line treatment of patients with MSI-H or mismatch repair deficient unresectable or metastatic colorectal cancer based on the results from the Phase 3 KEYNOTE-177 trial. *Keytruda* was approved for this indication by the FDA in June 2020.

In addition to the Breakthrough Therapy designation from the FDA for the combination of *Keytruda* with neoadjuvant chemotherapy for the treatment of high-risk, early-stage TNBC noted above, *Keytruda* 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 June 2020, Merck announced that the Phase 3 KEYNOTE-361 trial evaluating *Keytruda* in combination with chemotherapy for the first-line treatment of patients with advanced or metastatic urothelial carcinoma (bladder cancer) did not meet its pre-specified dual primary endpoints of OS or PFS, compared with standard of care chemotherapy. In the final analysis of the study, there was an improvement in OS and PFS for patients treated with *Keytruda* in combination with chemotherapy compared to chemotherapy alone; however, these results did not meet statistical significance per the pre-specified statistical plan. The monotherapy arm of the study was not formally tested, since superiority was not reached for OS or PFS in the *Keytruda* combination arm. *Keytruda* has three FDA-approved bladder cancer indications across multiple stages of bladder cancer. Additionally, Merck has an extensive clinical development program in bladder cancer and is continuing to evaluate *Keytruda* as monotherapy and in combination with other anti-cancer therapies across several disease settings (i.e., metastatic, muscle invasive bladder cancer, and non-muscle invasive bladder cancer).

Additionally in May 2020, Merck announced positive results from two studies from the Company's lung cancer research program. Initial results from the Phase 2 KEYNOTE-799 trial evaluating *Keytruda* plus concurrent chemoradiation therapy demonstrated an objective response rate (ORR) of 67.0% in Cohort A (squamous and nonsquamous NSCLC patients who received paclitaxel plus carboplatin) and 56.6% in Cohort B (nonsquamous NSCLC patients who received cisplatin plus pemetrexed) in untreated patients with unresectable, locally advanced stage III NSCLC.

In May 2020, Merck and Eisai presented data from analyses of two trials evaluating *Keytruda* plus Lenvima at the 2020 ASCO Annual Meeting, in which the *Keytruda* plus Lenvima combination demonstrated clinically meaningful ORR: the KEYNOTE-524/Study 116 trial in patients with unresectable HCC with no prior systemic therapy and the KEYNOTE-146/Study 111 trial in patients with metastatic clear cell renal cell carcinoma (ccRCC) who progressed following immune checkpoint inhibitor therapy.

In July 2020, Merck and Eisai announced that the FDA issued a Complete Response Letter (CRL) regarding Merck's and Eisai's applications seeking accelerated approval of *Keytruda* plus Lenvima for the first-line treatment of patients with unresectable HCC based on data from the Phase 1b KEYNOTE-524/Study 116 trial, which showed clinically meaningful efficacy in the single-arm setting. These data supported a Breakthrough Therapy designation granted by the FDA in July 2019. Ahead of the PDUFA action dates of Merck's and Eisai's applications, another combination therapy was approved based on a randomized, controlled trial that demonstrated OS. Consequently, the CRL stated that Merck's and Eisai's applications do not provide evidence that *Keytruda* in combination with Lenvima represents a meaningful advantage over available therapies for the treatment of unresectable or metastatic HCC with no prior systemic therapy for advanced disease. Since the applications for KEYNOTE-524/Study 116 no longer meet the criteria for accelerated approval, both companies plan to work with the FDA to take appropriate next steps, which include conducting a well-controlled clinical trial that demonstrates substantial evidence of effectiveness and the clinical benefit of the combination. As such, LEAP-002, the Phase 3 trial evaluating the *Keytruda* plus Lenvima combination as a first-line treatment for advanced HCC, is currently underway and fully enrolled. The CRL does not impact the current approved indications for *Keytruda* or for Lenvima.

