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

## FORM 10-Q

**(Mark One)**

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

For the quarterly period ended March 31, 2019

**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, NJ** | **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 April 30, 2019 : 2,574,644,410

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

| | Three Months Ended March 31, | |
|---|---|---|
| | 2019 | 2018 |
| Sales | $ 10,816 | $ 10,037 |
| Costs, Expenses and Other | | |
| Cost of sales | 3,052 | 3,184 |
| Selling, general and administrative | 2,425 | 2,508 |
| Research and development | 1,931 | 3,196 |
| Restructuring costs | 153 | 95 |
| Other (income) expense, net | 188 | (291) |
| | 7,749 | 8,692 |
| Income Before Taxes | 3,067 | 1,345 |
| Taxes on Income | 205 | 604 |
| Net Income | 2,862 | 741 |
| Less: Net (Loss) Income Attributable to Noncontrolling Interests | (53) | 5 |
| Net Income Attributable to Merck & Co., Inc. | $ 2,915 | $ 736 |
| Basic Earnings per Common Share Attributable to Merck & Co., Inc. Common Shareholders | $ 1.13 | $ 0.27 |
| Earnings per Common Share Assuming Dilution Attributable to Merck & Co., Inc. Common Shareholders | $ 1.12 | $ 0.27 |

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

| | Three Months Ended March 31, | |
|---|---|---|
| | 2019 | 2018 |
| Net Income Attributable to Merck & Co., Inc. | $ 2,915 | $ 736 |
| Other Comprehensive Income Net of Taxes: | | |
| Net unrealized loss on derivatives, net of reclassifications | (48) | (70) |
| Net unrealized gain (loss) on investments, net of reclassifications | 82 | (99) |
| Benefit plan net gain and prior service credit, net of amortization | 15 | 36 |
| Cumulative translation adjustment | 150 | 257 |
| | 199 | 124 |
| Comprehensive Income Attributable to Merck & Co., Inc. | $ 3,114 | $ 860 |

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

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

| | March 31, 2019 | December 31, 2018 |
|---|---|---|
| **Assets** | | |
| Current Assets | | |
| Cash and cash equivalents | $ 8,076 | $ 7,965 |
| Short-term investments | 722 | 899 |
| Accounts receivable (net of allowance for doubtful accounts of $116 in 2019 and $119 in 2018) | 7,608 | 7,071 |
| Inventories (excludes inventories of $1,398 in 2019 and $1,417 in 2018 classified in Other assets - see Note 6) | 5,712 | 5,440 |
| Other current assets | 3,233 | 4,500 |
| Total current assets | 25,351 | 25,875 |
| Investments | 5,621 | 6,233 |
| Property, Plant and Equipment, at cost, net of accumulated depreciation of $16,623 in 2019 and $16,324 in 2018 | 13,506 | 13,291 |
| Goodwill | 18,170 | 18,253 |
| Other Intangibles, Net | 10,999 | 11,431 |
| Other Assets | 8,707 | 7,554 |
| | $ 82,354 | $ 82,637 |
| **Liabilities and Equity** | | |
| Current Liabilities | | |
| Loans payable and current portion of long-term debt | $ 3,175 | $ 5,308 |
| Trade accounts payable | 3,018 | 3,318 |
| Accrued and other current liabilities | 10,081 | 10,151 |
| Income taxes payable | 807 | 1,971 |
| Dividends payable | 1,462 | 1,458 |
| Total current liabilities | 18,543 | 22,206 |
| Long-Term Debt | 22,721 | 19,806 |
| Deferred Income Taxes | 1,835 | 1,702 |
| Other Noncurrent Liabilities | 11,585 | 12,041 |
| Merck & Co., Inc. Stockholders' Equity | | |
| Common stock, $0.50 par value<br>Authorized - 6,500,000,000 shares<br>Issued - 3,577,103,522 shares in 2019 and 2018 | 1,788 | 1,788 |
| Other paid-in capital | 38,768 | 38,808 |
| Retained earnings | 44,065 | 42,579 |
| Accumulated other comprehensive loss | (5,346) | (5,545) |
| | 79,275 | 77,630 |
| Less treasury stock, at cost:<br>994,032,308 shares in 2019 and 984,543,979 shares in 2018 | 51,736 | 50,929 |
| Total Merck & Co., Inc. stockholders' equity | 27,539 | 26,701 |
| Noncontrolling Interests | 131 | 181 |
| Total equity | 27,670 | 26,882 |
| | $ 82,354 | $ 82,637 |

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

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

| | Three Months Ended March 31, | |
|---|---|---|
| | 2019 | 2018 |
| **Cash Flows from Operating Activities** | | |
| Net income | $ 2,862 | $ 741 |
| Adjustments to reconcile net income to net cash provided by operating activities: | | |
| Depreciation and amortization | 898 | 1,137 |
| Intangible asset impairment charges | 104 | — |
| Charge for future payments related to collaboration license options | — | 650 |
| Deferred income taxes | 194 | (30) |
| Share-based compensation | 93 | 80 |
| Other | 120 | 50 |
| Net changes in assets and liabilities | (2,935) | (1,473) |
| Net Cash Provided by Operating Activities | 1,336 | 1,155 |
| **Cash Flows from Investing Activities** | | |
| Capital expenditures | (595) | (450) |
| Purchases of securities and other investments | (974) | (1,326) |
| Proceeds from sales of securities and other investments | 1,899 | 1,848 |
| Other | 38 | (269) |
| Net Cash Provided by (Used in) Investing Activities | 368 | (197) |
| **Cash Flows from Financing Activities** | | |
| Net change in short-term borrowings | (4,135) | (1) |
| Payments on debt | — | (1,003) |
| Proceeds from issuance of debt | 4,958 | — |
| Purchases of treasury stock | (1,090) | (566) |
| Dividends paid to stockholders | (1,428) | (1,299) |
| Proceeds from exercise of stock options | 173 | 230 |
| Other | (92) | (83) |
| Net Cash Used in Financing Activities | (1,614) | (2,722) |
| Effect of Exchange Rate Changes on Cash, Cash Equivalents and Restricted Cash | 20 | 154 |
| Net Increase (Decrease) in Cash, Cash Equivalents and Restricted Cash | 110 | (1,610) |
| Cash, Cash Equivalents and Restricted Cash at Beginning of Year (includes restricted cash of $2 million at January 1, 2019 included in Other Assets) | 7,967 | 6,096 |
| Cash, Cash Equivalents and Restricted Cash at End of Period (includes restricted cash of $1 million at March 31, 2019 included in Other Assets) | $ 8,077 | $ 4,486 |

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 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 27, 2019.

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

*Recently Adopted Accounting Standards*

In February 2016, the FASB issued new accounting guidance for the accounting and reporting of leases (ASU 2016-02) and subsequently issued several updates to the new guidance (ASC 842 or new guidance). The new guidance requires that lessees recognize a right-of-use asset and a lease liability for each of its leases (other than leases that meet the definition of a short-term lease). Leases will be classified as either operating or finance. Operating leases will result in straight-line expense in the income statement (similar to current operating leases), while finance leases will result in more expense being recognized in the earlier years of the lease term (similar to current capital leases). The Company adopted the new standard on January 1, 2019 using a modified retrospective approach. Merck elected the transition method that allows for application of the standard at the adoption date rather than at the beginning of the earliest comparative period presented in the financial statements. The Company also elected available practical expedients. Upon adoption, the Company recognized $1.1 billion of additional assets and related liabilities on its consolidated balance sheet (see Note 7). The adoption of the new guidance did not impact the Company's consolidated statements of income or cash flows.

*Recently Issued Accounting Standards Not Yet Adopted*

In June 2016, the FASB issued amended guidance on the accounting for credit losses on financial instruments. The 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 new guidance is effective for interim and annual periods beginning in 2020, with earlier application permitted in 2019, including adoption in any interim period. The new guidance is to be applied on a modified retrospective basis through a cumulative-effect adjustment directly to retained earnings in the beginning of the period of adoption. The Company is currently evaluating the impact of adoption on its consolidated financial statements.

In April 2018, the FASB issued new guidance on the accounting for costs incurred to implement a cloud computing arrangement that is considered a service arrangement. The new guidance requires the capitalization of such costs, aligning it with the accounting for costs associated with developing or obtaining internal-use software. The new guidance is effective for interim and annual periods beginning in 2020. Early adoption is permitted, including adoption in any interim period. Prospective adoption for eligible costs incurred on or after the date of adoption or retrospective adoption is permitted. The Company is currently evaluating the impact of adoption on its consolidated financial statements.

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 the recently issued guidance on revenue recognition (ASC 606). The new guidance is effective for interim and annual periods beginning in 2020. Early adoption is permitted, including adoption in any interim period. The new guidance is to be applied on a retrospective basis through a cumulative-effect adjustment directly to retained earnings. The Company does not anticipate the adoption of this standard will have a material effect on its consolidated financial statements.

## 2. Acquisitions, Research Collaborations and License Agreements

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

In April 2019, Merck acquired Antelliq Corporation (Antelliq) from funds advised by BC Partners. Antelliq is 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 will be accounted for as an acquisition of a business. The Company is in the process of determining the preliminary fair value of assets acquired and liabilities assumed for this transaction.

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. Immune Design's proprietary technologies, GLAAS and ZVex, are engineered to activate the immune system's natural ability to generate and/or expand antigen-specific cytotoxic immune cells to fight cancer and other chronic diseases. The transaction will be accounted for as an acquisition of a business. The Company is in the process of determining the preliminary fair value of assets acquired and liabilities assumed for this transaction.

In March 2018, Merck and Eisai Co., Ltd. (Eisai) entered into a strategic collaboration for the worldwide co-development and co-commercialization of Lenvima, an orally available tyrosine kinase inhibitor discovered by Eisai (see Note 3).

## 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 for multiple cancer types. Lynparza is an oral poly (ADP-ribose) polymerase (PARP) inhibitor currently approved for certain types of ovarian and breast cancer. The companies are jointly developing and commercializing Lynparza, both as monotherapy and in combination trials with other potential medicines. Independently, Merck and AstraZeneca will develop and commercialize Lynparza in combinations with their respective PD-1 and PD-L1 medicines, *Keytruda* and Imfinzi. The companies will also jointly develop and commercialize AstraZeneca's selumetinib, an oral, potent, selective inhibitor of MEK, part of the mitogen-activated protein kinase (MAPK) pathway, currently being developed for multiple indications. Under the terms of the agreement, AstraZeneca and Merck will share the development and commercialization costs for Lynparza and selumetinib monotherapy and non-PD-L1/PD-1 combination therapy opportunities.