Lynparza is an oral PARP inhibitor currently approved for certain types of advanced ovarian, breast, pancreatic and prostate cancers being co-developed for multiple cancer types as part of a collaboration with AstraZeneca (see Note 3 to the condensed consolidated financial statements).

Lynparza is under review in the EU in combination with bevacizumab for the maintenance treatment of women with advanced ovarian cancer whose disease showed a complete or partial response to first-line treatment with platinum-based chemotherapy and bevacizumab based on the results from the pivotal Phase 3 PAOLA-1 trial. The FDA approved Lynparza for this indication in May 2020.

Lynparza is also under review in the EU for the treatment of patients with mCRPC and deleterious or suspected deleterious germline or somatic HRR gene mutations, who have progressed following prior treatment with a new hormonal agent based on positive results from the Phase 3 PROfound trial. This indication was approved by the FDA in May 2020 and is under review in other jurisdictions. In April 2020, Merck and AstraZeneca announced further positive results from the Phase 3 PROfound trial which showed a statistically significant and clinically meaningful improvement in the key secondary endpoint of OS with Lynparza vs. enzalutamide or abiraterone in men with mCRPC selected for *BRCA*1/2 or *ATM* gene mutations, a subpopulation of HRR gene mutations.

In May 2020, the results from the Phase 3 GY004 trial, led by NRG Oncology and sponsored by the U.S. NCI, were presented at the 2020 ASCO Annual Meeting. This follows the March 2020, Merck and AstraZeneca announcement of the high-level results from the Phase 3 GY004 trial that examined primarily the efficacy and safety of investigational medicine cediranib in combination with Lynparza versus platinum-based chemotherapy in patients with platinum-sensitive relapsed ovarian cancer. The trial did not meet the primary endpoint in the intent-to-treat population of a statistically significant improvement in PFS with cediranib in combination with Lynparza vs. platinum-based chemotherapy.

In July 2020, the FDA granted Breakthrough Therapy designation to the hypoxia-inducible factor-2 alpha (HIF-2α) inhibitor MK-6482, a novel investigational candidate for the treatment of patients with von Hippel-Lindau (VHL) disease-associated RCC with nonmetastatic RCC tumors less than three centimeters in size, unless immediate surgery is required. The FDA also granted orphan drug designation to MK-6482 for VHL disease. These designations are based on data from a Phase 2 trial evaluating MK-6482 in patients with VHL-associated ccRCC, which were presented at the 2020 ASCO Annual Meeting.

In March 2020, Merck announced top-line efficacy results from two ongoing pivotal Phase 3 trials (COUGH-1 and COUGH-2) evaluating the efficacy and safety of gefapixant (MK-7264), an investigational, orally administered, selective P2X3 receptor antagonist, for the treatment of refractory or unexplained chronic cough. In these studies, the primary efficacy endpoints were met for the gefapixant 45 mg twice daily treatment arms - demonstrating a statistically significant decrease in 24-hour coughs per hour versus placebo. The gefapixant 15 mg twice daily treatment arms did not meet the primary efficacy endpoint in either Phase 3 study. The detailed findings will be shared at an upcoming medical meeting.

In July 2020, Merck announced new analyses from the Phase 2b trial (NCT03272347) evaluating the safety and efficacy of islatravir, the company's investigational oral nucleoside reverse transcriptase translocation inhibitor (NRTTI), in combination with *Pifeltro* (doravirine), in adults with HIV-1 infection who had not previously received antiretroviral treatment. The first sub-analysis further characterized the tolerability and safety profile of islatravir in combination with doravirine (100 mg) through Week 48 across the three dose levels studied (0.25, 0.75, 2.25 mg). The second sub-analysis demonstrated that participants who initiated treatment with islatravir and doravirine in combination with 3TC and switched to islatravir and doravirine maintained antiviral activity at Week 48 as measured by HIV-1 RNA <50 copies/mL similar to *Delstrigo* (doravirine/lamivudine/tenofovir disoproxil fumarate), with low rates of protocol defined virologic failure. These latest findings were made available during the 2020 International AIDS Conference. The primary endpoints and full study design of the Phase 2b Week 48 trial results were originally presented at the 2019 International AIDS Society Conference on HIV Science.

In June 2020, Merck announced results from two initial Phase 3 studies evaluating the safety, tolerability and immunogenicity of V114, the Company's investigational 15-valent pneumococcal conjugate vaccine. Results from the PNEU-WAY (V114-018) study in adults 18 years of age or older living with HIV showed that V114 elicited an immune response to all 15 serotypes included in the vaccine, including serotypes 22F and 33F. Results from the PNEU-FLU (V114-021) study in healthy adults 50 years of age or older showed that V114 can be given concomitantly with the quadrivalent influenza vaccine. The V114 Phase 3 clinical development program is comprised of 16 trials investigating the safety, tolerability and immunogenicity of V114 in a variety of populations who are at increased risk for pneumococcal disease including both healthy older adult and healthy pediatric populations, as well as people who are immunocompromised or have certain chronic conditions. The Company plans to continue to work with the FDA and other regulatory authorities around the world on filing plans for licensure of this vaccine as additional data from the Phase 3 program become available. These data were announced and published in the International Symposium on Pneumococci and Pneumococcal Diseases (ISPPD) digital library in lieu of an in-person meeting.

In May 2020, Merck and Pfizer Inc. announced the presentation of results from the Phase 3 VERTIS CV cardiovascular (CV) outcomes trial that evaluated Steglatro (ertugliflozin), an oral sodium-glucose cotransporter 2 (SGLT2) inhibitor, versus placebo, added to background standard of care treatment, in patients with type 2 diabetes and atherosclerotic CV disease. The study met the primary endpoint of non-inferiority on major adverse CV events (MACE), which is composed of a composite of CV death, nonfatal myocardial infarction or nonfatal stroke, compared to placebo. The key secondary endpoints of superiority for Steglatro versus placebo for time to the first occurrence of the composite of CV death or hospitalization for heart failure, time to CV death alone and time to the first occurrence of the composite of renal death, dialysis/transplant or doubling of serum creatinine from baseline were not met. While not a pre-specified hypothesis for statistical testing, a reduction in hospitalization for heart failure was observed with Steglatro.

The chart below reflects the Company's research pipeline as of July 31, 2020. Candidates shown in Phase 3 include specific products and the date such candidate entered into Phase 3 development. Candidates shown in Phase 2 include the most advanced compound with a specific mechanism or, if listed compounds have the same mechanism, they are each currently intended for commercialization in a given therapeutic area. Small molecules and biologics are given MK-number designations and vaccine candidates are given V-number designations. Except as otherwise noted, candidates in Phase 1, additional indications in the same therapeutic area (other than with respect to cancer) and additional claims, line extensions or formulations for in-line products are not shown.