Gross profits from Lynparza and selumetinib 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 selumetinib. AstraZeneca will fund all development and commercialization costs of Imfinzi in combination with Lynparza or selumetinib. AstraZeneca is the principal on Lynparza sales transactions. Merck records its share of Lynparza product sales, net of cost of sales and commercialization costs, as alliance revenue within the Pharmaceutical segment and its share of development costs associated with the collaboration as part of *Research and development* costs. 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 will make payments of up to $750 million over a multi-year period for certain license options (of which $250 million was paid in December 2017, $400 million was paid in December 2018 and $100 million is expected to be paid in December 2019). The Company recorded an aggregate charge of $2.35 billion in *Research and development* expenses in 2017 related to the upfront payment and future license option payments. In addition, the agreement provides for additional contingent payments from Merck to AstraZeneca related to the successful achievement of sales-based and regulatory milestones.

Since inception of the collaboration agreement, Merck has accrued $700 million of sales-based milestone payments. Each of these milestones was accrued when the achievement of the milestone was deemed probable based on the sales of Lynparza. The recognition of these liabilities resulted in corresponding increases to the intangible asset related to Lynparza. Of these amounts, $250 million has been paid to AstraZeneca. Potential future sales-based milestone payments of $3.4 billion have not yet been accrued as they are not deemed by the Company to be probable at this time.

In April 2019, Lynparza received regulatory approval in the European Union as a monotherapy for the treatment of certain adult patients with advanced breast cancer, triggering a $30 million capitalized milestone payment from Merck to AstraZeneca. In 2018, Lynparza received regulatory approvals triggering capitalized milestone payments of $140 million in the aggregate from Merck to AstraZeneca. Potential future regulatory milestone payments of $1.73 billion remain under the agreement.

The asset balance related to Lynparza (which includes capitalized sales-based and regulatory milestone payments) was $724 million at March 31, 2019 and is included in *Other Assets* 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 information related to this collaboration is as follows:

| | Three Months Ended March 31, | |
|---|---|---|
| *($ in millions)* | 2019 | 2018 |
| Alliance revenue | $ 79 | $ 33 |
| Cost of sales [(1)] | 19 | 12 |
| Selling, general and administrative | 27 | 7 |
| Research and development | 45 | 29 |

| *($ in millions)* | March 31, 2019 | December 31, 2018 |
|---|---|---|
| Receivables from AstraZeneca included in *Other current assets* | $ 80 | $ 52 |
| Payables to AstraZeneca included in *Accrued and other current liabilities* [(2)] | 584 | 405 |
| Payables to AstraZeneca included in *Other Noncurrent Liabilities* [(2)] | — | 250 |

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

[(2)] *Includes accrued milestone and license option payments.*

**Eisai**

In March 2018, Merck and Eisai announced a strategic collaboration for the worldwide co-development and co-commercialization of Lenvima, an orally available tyrosine kinase inhibitor discovered by Eisai. Under the agreement, Merck and Eisai will develop and commercialize Lenvima jointly, both as monotherapy and in combination with Merck's anti-PD-1 therapy, *Keytruda* . Eisai records Lenvima product sales globally (Eisai is the principal on Lenvima sales transactions), and Merck and Eisai share gross 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* costs.

Under the agreement, Merck made an upfront payment to Eisai of $750 million and will make payments of up to $650 million for certain option rights through 2021 (of which $325 million was paid in March 2019, $200 million is expected to be paid in March 2020 and $125 million is expected to be paid in March 2021). The Company recorded an aggregate charge of $1.4 billion in *Research and development* expenses in the first quarter of 2018 related to the upfront payment and future option payments. In addition, the agreement provides for Eisai to receive up to $385 million associated with the achievement of certain clinical and regulatory milestones and up to $3.97 billion for the achievement of milestones associated with sales of Lenvima.

In the first quarter of 2019, Merck determined it was probable that annual sales of Lenvima in the future would trigger $282 million of sales-based milestone payments from Merck to Eisai. Accordingly, in the first quarter of 2019, Merck recorded $282 million of liabilities and corresponding increases to the intangible asset related to Lenvima and also recognized $35 million of cumulative amortization expense within *Cost of sales* . Merck previously accrued sales-based milestone payments aggregating $268 million in 2018. Potential future sales-based milestone payments of $3.42 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 asset balance related to Lenvima (which includes capitalized sales-based and regulatory milestone payments) was $711 million at March 31, 2019 and is included in *Other Assets* 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 information related to this collaboration is as follows:

| ($ in millions) | Three Months Ended March 31, 2019 | 2018 |
|---|---|---|
| Alliance revenue | $ 74 | $ — |
| Cost of sales [1] | 51 | — |
| Selling, general and administrative | 19 | — |
| Research and development [2] | 47 | 1,400 |

| ($ in millions) | March 31, 2019 | December 31, 2018 |
|---|---|---|
| Receivables from Eisai included in *Other current assets* | $ 75 | $ 71 |
| Payables to Eisai included in *Accrued and other current liabilities* [3] | 557 | 375 |
| Payables to Eisai included in *Other Noncurrent Liabilities* [3] | 325 | 543 |

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

[2] *Amount in 2018 reflects the upfront payment and future option payments.*

[3] *Includes accrued milestone and option 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, 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 Phase 3 trials for worsening heart failure, as well as opt-in rights for other early-stage sGC compounds in development by Bayer. Merck in turn made available its early-stage sGC compounds under similar terms. Under the agreement, Bayer leads commercialization of Adempas in the Americas, while Merck leads commercialization in the rest of the world. For vericiguat and other potential opt-in products, Bayer will lead commercialization in the rest of world and Merck will lead in the Americas. For all products and candidates included in the agreement, both companies will share in development costs and profits on sales and will have the right to co-promote in territories where they are not the lead. In 2016, Merck began promoting and distributing Adempas in Europe. Transition from Bayer in other Merck territories, including Japan, continued in 2017. Revenue from Adempas includes sales in Merck's marketing territories, as well as Merck's share of profits from the sale of Adempas in Bayer's marketing territories.

In the first quarter of 2018, Merck made a $350 million sales-based milestone payment to Bayer, which was accrued for in 2016 when Merck deemed the payment to be probable. In 2018, Merck determined it was probable that annual worldwide sales of Adempas in the future would trigger a $375 million sales-based milestone payment from Merck to Bayer; accordingly, Merck recorded a $375 million liability and a corresponding increase to the intangible asset related to Adempas. 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 Adempas (which includes the acquired intangible asset balance, as well as capitalized sales-based milestone payments) was $977 million at March 31, 2019 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 information related to this collaboration is as follows:

| ($ in millions) | Three Months Ended March 31, 2019 | 2018 |
|---|---|---|
| Net product sales recorded by Merck | $ 48 | $ 43 |
| Merck's profit share from sales in Bayer's marketing territories | 42 | 25 |
| Total sales | 90 | 68 |
| Cost of sales [1] | 29 | 27 |
| Selling, general and administrative | 8 | 8 |
| Research and development | 30 | 28 |

| ($ in millions) | March 31, 2019 | December 31, 2018 |
|---|---|---|
| Receivables from Bayer included in *Other current assets* | $ 33 | $ 32 |
| Payables to Bayer included in *Other Noncurrent Liabilities* [2] | 375 | 375 |

[1] *Includes amortization of intangible assets.*

[2] *Includes accrued milestone payments.*

## 4. Restructuring

Merck recently approved a new global restructuring program (the "2019 Restructuring Program") as part of a worldwide initiative focused primarily on further optimizing the Company's manufacturing and supply network, as well as reducing its global real estate footprint. This program is a continuation of the Company's plant rationalization and builds on prior restructuring programs. The Company will continue to evaluate its global footprint and overall operating model, which could result in the identification of additional actions over time. The actions contemplated under the 2019 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 $800 million to $1.2 billion . The Company estimates that approximately 55% of the cumulative pretax costs will result in cash outlays, primarily related to employee separation expense and facility shut-down costs. Approximately 45% 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 $500 million in 2019 related to the program. Actions under previous global restructuring programs have been substantially completed.

The Company recorded total pretax costs of $187 million and $104 million in the first quarter of 2019 and 2018 , respectively, related to restructuring program activities. For segment reporting, restructuring charges are unallocated expenses.

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

| | Three Months Ended March 31, 2019 | | | |
|---|---|---|---|---|
| ($ in millions) | Separation Costs | Accelerated Depreciation | Other | Total |
| Cost of sales | $ — | $ 34 | $ — | $ 34 |
| Selling, general and administrative | — | — | — | — |
| Research and development | — | — | — | — |
| Restructuring costs | 128 | — | 25 | 153 |
| | $ 128 | $ 34 | $ 25 | $ 187 |

| | Three Months Ended March 31, 2018 | | | |
|---|---|---|---|---|
| ($ in millions) | Separation Costs | Accelerated Depreciation | Other | Total |
| Cost of sales | $ — | $ — | $ 6 | $ 6 |
| Selling, general and administrative | — | 1 | — | 1 |
| Research and development | — | (3) | 5 | 2 |
| Restructuring costs | 55 | — | 40 | 95 |
| | $ 55 | $ (2) | $ 51 | $ 104 |

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 2019 and 2018 includes asset abandonment, shut-down and other related costs, as well as pretax gains and losses resulting from 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 three months ended March 31, 2019 :

| *($ in millions)* | Separation Costs | Accelerated Depreciation | Other | Total |
|---|---|---|---|---|
| Restructuring reserves January 1, 2019 | $ 443 | $ — | $ 91 | $ 534 |
| Expense | 128 | 34 | 25 | 187 |
| (Payments) receipts, net | (69) | — | (32) | (101) |
| Non-cash activity | — | (34) | (3) | (37) |
| Restructuring reserves March 31, 2019 [(1)] | $ 502 | $ — | $ 81 | $ 583 |

[(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 volatility 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 and Japanese yen. 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 is 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 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 Company hedges a portion of the net investment in certain of its foreign operations. 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 component). Changes in fair value of the excluded components are recognized in *OCI* . The Company recognizes in earnings the initial value of the excluded component on a straight-line basis over the life of the derivative instrument, rather than using the mark-to-market approach. The cash flows from these contracts are reported as investing activities in the Condensed Consolidated Statement of Cash Flows.

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

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

| | Amount of Pretax (Gain) Loss Recognized in Other Comprehensive Income [1] | | Amount of Pretax (Gain) Loss Recognized in *Other (income) expense, net* for Amounts Excluded from Effectiveness Testing | |
|---|---|---|---|---|
| | Three Months Ended March 31, | | Three Months Ended March 31, | |
| *($ in millions)* | 2019 | 2018 | 2019 | 2018 |
| *Net Investment Hedging Relationships* | | | | |
| Foreign exchange contracts | $ (11) | $ (2) | $ (8) | $ — |
| Euro-denominated notes | (30) | 178 | — | — |

[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.