Phase 2	Phase 3 (Phase 3 entry date)	Under Review
Cancer MK-1026 Hematological Malignancies MK-1308(1) Melanoma Non-Small-Cell Lung MK-1454(1) Head and Neck MK-3475 *Keytruda* Advanced Solid Tumors MK-4280(1) Hematological Malignancies Non-Small-Cell Lung MK-5890(1) Non-Small-Cell Lung MK-7339 Lynparza(2)(3) Advanced Solid Tumors MK-7684(1) Melanoma Non-Small-Cell Lung MK-7902 Lenvima(1)(2) Advanced Solid Tumors V937 Melanoma **Chikungunya virus** V184 **Cytomegalovirus** V160 **HIV-1 Prevention** MK-8591 (islatravir) **Overgrowth Syndrome** MK-7075 **Respiratory Syncytial Virus** MK-1654 **SARS-CoV-2 Infection** MK-4482(2) **Schizophrenia** MK-8189	**Cancer** MK-3475 *Keytruda* Biliary Tract (September 2019) Breast (October 2015) (EU) Cervical (October 2018) (EU) Cutaneous Squamous Cell (August 2019) (EU) Endometrial (August 2019) (EU) Esophageal (December 2015) (EU) Gastric (May 2015) (EU) Hepatocellular (May 2016) (EU) Mesothelioma (May 2018) Nasopharyngeal (April 2016) Ovarian (December 2018) Prostate (May 2019) Small-Cell Lung (May 2017) (EU) MK-6482 Renal Cell (February 2020) MK-7339 Lynparza(1)(2) Non-Small-Cell Lung (June 2019) MK-7902 Lenvima(1)(2) Bladder (May 2019) Endometrial (June 2018) (EU) Head and Neck (February 2020) Hepatocellular (May 2020) Melanoma (March 2019) Non-Small-Cell Lung (March 2019) **Cough** MK-7264 (gefapixant) (March 2018) **HIV-1 Infection** MK-8591A (doravirine/islatravir) (February 2020) **Pneumoconjugate Vaccine** V114 (June 2018)	**New Molecular Entities/Vaccines** **Heart Failure** MK-1242 (vericiguat)(2) (U.S.) (EU) (JPN) **Pediatric Neurofibromatosis Type 1** MK-5618 (selumetinib)(2) (EU) **Certain Supplemental Filings** **Cancer** MK-3475 *Keytruda* • Metastatic Triple-Negative Breast Cancer (KEYNOTE-355) (U.S.) • Early-Stage Triple-Negative Breast Cancer (KEYNOTE-522) (U.S.) • Refractory Classical Hodgkin Lymphoma (KEYNOTE-204) (U.S.) (EU) • Recurrent Locally Advanced or Metastatic Esophageal Cancer (KEYNOTE-180/KEYNOTE-181) (JPN) • Unresectable or Metastatic MSI-H or dMMR Colorectal Cancer (KEYNOTE-177) (EU) MK-7339 Lynparza(2) • First-Line Maintenance Newly Diagnosed Advanced Ovarian Cancer (PAOLA) (EU) • Metastatic Prostate Cancer (PROfound) (EU) MK-7902 Lenvima(1)(2) • First-Line Metastatic Hepatocellular Carcinoma (KEYNOTE-524) (U.S.)(4) • Thymic Carcinoma (NCCH1508/REMORA) (JPN) **Footnotes:** (1) Being developed in combination with *Keytruda*. (2) Being developed in a collaboration. (3) Being developed as monotherapy and in combination with *Keytruda*. (4) In July 2020, the FDA issued a CRL for Merck's and Eisai's applications. Merck and Eisai are reviewing the letter and will submit data to the FDA.

Liquidity and Capital Resources

($ in millions)	June 30, 2020	December 31, 2019
Cash and investments	$ 12,354	$ 11,919
Working capital	7,165	5,263
Total debt to total liabilities and equity	34.1%	31.2%

Cash provided by operating activities was $4.1 billion in the first six months of 2020 compared with $4.4 billion in the first six months of 2019. Cash provided by operating activities in the first six months of 2020 includes $1.1 billion of payments related to collaborations with AstraZeneca and Eisai compared with $385 million in the first six months of 2019 (see Note 3 to the condensed consolidated financial statements). 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 $2.5 billion in the first six months of 2020 compared with $2.1 billion in the first six months of 2019. The increase was driven primarily by lower proceeds from sales of securities and other investments and higher capital expenditures, partially offset by lower purchases of securities and other investments and lower use of cash for acquisitions.

Cash used in financing activities was $353 million in the first six months of 2020 compared with $3.7 billion in the first six months of 2019. The lower use of cash in financing activities was driven primarily by a net increase in short-term borrowings in 2020 compared with a net decrease in short-term borrowing in 2019, as well as lower purchases of treasury stock, partially offset by higher payments on debt (see below), lower proceeds from the issuance of debt (see below), higher dividends paid to shareholders, and lower proceeds from the exercise of stock options.

Capital expenditures totaled $1.7 billion and $1.4 billion for the first six months of 2020 and 2019, respectively. The increased capital expenditures reflect investment in new capital projects focused primarily on increasing manufacturing capacity for Merck's key products.

The Company has accounts receivable factoring agreements with financial institutions in certain countries to sell accounts receivable. The Company factored $1.9 billion and $2.7 billion of accounts receivable in the second quarter of 2020 and the fourth quarter of 2019, respectively, under these factoring arrangements, which reduced outstanding accounts receivable. The cash received from the financial institutions is reported within operating activities in the Condensed Consolidated Statement of Cash Flows. In certain of these factoring arrangements, for ease of administration, the Company will collect customer payments related to the factored receivables, which it then remits to the financial institutions. The net cash flows relating to these collections are reported as financing activities in the Condensed Consolidated Statement of Cash Flows.

Dividends paid to stockholders were $3.1 billion and $2.9 billion for the first six months of 2020 and 2019, respectively. In May 2020, the Board of Directors declared a quarterly dividend of $0.61 per share on the Company's common stock for the third quarter that was paid in July 2020. In July 2020, the Board of Directors declared a quarterly dividend of $0.61 per share on the Company's common stock for the fourth quarter that will be paid in October 2020.

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 intends to use 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 March 2019, the Company issued $5.0 billion principal amount of senior unsecured notes consisting of $750 million of 2.90% notes due 2024, $1.75 billion of 3.40% notes due 2029, $1.0 billion of 3.90% notes due 2039, and $1.5 billion of 4.00% notes due 2049. The Company used the net proceeds from the offering of $5.0 billion for general corporate purposes, including the repayment of outstanding commercial paper borrowings.

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. During the first six months of 2020, the Company purchased $1.3 billion (16 million shares) of its common stock for its treasury under this share repurchase program. As of June 30, 2020, the Company's remaining share repurchase authorization was $5.9 billion. In March 2020, the Company temporarily suspended its share repurchase program.

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 Policies

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, 2019 included in Merck's Form 10-K filed on February 26, 2020. Certain of these accounting policies are considered critical as disclosed in the Critical Accounting Policies section of Management's Discussion and Analysis of Financial Condition and Results of Operations included in Merck's Form 10-K because of the potential for a significant impact on the financial statements due to the inherent uncertainty in such estimates. There have been no significant changes in the Company's critical accounting policies since December 31, 2019. See

Note 1 to the condensed consolidated financial statements for information on the adoption of new accounting standards during 2020.

Recently Issued Accounting Standards

For a discussion of recently issued accounting standards, see Note 1 to the condensed consolidated financial statements.

Item 4. Controls and Procedures

Management of the Company, with the participation of its Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of the Company's disclosure controls and procedures over financial reporting. Based on their evaluation, the Company's Chief Executive Officer and Chief Financial Officer have concluded that as of June 30, 2020, the Company's disclosure controls and procedures are effective. For the second quarter of 2020, 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 development, product approvals, product potential and development programs. 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 the impact of the recent global outbreak of COVID-19 and other risks and uncertainties 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, 2019, as filed on February 26, 2020, in the Company's Form 10-Q for the quarterly period ended March 31, 2020, as filed on May 6, 2020, and in this Form 10-Q, the Company discusses in more detail various important risk factors that could cause actual results to differ from expected or historic results. The Company notes these factors for investors as permitted by the Private Securities Litigation Reform Act of 1995. One should understand that it is not possible to predict or identify all such factors. Consequently, the reader should not consider any such list to be a complete statement of all potential risks or uncertainties.

PART II - Other Information

Item 1. Legal Proceedings

The information called for by this Item is incorporated herein by reference to Note 8 included in Part I, Item 1, Financial Statements (unaudited) — Notes to Condensed Consolidated Financial Statements.