At March 31, 2019 , the Company was a party to 19 pay-floating, receive-fixed interest rate swap contracts designated as fair value hedges of fixed-rate notes in which the notional amounts match the amount of the hedged fixed-rate notes as detailed in the table below.

| | March 31, 2019 | | |
|---|---|---|---|
| *($ in millions)* | Par Value of Debt | Number of Interest Rate Swaps Held | Total Swap Notional Amount |
| 1.85% notes due 2020 | 1,250 | 5 | 1,250 |
| 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)* | March 31, 2019 | December 31, 2018 | March 31, 2019 | December 31, 2018 |
| *Balance Sheet Line Item in which Hedged Item is Included* | | | | |
| Loans payable and current portion of long-term debt | $ 1,237 | $ — | $ (12) | $ — |
| Long-Term Debt | 3,357 | 4,560 | (37) | (82) |

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

| | | March 31, 2019 | | | December 31, 2018 | | |
|---|---|---|---|---|---|---|---|
| | | Fair Value of Derivative | | U.S. Dollar Notional | Fair Value of Derivative | | U.S. Dollar Notional |
| *($ in millions)* | Balance Sheet Caption | Asset | Liability | | Asset | Liability | |
| *Derivatives Designated as Hedging Instruments* | | | | | | | |
| Interest rate swap contracts | Accrued and other current liabilities | $ — | $ 12 | $ 1,250 | $ — | $ — | $ — |
| Interest rate swap contracts | Other noncurrent liabilities | — | 36 | 3,400 | — | $ 81 | 4,650 |
| Foreign exchange contracts | Other current assets | 202 | — | 6,316 | 263 | — | 6,222 |
| Foreign exchange contracts | Other assets | 84 | — | 3,115 | 75 | — | 2,655 |
| Foreign exchange contracts | Accrued and other current liabilities | — | 8 | 730 | — | 7 | 774 |
| Foreign exchange contracts | Other noncurrent liabilities | — | 1 | 167 | — | 1 | 89 |
| | | $ 286 | $ 57 | $ 14,978 | $ 338 | $ 89 | $ 14,390 |
| *Derivatives Not Designated as Hedging Instruments* | | | | | | | |
| Foreign exchange contracts | Other current assets | $ 98 | $ — | $ 8,681 | $ 116 | $ — | $ 5,430 |
| Foreign exchange contracts | Accrued and other current liabilities | — | 138 | 11,684 | — | 71 | 9,922 |
| | | $ 98 | $ 138 | $ 20,365 | $ 116 | $ 71 | $ 15,352 |
| | | $ 384 | $ 195 | $ 35,343 | $ 454 | $ 160 | $ 29,742 |

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

| | March 31, 2019 | | December 31, 2018 | |
|---|---|---|---|---|
| *($ in millions)* | Asset | Liability | Asset | Liability |
| Gross amounts recognized in the consolidated balance sheet | $ 384 | $ 195 | $ 454 | $ 160 |
| Gross amount subject to offset in master netting arrangements not offset in the consolidated balance sheet | (155) | (155) | (121) | (121) |
| Cash collateral received | (37) | — | (107) | — |
| Net amounts | $ 192 | $ 40 | $ 226 | $ 39 |

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

| | Sales | | Other (income) expense, net [1] | | Other comprehensive income (loss) | |
|---|---|---|---|---|---|---|
| | Three Months Ended March 31, | | Three Months Ended March 31, | | Three Months Ended March 31, | |
| *($ in millions)* | 2019 | 2018 | 2019 | 2018 | 2019 | 2018 |
| *Financial Statement Line Items in which Effects of Fair Value or Cash Flow Hedges are Recorded* | $ 10,816 | $ 10,037 | $ 188 | (291) | $ 199 | $ 124 |
| (Gain) loss on fair value hedging relationships | | | | | | |
| Interest rate swap contracts | | | | | | |
| Hedged items | — | — | 33 | (62) | — | — |
| Derivatives designated as hedging instruments | — | — | (23) | 62 | — | — |
| Impact of cash flow hedging relationships | | | | | | |
| Foreign exchange contracts | | | | | | |
| Amount of loss recognized in *OCI* on derivatives | — | — | — | — | (13) | (181) |
| Increase (decrease) in *Sales* as a result of *AOCI* reclassifications | 44 | (93) | — | — | (44) | 93 |
| Interest rate contracts | | | | | | |
| Amount of gain recognized in *Other (income) expense, net* on derivatives | — | — | (1) | (1) | — | — |
| Amount of loss recognized in *OCI* on derivatives | — | — | — | — | (4) | (1) |

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

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

| | | Amount of Derivative Pretax (Gain) Loss Recognized in Income | |
|---|---|---|---|
| | | Three Months Ended March 31, | |
| *($ in millions)* | Income Statement Caption | 2019 | 2018 |
| *Derivatives Not Designated as Hedging Instruments* | | | |
| Foreign exchange contracts [1] | Other (income) expense, net | $ 118 | $ 28 |
| Foreign exchange contracts [2] | Sales | 10 | 8 |

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

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

At March 31, 2019 , the Company estimates $141 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:

| | March 31, 2019 | | | | December 31, 2018 | | | |
|---|---|---|---|---|---|---|---|---|
| | | | Gross Unrealized | | | | Gross Unrealized | |
| *($ in millions)* | Fair Value | Amortized Cost | Gains | Losses | Fair Value | Amortized Cost | Gains | Losses |
| Corporate notes and bonds | $ 4,310 | $ 4,307 | $ 22 | $ (19) | $ 4,920 | $ 4,985 | $ 3 | $ (68) |
| Asset-backed securities | 1,094 | 1,096 | 3 | (5) | 1,275 | 1,285 | 1 | (11) |
| U.S. government and agency securities | 832 | 828 | 5 | (1) | 892 | 895 | 2 | (5) |
| Foreign government bonds | 99 | 99 | — | — | 166 | 167 | — | (1) |
| Mortgage-backed securities | 8 | 8 | — | — | 8 | 8 | — | — |
| Total debt securities | $ 6,343 | $ 6,338 | $ 30 | $ (25) | $ 7,261 | $ 7,340 | $ 6 | $ (85) |
| Publicly traded equity securities [(1)] | 636 | | | | 456 | | | |
| Total debt and publicly traded equity securities | $ 6,979 | | | | $ 7,717 | | | |

[(1)] *During the first quarter of 2019 and 2018 , unrealized net gains of $114 million and $44 million , respectively, were recognized in* Other (income) expense, net *on equity securities still held at March 31, 2019 .*

At March 31, 2019 , the Company also had $542 million of equity investments without readily determinable fair values included in *Other Assets* . During the first three months of 2019 , the Company recognized unrealized losses of $9 million in *Other (income) expense, net* related to certain of these investments based on unfavorable observable price changes. Since January 1, 2018, cumulative unrealized gains and cumulative unrealized losses based on observable prices changes for investments in equity investments without readily determinable fair values were $167 million and $20 million , respectively.

Available-for-sale debt securities included in *Short-term investments* totaled $691 million at March 31, 2019 . Of the remaining debt securities, $5.2 billion mature within five years. At March 31, 2019 and December 31, 2018 , there were no debt securities pledged as collateral.

**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 | | | |
|---|---|---|---|---|---|---|---|---|
| | Quoted Prices In Active Markets for Identical Assets (Level 1) | Significant Other Observable Inputs (Level 2) | Significant Unobservable Inputs (Level 3) | Total | Quoted Prices In Active Markets for Identical Assets (Level 1) | Significant Other Observable Inputs (Level 2) | Significant Unobservable Inputs (Level 3) | Total |
| *($ in millions)* | March 31, 2019 | | | | December 31, 2018 | | | |
| **Assets** | | | | | | | | |
| *Investments* | | | | | | | | |
| Corporate notes and bonds | $ — | $ 4,231 | $ — | $ 4,231 | $ — | $ 4,835 | $ — | $ 4,835 |
| Asset-backed securities [1] | — | 1,069 | — | 1,069 | — | 1,253 | — | 1,253 |
| U.S. government and agency securities | — | 735 | — | 735 | — | 731 | — | 731 |
| Foreign government bonds | — | 99 | — | 99 | — | 166 | — | 166 |
| Publicly traded equity securities | 209 | — | — | 209 | 147 | — | — | 147 |
| | 209 | 6,134 | — | 6,343 | 147 | 6,985 | — | 7,132 |
| *Other assets [2]* | | | | | | | | |
| U.S. government and agency securities | 56 | 41 | — | 97 | 55 | 106 | — | 161 |
| Corporate notes and bonds | — | 79 | — | 79 | — | 85 | — | 85 |
| Asset-backed securities [1] | — | 25 | — | 25 | — | 22 | — | 22 |
| Mortgage-backed securities | — | 8 | — | 8 | — | 8 | — | 8 |
| Publicly traded equity securities | 427 | — | — | 427 | 309 | — | — | 309 |
| | 483 | 153 | — | 636 | 364 | 221 | — | 585 |
| *Derivative assets [3]* | | | | | | | | |
| Forward exchange contracts | — | 194 | — | 194 | — | 241 | — | 241 |
| Purchased currency options | — | 190 | — | 190 | — | 213 | — | 213 |
| | — | 384 | — | 384 | — | 454 | — | 454 |
| Total assets | $ 692 | $ 6,671 | $ — | $ 7,363 | $ 511 | $ 7,660 | $ — | $ 8,171 |
| **Liabilities** | | | | | | | | |
| *Other liabilities* | | | | | | | | |
| Contingent consideration | $ — | $ — | $ 667 | $ 667 | $ — | $ — | $ 788 | $ 788 |
| *Derivative liabilities [3]* | | | | | | | | |
| Forward exchange contracts | — | 144 | — | 144 | — | 74 | — | 74 |
| Interest rate swaps | — | 48 | — | 48 | — | 81 | — | 81 |
| Written currency options | — | 3 | — | 3 | — | 5 | — | 5 |
| | — | 195 | — | 195 | — | 160 | — | 160 |
| Total liabilities | $ — | $ 195 | $ 667 | $ 862 | $ — | $ 160 | $ 788 | $ 948 |

[1] *Primarily all of the asset-backed securities are 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, primarily 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.*

There were no transfers between Level 1 and Level 2 during the first three months of 2019 . As of March 31, 2019 , *Cash and cash equivalents* of $8.1 billion included $7.3 billion of cash equivalents (which would be considered Level 2 in the fair value hierarchy).

*Contingent Consideration*

Summarized information about the changes in liabilities for contingent consideration is as follows:

| | Three Months Ended March 31, | |
|---|---|---|
| *($ in millions)* | 2019 | 2018 |
| Fair value January 1 | $ 788 | $ 935 |
| Changes in estimated fair value [(1)] | (36) | 36 |
| Additions | — | 8 |
| Payments | (85) | (60) |
| Fair value March 31 [(2)] | $ 667 | $ 919 |

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

[(2)] *Balance at March 31, 2019 includes $100 million recorded as a current liability for amounts expected to be paid within the next 12 months.*

The decline in the estimated fair value of liabilities for contingent consideration in the first quarter of 2019 primarily relates to a decision not to pursue an acute cough indication for MK-7264 (gefapixant), a program obtained in connection with the acquisition of Afferent Pharmaceuticals. Gefapixant remains in clinical development for other indications, including chronic cough. The payments of contingent consideration in both periods relate to liabilities recorded in connection with the 2016 termination of the Sanofi-Pasteur MSD joint venture.