Item 1A. Risk Factors

For a discussion of risks that affect the Company's business, please refer to Part I, Item IA, "Risk Factors" in the Company's Annual Report on Form 10-K for the year ended December 31, 2019. 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.

While the Company expects to rely on governmental authorities to determine when operations can return to normal, and is cognizant that the duration, spread and severity of the outbreak will be critical determinants for purposes of the full-year estimates provided below, Merck has assumed that the majority of the negative impact occurred in the second quarter of 2020, with a gradual recovery having commenced in the second quarter and extending through the third quarter, with a return to normal operating levels in the fourth quarter of 2020. 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 2020, 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 second quarter of 2020, the negative impact of the COVID-19 pandemic to Merck's sales was estimated to be $1.6 billion, including approximately $1.5 billion for Pharmaceutical revenue and approximately $100 million for Animal Health revenue. The impact to sales in the first quarter of 2020 was immaterial. For the full-year 2020, Merck expects an unfavorable impact to sales of approximately $1.95 billion (excluding the impact of foreign exchange) due to the COVID-19 pandemic, comprised of approximately $1.8 billion for Pharmaceutical revenue and approximately $150 million for Animal Health revenue. These estimates include the impacts for the first half of the year.

Roughly two-thirds of Merck's Pharmaceutical revenue is comprised of physician-administered products, which, despite strong underlying demand, were affected by social distancing measures, fewer well visits and delays in elective surgeries due to the COVID-19 pandemic. These impacts, as well as the prioritization of COVID-19 patients at health care providers, have resulted in reduced administration of many of the Company's human health products, in particular for its vaccines as well as for *Keytruda* and *Implanon/Nexplanon*. The Company anticipates reduced demand for its physician-administered products while pandemic-related access measures remain in place. In addition, declines in medical visits and elective surgeries also negatively affected the demand for certain products, including *Bridion*. In Merck's Animal Health business, reduced veterinary visits and lower demand for protein and milk due to restaurant and school closures have negatively affected sales.

Operating expenses were positively impacted in the second quarter and first six months of 2020 by approximately $325 million and $425 million, respectively, primarily driven by lower promotional and selling costs, as well as lower research and development expenses due to the COVID-19 pandemic. For the full-year 2020, Merck continues to expect a net favorable impact to operating expenses of approximately $400 million including both the favorable impact of lower spending, largely reflected in the first half of 2020, partially offset by anticipated spending on recently initiated COVID-19-related vaccine and antiviral research programs.

Item 6. Exhibits

Number		Description
3.1	—	Restated Certificate of Incorporation of Merck & Co., Inc. (November 3, 2009) – Incorporated by reference to Current Report on Form 8-K filed on November 4, 2009 (No. 1-6571)
3.2	—	By-Laws of Merck & Co., Inc. (effective July 22, 2015) – Incorporated by reference to Current Report on Form 8-K filed on July 28, 2015 (No. 1-6571)
31.1	—	Rule 13a – 14(a)/15d – 14(a) Certification of Chief Executive Officer
31.2	—	Rule 13a – 14(a)/15d – 14(a) Certification of Chief Financial Officer
32.1	—	Section 1350 Certification of Chief Executive Officer
32.2	—	Section 1350 Certification of Chief Financial Officer
101.INS	—	XBRL Instance Document - The instance document does not appear in the interactive data file because its XBRL tags are embedded within the Inline XBRL document.
101.SCH	—	XBRL Taxonomy Extension Schema Document.
101.CAL	—	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	—	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	—	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	—	XBRL Taxonomy Extension Presentation Linkbase Document.
104	—	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

Signatures

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

MERCK & CO., INC.

Date: August 5, 2020	/s/ Jennifer Zachary
	JENNIFER ZACHARY
	Executive Vice President and General Counsel
Date: August 5, 2020	/s/ Rita A. Karachun
	RITA A. KARACHUN
	Senior Vice President Finance - Global Controller