*Other Fair Value Measurements*

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

The estimated fair value of loans payable and long-term debt (including current portion) at March 31, 2019 , was $27.1 billion compared with a carrying value of $25.9 billion and at December 31, 2018 , was $25.6 billion compared with a carrying value of $25.1 billion . Fair value was estimated using recent observable market prices and would be considered Level 2 in the fair value hierarchy.

*Concentrations of Credit Risk*

On an ongoing basis, the Company monitors concentrations of credit risk associated with corporate and government issuers of securities and financial institutions with which it conducts business. Credit exposure limits are established to limit a concentration with any single issuer or institution. Cash and investments are placed in instruments that meet high credit quality standards as specified in the Company's investment policy guidelines.

The majority of the Company's accounts receivable arise from product sales in the United States and Europe 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 does not expect to have write-offs or adjustments to accounts receivable which would have a material adverse effect on its financial position, liquidity or results of operations.

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 received by the Company from various counterparties was $37 million and $107 million at March 31, 2019 and December 31, 2018 , 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 March 31, 2019 or December 31, 2018 .

## 6. Inventories

Inventories consisted of:

| *($ in millions)* | March 31, 2019 | December 31, 2018 |
|---|---|---|
| Finished goods | $ 1,698 | $ 1,658 |
| Raw materials and work in process | 5,217 | 5,004 |
| Supplies | 201 | 194 |
| Total (approximates current cost) | 7,116 | 6,856 |
| (Decrease) increase to LIFO costs | (6) | 1 |
| | $ 7,110 | $ 6,857 |
| Recognized as: | | |
| Inventories | $ 5,712 | $ 5,440 |
| Other assets | 1,398 | 1,417 |

Amounts recognized as *Other assets* are comprised almost entirely of raw materials and work in process inventories. At March 31, 2019 and December 31, 2018 , these amounts included $1.3 billion and $1.4 billion , respectively, of inventories not expected to be sold within one year. In addition, these amounts included $85 million and $7 million at March 31, 2019 and December 31, 2018 , respectively, of inventories produced in preparation for product launches.

## 7. Loans Payable, Long-Term Debt and Leases

*Long-Term Debt*

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 intends to use the net proceeds from the offering of $5.0 billion for general corporate purposes, including the repayment of outstanding commercial paper borrowings and other indebtedness with upcoming maturities.

*Leases*

As discussed in Note 1, on January 1, 2019, Merck adopted new guidance for the accounting and reporting of leases. The Company has operating leases primarily for manufacturing facilities, research and development facilities, corporate offices, employee housing, vehicles and certain equipment. As permitted under the transition guidance in ASC 842, the Company elected a package of practical expedients which, among other provisions, allowed the Company to carry forward historical lease classifications. The Company determines if an arrangement is a lease at inception. When evaluating contracts for embedded leases, the Company exercises judgment to determine if there is an explicit or implicit identified asset in the contract and if Merck controls the use of that asset. Embedded leases, primarily associated with contract manufacturing organizations, are immaterial.

Under ASC 842 transition guidance, Merck elected the hindsight practical expedient to determine the lease term for existing leases, which permits companies to consider available information prior to the effective date of the new guidance as to the actual or likely exercise of options to extend or terminate the lease. The lease term includes options to extend or terminate the lease when it is reasonably certain that Merck will exercise that option. Real estate leases for facilities have an average remaining lease term of eight years, which include options to extend the leases for up to four years where applicable. Vehicle leases are generally in effect for four years. The Company has made an accounting policy election not to record short-term leases (leases with an initial term of 12 months or less) on the balance sheet; however, Merck currently has no short-term leases.

Lease expense for operating lease payments is recognized on a straight-line basis over the term of the lease. Operating lease assets and liabilities are recognized based on the present value of lease payments over the lease term. Since most of the Company's leases do not have a readily determinable implicit discount rate, the Company uses its incremental borrowing rate to calculate the present value of lease payments. As a practical expedient, the Company has made an accounting policy election not to separate lease components (e.g. payments for rent, real estate taxes and insurance costs) from non-lease components (e.g. common-area maintenance costs) in the event that the agreement contains both. Merck includes both the lease and non-lease components for purposes of calculating the right-of-use asset and related lease liability (if the non-lease components are fixed). For vehicle leases and employee housing, the Company applies a portfolio approach to effectively account for the operating lease assets and liabilities.

Certain of the Company's lease agreements contain variable lease payments that are adjusted periodically for inflation or for actual operating expense true-ups compared with estimated amounts; however, these amounts are immaterial. Sublease income and activity related to sale and leaseback transactions are immaterial. Merck's lease agreements do not contain any material residual value guarantees or material restrictive covenants.

Operating lease cost was $83 million for the first quarter of 2019. Cash paid for amounts included in the measurement of operating lease liabilities was $73 million for the first quarter of 2019.

Supplemental balance sheet information related to operating leases is as follows:

| *($ in millions)* | March 31, 2019 |
|---|---|
| **Assets** | |
| Other Assets [1] | $ 1,096 |
| **Liabilities** | |
| Accrued and other current liabilities | 248 |
| Other Noncurrent Liabilities | 777 |
| | |
| Weighted-average remaining lease term (years) | 7.5 |
| Weighted-average discount rate | 3.4% |

[1] *Includes prepaid leases that have no related lease liability.*

Maturities of operating leases liabilities are as follows:

| *($ in millions)* | March 31, 2019 |
|---|---|
| 2019 (excluding the three months ended March 31, 2019) | $ 260 |
| 2020 | 206 |
| 2021 | 164 |
| 2022 | 132 |
| 2023 | 94 |
| Thereafter | 308 |
| Total lease payments | 1,164 |
| Less: imputed interest | (139) |
| | 1,025 |

As of March 31, 2019, the Company has entered into additional real estate operating leases that have not yet commenced. The obligations associated with these leases total $110 million , of which $72 million relates to a lease that will commence in July 2019 and has a lease term of 10 years.

As of December 31, 2018, prior to the adoption of ASC 842, the minimum aggregate rental commitments under noncancellable leases were as follows: 2019, $188 million ; 2020, $198 million ; 2021, $150 million ; 2022, $134 million ; 2023, $84 million and thereafter, $243 million .

## 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 position, 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 effective August 1, 2004.

**Product Liability Litigation**

*Fosamax*

As previously disclosed, Merck is a defendant in product liability lawsuits in the United States involving *Fosamax* ( *Fosamax* Litigation). As of March 31, 2019 , approximately 3,900 cases have been filed and either are pending or conditionally dismissed (as noted below) 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* .

In March 2011, Merck submitted a Motion to Transfer to the Judicial Panel on Multidistrict Litigation (JPML) seeking to have all federal cases alleging Femur Fractures consolidated into one multidistrict litigation for coordinated pre-trial proceedings. All federal cases involving allegations of Femur Fracture 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. Merck filed a petition for a writ of certiorari to the U.S. Supreme Court in August 2017 seeking review of the Third Circuit's decision. In December 2017, the Supreme Court invited the Solicitor General to file a brief in the case expressing the views of the United States, and in May 2018, the Solicitor General submitted a brief stating that the Third Circuit's decision was wrongly decided and recommended that the Supreme Court grant Merck's cert petition. The Supreme Court granted Merck's petition in June 2018, and an oral argument before the Supreme Court was held on January 7, 2019. The final decision on the Femur Fracture MDL court's preemption ruling is now pending before the Supreme Court.

Accordingly, as of March 31, 2019 , ten cases were actively pending in the Femur Fracture MDL, and approximately 1,060 cases have either been dismissed without prejudice or administratively closed pending final resolution by the Supreme Court of the appeal of the Femur Fracture MDL court's preemption order.

As of March 31, 2019 , approximately 2,555 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. Merck has continued to select additional cases to be reviewed through fact discovery from 2016 to the present.

As of March 31, 2019 , 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 cases in California. Merck intends to defend against these lawsuits.

*Januvia/Janumet*

As previously disclosed, Merck is a defendant in product liability lawsuits in the United States involving *Januvia* and/or *Janumet* . As of March 31, 2019 , Merck is aware of approximately 1,320 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, which is ongoing. 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 proceeding 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 filing deadline for *Daubert* and summary judgment motions will take place in May 2020.

As of March 31, 2019 , seven 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. Merck also filed in March 2019 a motion to stay the Illinois Supreme Court's consideration of the pending petition to appeal until the United States Supreme Court issues its opinion in *Merck Sharp & Dohme Corp. v. Albrecht* , No. 17-290 discussed above.

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 is currently scheduled for April 20, 2020.

**Governmental Proceedings**

As previously disclosed, the Prosecution Office of Milan, Italy has investigated interactions between the Company's Italian subsidiary, certain employees of the subsidiary and certain Italian health care providers. The Company understands that this is part of a larger investigation involving engagements between various health care companies and those health care providers. The Company is cooperating with the investigation. On January 8, 2019, the Company learned that the Milan Prosecutor formally requested that the investigation against the Italian subsidiary's employees be closed without further action. This request is subject to review by the Italian courts before the matter can be officially closed. In addition, on March 1, 2019, the Company learned that the Milan Prosecutor formally archived the investigation against the Italian subsidiary and the investigation as it pertains to the subsidiary is now closed.

As previously disclosed, the United Kingdom (UK) Competition and Markets Authority (CMA) issued a Statement of Objections against the Company and MSD Sharp & Dohme Limited (MSD UK) in May 2017. In the Statement of Objections, the CMA alleged that MSD UK abused a dominant position through a discount program for *Remicade* over the period from March 2015 to February 2016. The Company and MSD UK contested the CMA's allegations. On March 14, 2019, the CMA issued a "no grounds for action" decision and closed the matter without further action against MSD UK.

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. On December 6, 2018, the court denied the Merck Defendants' motions to dismiss or stay the direct purchaser putative class actions pending bilateral arbitration. On February 6, 2019, the magistrate judge issued a report and recommendation recommending that the district judge grant in part and deny in part defendants' motions to dismiss on non-arbitration issues. On February 20, 2019, defendants and retailer opt-out plaintiffs filed objections to the report and recommendation. The parties await a decision from the district judge.

*Rotavirus Vaccines Antitrust Litigation*

As previously disclosed, MSD is a defendant in putative class action lawsuits filed in 2018 on behalf of direct purchasers of *RotaTeq* , alleging violations of federal antitrust laws. The cases were consolidated in the Eastern District of Pennsylvania. On January 23, 2019, the court denied MSD's motions to compel arbitration and to dismiss the consolidated complaint. On February 19, 2019, MSD appealed the court's order on arbitration to the Third Circuit. The appellate briefing is currently ongoing, and the district court case is stayed pending the outcome of the appeal.

*Merck KGaA Litigation*

As previously disclosed, in January 2016, to protect its long-established brand rights in the United States, the Company filed a lawsuit against Merck KGaA, Darmstadt, Germany (KGaA), historically operating as the EMD Group in the United States, alleging it improperly uses the name "Merck" in the United States. KGaA has filed suit against the Company in France, the UK, Germany, Switzerland, Mexico, India, Australia, Singapore, Hong Kong, and China alleging, among other things, unfair competition, trademark infringement and/or corporate name infringement. In the UK, Australia, Singapore, Hong Kong, and India, KGaA also alleges breach of the parties' coexistence agreement. In December 2015, the Paris Court of First Instance issued a judgment finding that certain activities by the Company directed towards France did not constitute trademark infringement and unfair competition while other activities were found to infringe and constitute unfair competition. The Company and KGaA appealed the decision, and the appeal was heard in May 2017. In June 2017, the French appeals court held that certain of the activities by the Company directed to France constituted unfair competition or trademark infringement and, in December 2017, the Company decided not to pursue any further appeal. In January 2016, the UK High Court issued a judgment finding that the Company had breached the co-existence agreement and infringed KGaA's trademark rights as a result of certain activities directed towards the UK based on use of the word MERCK on promotional and information activity. As noted in the UK decision, this finding was not based on the Company's use of the sign MERCK in connection with the sale of products or any material pharmaceutical business transacted in the UK. The Company and KGaA have both appealed this decision, and the appeal was heard in June 2017. In November 2017, the UK Court of Appeals affirmed the decision on the co-existence agreement and remitted for re-hearing issues of trademark infringement, the scope of KGaA's UK trademarks for pharmaceutical products, and the relief to which KGaA would be entitled. The re-hearing was held, and no decision has been handed down.

In November 2018, the District Court in Hamburg, Germany dismissed all of KGaA's claims concerning KGaA's EU trademark with respect to the territory of the EU. KGaA appealed this decision. In February 2019, the District Court in Hamburg dismissed all of KGaA's claims for alleged infringement of its German trademark and trade name rights and breach of unfair competition law brought against the Company in the territory of Germany. In February 2019, the District Court in Hamburg also dismissed most of KGaA's claims for alleged infringement of its German trademark and trade name rights and breach of unfair competition law brought against MSD Sharp & Dohme GmbH in the territory of Germany. MSD Sharp & Dohme Corp. filed an appeal of this decision, and KGaA appealed both of the February 2019 decisions of the District Court in Hamburg. In January 2019, the Mexican Trademark Office issued a decision on KGaA's action. The court found no trademark infringement by the Company and dismissed all of KGaA's claims for trademark infringement. The court ruled against the Company on KGaA's unfair competition claim. Both KGaA and the Company appealed this decision, and in April 2019, KGaA's appeal was denied, and the decision was affirmed. The Company expects that KGaA will file a further appeal of the January 2019 Mexican Trademark Office's decision.

**Patent Litigation**

From time to time, generic manufacturers of pharmaceutical products file abbreviated New Drug Applications (NDAs) with the U.S. Food and Drug Administration (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.

*Inegy* — The patents protecting *Inegy* in Europe expired; supplemental protection certificates (SPCs) in many European countries expired in April 2019. The Company filed actions for patent infringement seeking damages against those companies that launched generic products before April 2019.

*Noxafil* — In August 2015, the Company filed a lawsuit against Actavis Laboratories Fl, Inc. (Actavis) in the United States in respect of that company's application to the FDA seeking pre-patent expiry approval to sell a generic version of *Noxafil* . In October 2017, the district court held the patent valid and infringed. Actavis appealed this decision. While the appeal was pending, the parties reached a settlement, subject to certain terms of the agreement being met, whereby Actavis can launch its generic version prior to expiry of the patent and pediatric exclusivity under certain conditions. In March 2016, the Company filed a lawsuit against Roxane Laboratories, Inc. (Roxane) in the United States in respect of that company's application to the FDA seeking pre-patent

expiry approval to sell a generic version of *Noxafil* . In November 2017, the parties reached a settlement whereby Roxane can launch its generic version prior to expiry of the patent under certain conditions. In February 2016, the Company filed a lawsuit against Par Sterile Products LLC, Par Pharmaceutical, Inc., Par Pharmaceutical Companies, Inc. and Par Pharmaceutical Holdings, Inc. (collectively, Par) in the United States in respect of that company's application to the FDA seeking pre-patent expiry approval to sell a generic version of *Noxafil* injection. In October 2016, the parties reached a settlement whereby Par can launch its generic version in January 2023, or earlier under certain conditions. In February 2018, the Company filed a lawsuit against Fresenius Kabi USA, LLC., (Fresenius) in the United States in respect of that company's application to the FDA seeking pre-patent expiry approval to sell a generic version of *Noxafil* injection . In November 2018, the Company reached a settlement with Fresenius, whereby Fresenius can launch its generic version of the intravenous product prior to expiry of the patent under certain conditions. In March 2018, the Company filed a lawsuit against Mylan Laboratories Limited in the United States in respect of that company's application to the FDA seeking pre-patent expiry approval to sell a generic version of *Noxafil* injection.

*Januvia, Janumet, Janumet XR* - In February 2019, Par Pharmaceutical, Inc. (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. No schedule for the cases has been set by the court.

**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 position, results of operations or cash flows either individually or in the aggregate.

**Legal Defense Reserves**

Legal defense costs expected to be incurred in connection with a loss contingency are accrued when probable and reasonably estimable. Some of the significant factors considered in the review of these legal defense reserves are as follows: the actual costs incurred by the Company; the development of the Company's legal defense strategy and structure in light of the scope of its litigation; the number of cases being brought against the Company; the costs and outcomes of completed trials and the most current information regarding anticipated timing, progression, and related costs of pre-trial activities and trials in the associated litigation. The amount of legal defense reserves as of March 31, 2019 and December 31, 2018 of approximately $250 million and $245 million , respectively, represents the Company's best estimate of the minimum amount of defense costs to be incurred in connection with its outstanding litigation; however, events such as additional trials and other events that could arise in the course of its litigation could affect the ultimate amount of legal defense costs to be incurred by the Company. The Company will continue to monitor its legal defense costs and review the adequacy of the associated reserves and may determine to increase the reserves at any time in the future if, based upon the factors set forth, it believes it would be appropriate to do so.

## 9. Equity

| | Three Months Ended March 31, | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | Common Stock | | Other Paid-In Capital | Retained Earnings | Accumulated Other Comprehensive Loss | Treasury Stock | | Non-Controlling Interests | Total |
| *($ and shares in millions)* | Shares | Par Value | | | | Shares | Cost | | |
| Balance at January 1, 2018 | 3,577 | $ 1,788 | $ 39,902 | $ 41,350 | $ (4,910) | 880 | $ (43,794) | $ 233 | $ 34,569 |
| Net income attributable to Merck & Co., Inc. | — | — | — | 736 | — | — | — | — | 736 |
| Adoption of new accounting standards | — | — | — | 322 | (274) | — | — | — | 48 |
| Other comprehensive income, net of taxes | — | — | — | — | 124 | — | — | — | 124 |
| Cash dividends declared on common stock ($0.48 per share) | — | — | — | (1,301) | — | — | — | — | (1,301) |
| Treasury stock shares purchased | — | — | — | — | — | 10 | (566) | — | (566) |
| Share-based compensation plans and other | — | — | (28) | — | — | (5) | 319 | — | 291 |
| Net income attributable to noncontrolling interests | — | — | — | — | — | — | — | 5 | 5 |
| Distributions attributable to noncontrolling interests | — | — | — | — | — | — | — | (5) | (5) |
| Balance at March 31, 2018 | 3,577 | $ 1,788 | $ 39,874 | $ 41,107 | $ (5,060) | 885 | $ (44,041) | $ 233 | $ 33,901 |
| 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. | — | — | — | 2,915 | — | — | — | — | 2,915 |
| Other comprehensive income, net of taxes | — | — | — | — | 199 | — | — | — | 199 |
| Cash dividends declared on common stock ($0.55 per share) | — | — | — | (1,429) | — | — | — | — | (1,429) |
| Treasury stock shares purchased | — | — | — | — | — | 14 | (1,090) | — | (1,090) |
| Share-based compensation plans and other | — | — | (40) | — | — | (5) | 283 | — | 243 |
| Net loss attributable to noncontrolling interests | — | — | — | — | — | — | — | (53) | (53) |
| Other changes in noncontrolling ownership interests | — | — | — | — | — | — | — | 3 | 3 |
| Balance at March 31, 2019 | 3,577 | $ 1,788 | $ 38,768 | $ 44,065 | $ (5,346) | 994 | $ (51,736) | $ 131 | $ 27,670 |

On October 25, 2018, the Company entered into accelerated share repurchase (ASR) agreements with two third-party financial institutions (Dealers). Under the ASR agreements, Merck agreed to purchase $5 billion of Merck's common stock, in total, with an initial delivery of 56.7 million shares of Merck's common stock, based on the then-current market price, made by the Dealers to Merck, and payments of $5 billion made by Merck to the Dealers on October 29, 2018, which were funded with existing cash and investments, as well as short-term borrowings. The payments to the Dealers were recorded as reductions to shareholders' equity, consisting of a $4 billion increase in treasury stock, which reflected the value of the initial 56.7 million shares received on October 29, 2018, and a $1 billion decrease in other-paid-in capital, which reflected the value of the stock held back by the Dealers pending final settlement. Upon settlement of the ASR agreements in April 2019, Merck received an additional 7.7 million shares as determined by the average daily volume weighted-average price of Merck's common stock during the term of the ASR program, less a negotiated discount, bringing the total shares received by Merck under this program to 64.4 million . The receipt of the additional shares will be reflected as an increase to treasury stock and an increase to other-paid-in capital in the second quarter of 2019.

## 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:

| | Three Months Ended March 31, | |
|---|---|---|
| *($ in millions)* | 2019 | 2018 |
| Pretax share-based compensation expense | $ 93 | $ 80 |
| Income tax benefit | (14) | (15) |
| Total share-based compensation expense, net of taxes | $ 79 | $ 65 |

During the first three months of 2019 and 2018 , the Company granted 70 thousand RSUs with a weighted-average grant date fair value of $77.39 per RSU and 121 thousand RSUs with a weighted-average grant date fair value of $55.88 per RSU, respectively. During the first three months of 2019 and 2018 , the Company granted 609 thousand PSUs with a weighted-average grant date fair value of $90.50 per PSU and 831 thousand PSUs with a weighted-average grant date fair value of $56.60 per PSU, respectively.

The Company did not grant any stock options during the first three months of 2019 . During the first three months of 2018 , the Company granted 46 thousand stock options with a weighted-average exercise price of $55.88 per option and a weighted-average fair value of $7.83 per option. The weighted-average fair value was determined using the following assumptions:

| | Three Months Ended March 31, |
|---|---|
| | 2018 |
| Expected dividend yield | 3.4% |
| Risk-free interest rate | 2.7% |
| Expected volatility | 19.5% |
| Expected life (years) | 6.0 |

At March 31, 2019 , there was $906 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 2.4 years . The Company typically communicates the value of annual share-based compensation awards to employees during the first quarter, but the related share amounts are not established and communicated until early May. Therefore, while the number of RSU, PSU and stock option grants disclosed above do not reflect any amounts relating to the annual grants, share-based compensation costs for the first quarter of 2019 and 2018 and unrecognized compensation expense at March 31, 2019 reflect an impact relating to the awards communicated to employees. 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 March 31, | | | |
|---|---|---|---|---|
| | 2019 | | 2018 | |
| *($ in millions)* | U.S. | International | U.S. | International |
| Service cost | $ 71 | $ 60 | $ 83 | $ 67 |
| Interest cost | 114 | 45 | 108 | 46 |
| Expected return on plan assets | (206) | (108) | (214) | (113) |
| Amortization of unrecognized prior service credit | (12) | (3) | (13) | (3) |
| Net loss amortization | 35 | 16 | 56 | 21 |
| Termination benefits | 2 | — | 11 | — |
| Curtailments | — | — | (2) | — |
| Settlements | — | — | 1 | — |
| | $ 4 | $ 10 | $ 30 | $ 18 |

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

| | Three Months Ended March 31, | |
|---|---|---|
| *($ in millions)* | 2019 | 2018 |
| Service cost | $ 12 | $ 14 |
| Interest cost | 17 | 18 |
| Expected return on plan assets | (18) | (21) |
| Amortization of unrecognized prior service credit | (21) | (21) |
| Termination benefits | — | 1 |
| Curtailments | — | (4) |
| | $ (10) | $ (13) |

In connection with restructuring actions (see Note 4), termination charges were recorded on pension and other postretirement benefit plans related to expanded eligibility for certain employees exiting Merck. Also, in connection with these restructuring actions, curtailments and settlements were recorded on pension and other postretirement benefit 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 March 31, | |
|---|---|---|
| *($ in millions)* | 2019 | 2018 |
| Interest income | $ (89) | $ (85) |
| Interest expense | 209 | 185 |
| Exchange losses | 101 | 7 |
| Loss (income) from investments in equity securities, net [(1)] | 25 | (25) |
| Net periodic defined benefit plan (credit) cost other than service cost | (141) | (135) |
| Other, net | 83 | (238) |
| | $ 188 | $ (291) |

[(1)] *Includes net realized and unrealized gains and losses from investments in equity securities either owned directly or through ownership interests in investments funds.*

The higher exchange losses in 2019 reflect losses on forward exchange contracts related to the acquisition of Antelliq.

Other, net (as reflected in the table above) in the first quarter of 2019 includes $84 million of goodwill impairment charges related to certain businesses in the Healthcare Services segment. Other, net in the first quarter of 2018 includes a $115 million gain on the settlement of certain patent litigation.

Interest paid for the three months ended March 31, 2019 and 2018 was $195 million and $186 million , respectively.

**13. Taxes on Income**

The effective income tax rates of 6.7% and 44.9% for the first quarter of 2019 and 2018 , 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 quarter of 2019 reflects the favorable impact of a $360 million net tax benefit related to the settlement of certain federal income tax matters (discussed below). The effective income tax rate for the first quarter of 2018 reflects the unfavorable impact of a $1.4 billion pretax charge recorded in connection with the formation of a collaboration with Eisai for which no tax benefit was recognized.

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 quarter 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 March 31, | |
|---|---|---|
| *($ and shares in millions except per share amounts)* | 2019 | 2018 |
| Net income attributable to Merck & Co., Inc. | $ 2,915 | $ 736 |
| Average common shares outstanding | 2,585 | 2,695 |
| Common shares issuable [1] | 18 | 15 |
| Average common shares outstanding assuming dilution | 2,603 | 2,710 |
| Basic earnings per common share attributable to Merck & Co., Inc. common shareholders | $ 1.13 | $ 0.27 |
| Earnings per common share assuming dilution attributable to Merck & Co., Inc. common shareholders | $ 1.12 | $ 0.27 |

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

For the three months ended March 31, 2019 and 2018 , 2 million and 14 million , respectively, of common shares issuable under share-based compensation plans were excluded from the computation of earnings per common share assuming dilution because the effect would have been antidilutive.

## 15. Other Comprehensive Income (Loss)

Changes in *AOCI* by component are as follows:

| | Three Months Ended March 31, | | | | |
|---|---|---|---|---|---|
| *($ in millions)* | Derivatives | Investments | Employee Benefit Plans | Cumulative Translation Adjustment | Accumulated Other Comprehensive Income (Loss) |
| Balance January 1, 2018, net of taxes | $ (108) | $ (61) | $ (2,787) | $ (1,954) | $ (4,910) |
| Other comprehensive income (loss) before reclassification adjustments, pretax | (181) | (112) | (1) | 319 | 25 |
| Tax | 38 | — | 3 | (62) | (21) |
| Other comprehensive income (loss) before reclassification adjustments, net of taxes | (143) | (112) | 2 | 257 | 4 |
| Reclassification adjustments, pretax | 92 [1] | 12 [2] | 41 [3] | — | 145 |
| Tax | (19) | 1 | (7) | — | (25) |
| Reclassification adjustments, net of taxes | 73 | 13 | 34 | — | 120 |
| Other comprehensive income (loss), net of taxes | (70) | (99) | 36 | 257 | 124 |
| | | | | | |
| Adoption of ASU 2018-02 | (23) | 1 | (344) | 100 | (266) |
| Adoption of ASU 2016-01 | — | (8) | — | — | (8) |
| Balance March 31, 2018, net of taxes | $ (201) | $ (167) | $ (3,095) | $ (1,597) | $ (5,060) |
| Balance January 1, 2019, net of taxes | $ 166 | $ (78) | $ (3,556) | $ (2,077) | $ (5,545) |
| Other comprehensive income (loss) before reclassification adjustments, pretax | (13) | 76 | (1) | 156 | 218 |
| Tax | 3 | — | 6 | (6) | 3 |
| Other comprehensive income (loss) before reclassification adjustments, net of taxes | (10) | 76 | 5 | 150 | 221 |
| Reclassification adjustments, pretax | (48) [1] | 6 [2] | 14 [3] | — | (28) |
| Tax | 10 | — | (4) | — | 6 |
| Reclassification adjustments, net of taxes | (38) | 6 | 10 | — | (22) |
| Other comprehensive income (loss), net of taxes | (48) | 82 | 15 | 150 | 199 |
| Balance March 31, 2019, net of taxes | $ 118 | $ 4 | $ (3,541) | $ (1,927) | $ (5,346) |

[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 four operating segments, which are the Pharmaceutical, Animal Health, Healthcare Services and Alliances 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. During 2019, as a result of changes to the Company's internal reporting structure, certain costs that were previously included in the Pharmaceutical segment are now being included as part of non-segment expenses within Merck Research Laboratories. Prior period Pharmaceutical segment profits have been recast to reflect these changes on a comparable basis.

The Animal Health segment discovers, develops, manufactures and markets animal health products, including pharmaceutical and vaccine products, for the prevention, treatment and control of disease in all major livestock and companion animal species, which the Company sells to veterinarians, distributors and animal producers.

The Healthcare Services segment provides services and solutions that focus on engagement, health analytics and clinical services to improve the value of care delivered to patients.

The Alliances segment primarily includes activity from the Company's relationship with AstraZeneca LP related to sales of Nexium and Prilosec, which concluded in 2018.

Sales of the Company's products were as follows:

| | Three Months Ended March 31, | | | | | |
|---|---|---|---|---|---|---|
| | 2019 | | | 2018 | | |
| *($ in millions)* | U.S. | Int'l | Total | U.S. | Int'l | Total |
| **Pharmaceutical:** | | | | | | |
| Oncology | | | | | | |
| *Keytruda* | $ 1,284 | $ 985 | $ 2,269 | $ 838 | $ 626 | $ 1,464 |
| *Emend* | 63 | 53 | 117 | 79 | 46 | 125 |
| Alliance revenue - Lynparza | 50 | 29 | 79 | 24 | 9 | 33 |
| Alliance revenue - Lenvima | 50 | 24 | 74 | — | — | — |
| Vaccines | | | | | | |
| *Gardasil/Gardasil* 9 | 362 | 476 | 838 | 380 | 280 | 660 |
| *ProQuad/M-M-R* II */Varivax* | 343 | 153 | 496 | 312 | 80 | 392 |
| *RotaTeq* | 154 | 57 | 211 | 151 | 42 | 193 |
| *Pneumovax* 23 | 125 | 59 | 185 | 112 | 66 | 179 |
| *Vaqta* | 29 | 18 | 47 | 18 | 18 | 37 |
| Hospital Acute Care | | | | | | |
| *Bridion* | 119 | 136 | 255 | 80 | 124 | 204 |
| *Noxafil* | 91 | 99 | 190 | 81 | 94 | 176 |
| *Cubicin* | 42 | 46 | 88 | 47 | 51 | 98 |
| *Invanz* | 14 | 58 | 72 | 91 | 60 | 151 |
| *Cancidas* | 1 | 60 | 61 | 3 | 88 | 91 |
| *Primaxin* | — | 59 | 59 | 5 | 67 | 72 |
| Immunology | | | | | | |
| *Simponi* | — | 208 | 208 | — | 231 | 231 |
| *Remicade* | — | 123 | 123 | — | 167 | 167 |
| Neuroscience | | | | | | |
| *Belsomra* | 24 | 44 | 67 | 23 | 31 | 54 |
| Virology | | | | | | |
| *Isentress/Isentress HD* | 108 | 147 | 255 | 128 | 152 | 281 |
| *Zepatier* | 33 | 81 | 114 | — | 131 | 131 |
| Cardiovascular | | | | | | |
| *Zetia* | — | 140 | 140 | 17 | 287 | 305 |
| *Vytorin* | 3 | 94 | 97 | 8 | 158 | 167 |
| *Atozet* | — | 94 | 94 | — | 73 | 73 |
| Adempas | — | 90 | 90 | — | 68 | 68 |
| Diabetes | | | | | | |
| *Januvia* | 384 | 440 | 824 | 465 | 416 | 880 |
| *Janumet* | 167 | 364 | 530 | 192 | 352 | 544 |
| Women's Health | | | | | | |
| *NuvaRing* | 185 | 34 | 219 | 171 | 46 | 216 |
| *Implanon/Nexplanon* | 149 | 50 | 199 | 128 | 46 | 174 |
| Diversified Brands | | | | | | |
| *Singulair* | 5 | 186 | 191 | 6 | 170 | 175 |
| *Cozaar/Hyzaar* | 4 | 99 | 103 | 7 | 113 | 120 |
| *Nasonex* | (1) | 97 | 96 | 1 | 121 | 122 |
| *Arcoxia* | — | 75 | 75 | — | 83 | 83 |
| *Follistim AQ* | 29 | 28 | 57 | 29 | 39 | 67 |
| Other pharmaceutical *(1)* | 358 | 782 | 1,140 | 320 | 867 | 1,186 |
| Total Pharmaceutical segment sales | 4,175 | 5,488 | 9,663 | 3,716 | 5,202 | 8,919 |
| **Animal Health:** | | | | | | |
| Livestock | 117 | 494 | 611 | 124 | 529 | 652 |
| Companion Animals | 177 | 237 | 414 | 183 | 229 | 413 |
| Total Animal Health segment sales | 294 | 731 | 1,025 | 307 | 758 | 1,065 |

| | | | | | | |
|---|---|---|---|---|---|---|
| Other segment sales [2] | 39 | — | 39 | 84 | — | 84 |
| Total segment sales | 4,508 | 6,219 | 10,727 | 4,107 | 5,960 | 10,068 |
| Other [3] | 7 | 82 | 89 | 26 | (56) | (31) |
| | $ 4,515 | $ 6,301 | $ 10,816 | $ 4,133 | $ 5,904 | $ 10,037 |

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

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

*[2] Represents the non-reportable segments of Healthcare Services and Alliances.*

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

Product sales are recorded net of the provision for discounts, including chargebacks, which are customer discounts that occur when a contracted customer purchases through an intermediary wholesale purchaser, and rebates that are owed based upon definitive contractual agreements or legal requirements with private sector and public sector (Medicaid and Medicare Part D) benefit providers, after the final dispensing of the product by a pharmacy to a benefit plan participant. These discounts, in the aggregate, reduced U.S. sales by $2.6 billion and $2.4 billion for the three months ended March 31, 2019 and 2018 , respectively.

Consolidated sales by geographic area where derived are as follows:

| | Three Months Ended March 31, | |
|---|---|---|
| *($ in millions)* | 2019 | 2018 |
| United States | $ 4,515 | $ 4,133 |
| Europe, Middle East and Africa | 3,103 | 3,191 |
| Japan | 799 | 737 |
| China | 746 | 486 |
| Asia Pacific (other than Japan and China) | 745 | 752 |
| Latin America | 561 | 532 |
| Other | 347 | 206 |
| | $ 10,816 | $ 10,037 |

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

| | Three Months Ended March 31, | |
|---|---|---|
| *($ in millions)* | 2019 | 2018 |
| Segment profits: | | |
| Pharmaceutical segment | $ 6,574 | $ 5,939 |
| Animal Health segment | 415 | 413 |
| Other segments | 2 | 63 |
| Total segment profits | 6,991 | 6,415 |
| Other profits (losses) | 30 | (87) |
| Unallocated: | | |
| Interest income | 89 | 85 |
| Interest expense | (209) | (185) |
| Depreciation and amortization | (359) | (350) |
| Research and development | (1,843) | (3,117) |
| Amortization of purchase accounting adjustments | (397) | (733) |
| Restructuring costs | (153) | (95) |
| Other unallocated, net | (1,082) | (588) |
| | $ 3,067 | $ 1,345 |

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 of contingent consideration, and other miscellaneous income or expense items.

**Recent Developments**

*Business Developments*

In April 2019, Merck acquired Antelliq Corporation (Antelliq) from funds advised by BC Partners. Antelliq is 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.

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. Immune Design's proprietary technologies, GLAAS and ZVex, are engineered to activate the immune system's natural ability to generate and/or expand antigen-specific cytotoxic immune cells to fight cancer and other chronic diseases.

*Restructuring Program*

Merck recently approved a new global restructuring program (the "2019 Restructuring Program") as part of a worldwide initiative focused primarily on further optimizing the Company's manufacturing and supply network, as well as reducing its global real estate footprint. This program is a continuation of the Company's plant rationalization and builds on prior restructuring programs. The Company will continue to evaluate its global footprint and overall operating model, which could result in the identification of additional actions over time. The actions contemplated under the 2019 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 $800 million to $1.2 billion . The Company expects to record charges of approximately $500 million in 2019 related to the program. The Company anticipates the actions under the 2019 Restructuring Program to result in annual net cost savings of approximately $500 million by the end of 2023.

*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 quarter of 2019 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 will continue to negatively affect revenue performance for the remainder of 2019 .

**Operating Results**

*Sales*

Worldwide sales were $10.8 billion for the first quarter of 2019 , an increase of 8% compared with the first quarter of 2018 including a 3% unfavorable effect from foreign exchange. Sales growth was driven primarily by higher sales in the oncology franchise reflecting strong growth of *Keytruda* (pembrolizumab), as well as increased alliance revenue related to Lynparza (olaparib) and Lenvima (lenvatinib). Sales growth in the first quarter of 2019 also reflects higher sales of vaccines, including human papillomavirus (HPV) vaccine *Gardasil* (Human Papillomavirus Quadrivalent [Types 6, 11, 16 and 18] Vaccine, Recombinant) */Gardasil* 9 (Human Papillomavirus 9-valent Vaccine, Recombinant), and 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).

Sales growth in the first quarter of 2019 was partially offset by the ongoing effects of generic competition for cardiovascular products *Zetia* (ezetimibe) and *Vytorin* (ezetimibe and simvastatin), hospital acute care products *Invanz* (ertapenem sodium) and *Cancidas* (caspofungin acetate), and biosimilar competition for immunology product *Remicade* (infliximab). Lower sales of products within the diversified brands franchise and lower sales of diabetes products *Januvia* (sitagliptin) and *Janumet* (sitagliptin/metformin HCl) also partially offset revenue growth in the quarter. 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.

International sales represented 58% of total sales in the first quarter of 2019 . Performance in international markets was led by China, which had total sales of $746 million in the first quarter of 2019 , including $725 million of sales in the Pharmaceutical segment, representing growth of 54% and 58%, respectively, compared to the first quarter of 2018 . Excluding the unfavorable effect of foreign exchange, total sales in China increased 62% in the first quarter of 2019 , while Pharmaceutical segment sales in China increased 67%.

**Pharmaceutical Segment**

*Oncology*

*Keytruda* , an anti-PD-1 therapy, is approved in the United States and in the European Union (EU) as monotherapy for the treatment of certain patients with non-small-cell lung cancer (NSCLC), melanoma, classical Hodgkin lymphoma (cHL), head and neck squamous cell carcinoma (HNSCC) and urothelial carcinoma, a type of bladder cancer, and in combination with chemotherapy for certain patients with either nonsquamous or squamous NSCLC. *Keytruda* is also approved in the United States as monotherapy for the treatment of certain patients with cervical cancer, primary mediastinal large B-cell lymphoma (a type of non-Hodgkin lymphoma), hepatocellular carcinoma, Merkel cell carcinoma, gastric or gastroesophageal junction adenocarcinoma and microsatellite instability-high (MSI-H) or mismatch repair deficient cancer, and most recently for the treatment of renal cell carcinoma (see below). *Keytruda* is approved in Japan for the treatment of certain patients with NSCLC, both as monotherapy and in combination with chemotherapy, melanoma, cHL, MSI-H tumors, and urothelial carcinoma. Additionally, *Keytruda* is approved in China for the treatment of certain patients with melanoma and was recently approved for the treatment of certain patients with NSCLC (see below). *Keytruda* is also approved in many other international markets. The *Keytruda* clinical development program includes studies across a broad range of cancer types (see "Research and Development" below).

In April 2019, the U.S. Food and Drug Administration (FDA) approved *Keytruda* in combination with Inlyta (axitinib), a tyrosine kinase inhibitor, for the first-line treatment of patients with advanced renal cell carcinoma, the most common type of kidney cancer. The approval is based on findings from the pivotal Phase 3 KEYNOTE-426 trial, which demonstrated significant improvements in overall survival (OS), progression-free survival (PFS) and objective response rate (ORR) for *Keytruda* in combination with axitinib ( *Keytruda* -axitinib combination) compared to sunitinib. For the main efficacy outcome measures of OS and PFS, the *Keytruda* -axitinib combination reduced the risk of death by 47% compared to sunitinib; and for PFS, the *Keytruda* -axitinib combination showed a reduction in the risk of progression of disease or death of 31% compared to sunitinib. The ORR, an additional efficacy outcome measure, was 59% for patients who received the *Keytruda* -axitinib combination and 36% for those who received sunitinib.

Also in April 2019, the FDA approved an expanded label for *Keytruda* as monotherapy for the first-line treatment of patients with stage III NSCLC who are not candidates for surgical resection or definitive chemoradiation, or metastatic NSCLC, and whose tumors express PD-L1 (tumor proportion score [TPS] ≥1%) as determined by an FDA-approved test, with no EGFR or ALK genomic tumor aberrations. The approval is based on results from the Phase 3 KEYNOTE-042 trial, in which OS was sequentially tested as part of a pre-specified analysis plan. In the trial, *Keytruda* monotherapy demonstrated a statistically significant improvement in OS compared with chemotherapy alone in patients whose tumors expressed PD-L1 with a TPS ≥50%, with a TPS ≥20%, and then in the entire study population (TPS ≥1%).

Additionally, in April 2019, Merck announced that *Keytruda* was approved by China's National Medical Products Administration in combination with pemetrexed and platinum chemotherapy for the first-line treatment of patients with metastatic nonsquamous NSCLC, with no EGFR or ALK genomic tumor aberrations, based on data from the pivotal Phase 3 KEYNOTE-189 trial.

In March 2019, the European Commission (EC) approved *Keytruda* in combination with carboplatin and either paclitaxel or nab-paclitaxel, for the first-line treatment of adults with metastatic squamous NSCLC. This approval is based on data from the Phase 3 KEYNOTE-407 trial, which demonstrated that *Keytruda* in combination with chemotherapy significantly improved OS in adults with metastatic squamous NSCLC regardless of PD-L1 tumor expression status, reducing the risk of death by 36% percent compared to chemotherapy alone. *Keytruda* was approved for this indication in the United States in October 2018.

In April 2019, the EC approved a new extended dosing schedule of 400 mg every six weeks (Q6W) delivered as an intravenous infusion over 30 minutes for all approved monotherapy indications in the EU. The Q6W dose is available in addition to the formerly approved dose of *Keytruda* 200 mg every three weeks (Q3W) infused over 30 minutes.

Global sales of *Keytruda* were $2.3 billion in the first quarter of 2019 compared with $1.5 billion in the first quarter of 2018 . Sales growth was driven by volume growth as the Company continues to launch *Keytruda* with multiple new indications globally. Sales in the United States continue to build across the multiple approved indications, in particular for the treatment of NSCLC both as monotherapy, and combination with chemotherapy for either nonsquamous or squamous NSCLC. Other indications contributing to U.S. sales growth include HNSCC, bladder, melanoma, and MSI-H cancer. *Keytruda* sales growth in international markets was driven primarily by use in the treatment of NSCLC as monotherapy, as well as in combination with chemotherapy as that indication begins to launch in certain markets, including in Europe. The approval of m ultiple new indications in Japan and performance in China for the treatment of melanoma also drove growth in the quarter.

Global sales of *Emend* (aprepitant), for the prevention of chemotherapy-induced and post-operative nausea and vomiting, were $117 million in the first quarter of 2019 , a decline of 7% compared with the first quarter of 2018 including a 3% unfavorable effect from foreign exchange. The decline primarily reflects lower demand in the United States due to competition.

The patent that provided U.S. market exclusivity for *Emend* expired in 2015 and the patent that provides market exclusivity in most major European markets will expire in May 2019. The patent that provides U.S. market exclusivity for *Emend* for Injection expires in September 2019 and the patent that provides market exclusivity in major European markets expires in February 2020 (although six-month pediatric exclusivity may extend this date). The Company anticipates that sales of *Emend* in these markets will decline significantly after these patent expiries.

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 currently approved for certain types of ovarian and breast cancer. Merck recorded alliance revenue related to Lynparza of $79 million in the first quarter of 2019 compared with $33 million in the first quarter of 2018 . The increase in alliance revenue reflects, in part, uptake in the treatment of ovarian cancer following U.S. approval in December 2018 based on the SOLO-1 trial. In April 2019, the EC approved Lynparza as a monotherapy for the treatment of certain adult patients with germline *BRCA* 1/2-mutations, and who have human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer, triggering a $30 million milestone payment from Merck to AstraZeneca. The approval was based on the results of the Phase 3 OlympiAD trial.

Lenvima, an oral receptor tyrosine kinase inhibitor being developed as part of a collaboration with Eisai entered into in March 2018 (see Note 3 to the condensed consolidated financial statements), is approved for certain types of thyroid cancer, hepatocellular carcinoma, and in combination for certain patients with renal cell carcinoma. Merck recorded alliance revenue of $74 million in the first quarter of 2019 related to Lenvima. Lenvima sales in the first quarter of 2019 reflect strong performance in hepatocellular carcinoma following recent worldwide launches.

*Vaccines*

Worldwide sales of *Gardasil/Gardasil* 9, vaccines to help prevent certain cancers and other diseases caused by certain types of HPV, were $838 million in the first quarter of 2019 , an increase of 27% compared with the first quarter of 2018 including a 4% unfavorable effect from foreign exchange. Sales growth was driven primarily by the ongoing launch in China. Higher demand in Europe, reflecting increased vaccination rates for both boys and girls, and higher sales in Latin America attributable to the timing of customer purchases, also contributed to sales growth. Growth was partially offset by lower sales in the United States reflecting public sector buying patterns.

Global sales of *ProQuad* , a pediatric combination vaccine to help protect against measles, mumps, rubella and varicella, were $152 million in the first quarter of 2019 , an increase of 24% compared with $123 million in the first quarter of 2018 . Foreign exchange unfavorably affected global sales performance by 2% in the first quarter of 2019 . Sales growth was driven primarily by higher volumes and pricing in the United States and volume growth in certain European markets.

Worldwide sales of *M-M-R* II, a vaccine to help protect against measles, mumps and rubella, were $123 million for the first quarter of 2019 , an increase of 31% compared with $94 million for the first quarter of 2018 . Foreign exchange unfavorably affected global sales performance by 1% in the first quarter of 2019 . Sales growth was driven primarily by government tenders in Latin America and higher pricing and volumes in the United States.

Global sales of *Varivax* , a vaccine to help prevent chickenpox (varicella), were $221 million for the first quarter of 2019 , an increase of 26% compared with $175 million for the first quarter of 2018 . Foreign exchange unfavorably affected global sales performance by 5% in the first quarter of 2019 . Sales growth was driven primarily by government tenders in Latin America.

Worldwide sales of *RotaTeq* (Rotavirus Vaccine, Live Oral, Pentavalent), a vaccine to help protect against rotavirus gastroenteritis in infants and children, were $211 million in the first quarter of 2019 , an increase of 10% compared with the first quarter of 2018 including a 1% unfavorable effect from foreign exchange. Sales growth was driven primarily by continued uptake from the launch in China.

*Hospital Acute Care*

Worldwide sales of *Bridion* (sugammadex) Injection, for the reversal of two types of neuromuscular blocking agents used during surgery, were $255 million in the first quarter of 2019 , an increase of 25% compared with the first quarter of 2018 including a 5% unfavorable effect from foreign exchange. Sales growth was driven primarily by volume growth in the United States.

Worldwide sales of *Noxafil* (posaconazole), for the prevention of invasive fungal infections, were $190 million in the first quarter of 2019 , an increase of 8% compared with the first quarter of 2018 including a 5% unfavorable effect from foreign exchange. Sales growth primarily reflects higher pricing in the United States and higher demand in China. The patent that provides U.S. market exclusivity for *Noxafil* expires in July 2019. Additionally, the patent for *Noxafil* will expire in a number of major European markets in December 2019. The Company anticipates sales of *Noxafil* in these markets will decline significantly thereafter.

Global sales of *Invanz* , for the treatment of certain infections, were $72 million in the first quarter of 2019 , a decline of 53% compared with the first quarter of 2018 including a 4% unfavorable effect from foreign exchange. The sales decline was

driven by generic competition in the United States. The patent that provided U.S. market exclusivity for *Invanz* expired in November 2017. Accordingly, the Company is experiencing a significant decline in U.S. *Invanz* sales and expects the decline to continue.

Global sales of *Cancidas* , an anti-fungal product sold primarily outside of the United States, were $61 million in the first quarter of 2019 , a decline of 33% compared with the same period of 2018 . Foreign exchange unfavorably affected global sales performance by 5% in the first quarter of 2019 . The sales decline was driven by generic competition in certain European markets. The EU compound patent for *Cancidas* expired in April 2017. Accordingly, the Company is experiencing a significant decline in *Cancidas* sales in these European markets and expects the decline to continue.

*Immunology*

Sales of *Simponi* (golimumab), a once-monthly subcutaneous treatment for certain inflammatory diseases (marketed by the Company in Europe, Russia and Turkey), were $208 million in the first quarter of 2019 , a decline of 10% compared with the first quarter of 2018 including a 7% unfavorable effect from foreign exchange. The sales decline reflects lower pricing, partially offset by higher volumes in Europe. The Company anticipates sales of *Simponi* will be unfavorably affected in future periods by the recent launch of biosimilars for a competing product.

Sales of *Remicade,* a treatment for inflammatory diseases (marketed by the Company in Europe, Russia and Turkey), were $123 million in the first quarter of 2019 , a decline of 26% compared with the first quarter of 2018 . Foreign exchange unfavorably affected sales performance by 6% in the first quarter of 2019 . 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*

Global 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, were $255 million in the first quarter of 2019 , a decline of 9% compared with the first quarter of 2018 including a 6% unfavorable effect from foreign exchange. The sales decline was driven by competitive pressure in the United States and Europe.

*Cardiovascular*

Combined global sales of *Zetia* (marketed in most countries outside the United States as *Ezetrol* ), *Vytorin* (marketed outside the United States as *Inegy* ), as well as *Atozet* (ezetimibe and atorvastatin) and *Rosuzet* (ezetimibe and rosuvastatin) (both marketed in certain countries outside of the United States), medicines for lowering LDL cholesterol, were $346 million in the first quarter of 2019 , a decline of 38% compared with the first quarter of 2018 including a 3% unfavorable effect from foreign exchange. The sales decline was driven primarily by lower sales in Europe. The Company lost market exclusivity in major European markets for *Ezetrol* in April 2018 and has also lost market exclusivity in certain European markets for *Inegy* (see Note 8 to the condensed consolidated financial statements). Accordingly, the Company is experiencing sales declines in these markets as a result of generic competition and expects the declines to continue. Merck lost market exclusivity in the United States for *Zetia* in 2016 and *Vytorin* in 2017 and has lost nearly all U.S. sales of these products as a result of generic competition.

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 sales in Merck's marketing territories, as well as Merck's share of profits from the sale of Adempas in Bayer's marketing territories. Merck recorded revenue related to Adempas of $90 million in the first quarter of 2019 , an increase of 33% compared with the first quarter of 2018 including a 3% unfavorable effect from foreign exchange. Sales growth reflects higher profit sharing from Bayer.

*Diabetes*

Worldwide combined sales of *Januvia* and *Janumet* , medicines that help lower blood sugar levels in adults with type 2 diabetes, were $1.4 billion in the first quarter of 2019 , a decline of 5% compared with the first quarter of 2018 including a 4% unfavorable effect from foreign exchange. The sales decline reflects continued pricing pressure in the United States, partially offset by higher demand globally. The Company expects U.S. pricing pressure to continue.

*Women's Health*

Worldwide sales of *NuvaRing* (etonogestrel/ethinyl estradiol vaginal ring), a vaginal contraceptive product, were $219 million in the first quarter of 2019 , an increase of 1% compared with the first quarter of 2018 . Foreign exchange unfavorably affected global sales performance by 2% in the first quarter of 2019 . The patent that provided U.S. market exclusivity for *NuvaRing* expired in April 2018 and the Company anticipates a significant decline in U.S. *NuvaRing* sales in future periods as a result of generic competition.

**Animal Health Segment**

Global sales of Animal Health products totaled $1.0 billion for the first quarter of 2019 , a decline of 4% compared with the first quarter of 2018 including a 7% unfavorable effect from foreign exchange. Excluding the unfavorable effect of foreign exchange, sales performance reflects higher demand for companion animal products, primarily the *Bravecto* (fluralaner) line of products for parasitic control, and volume growth in livestock products, particularly from sales of new poultry and swine products. Sales of livestock products were unfavorably affected by lower demand for ruminant products reflecting distributor purchasing patterns and the delayed movement of cattle into feedlots in the United States.

In April 2019, Merck acquired Antelliq, a leader in digital animal identification, traceability and monitoring solutions (see Note 2 to the condensed consolidated financial statements).

**Costs, Expenses and Other**

*Cost of Sales*

Cost of sales were $3.1 billion for the first quarter of 2019 , a decline of 4% compared with the first quarter of 2018 . Costs in the first quarter of 2019 and 2018 include $397 million and $733 million, respectively, of expenses for the amortization of intangible assets recorded in connection with business acquisitions. Cost of sales also include expenses for the amortization of capitalized milestone payments related to collaborations of $98 million and $39 million in the first quarter of 2019 and 2018 , respectively. Amortization in the first quarter of 2019 includes $35 million of catch-up amortization from the accrual of sales-based milestones that were deemed by the Company to be probable in the first quarter of 2019 (see Note 3 to the condensed consolidated financial statements). Also included in cost of sales are expenses associated with restructuring activities which amounted to $34 million and $6 million in the first quarter of 2019 and 2018 , 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 71.8% in the first quarter of 2019 compared with 68.3% in the first quarter of 2018 . The gross margin improvement largely reflects a lower aggregate impact from the amortization of intangible assets related to business acquisitions and restructuring costs as noted above, which unfavorably affected gross margin by 4.1 percentage points in the first quarter of 2019 compared with 7.4 percentage points in the first quarter of 2018 . The gross margin improvement also reflects the favorable effects of foreign exchange and product mix, partially offset by increased amortization of capitalized milestone payments related to collaborations as noted above and the unfavorable effects of pricing pressure and royalties.

*Selling, General and Administrative*

Selling, general and administrative (SG&A) expenses were $2.4 billion in the first quarter of 2019 , a decline of 3% compared with the first quarter of 2018 , reflecting lower selling and promotional costs and the favorable effect of foreign exchange, partially offset by higher administrative costs.

*Research and Development*

Research and development (R&D) expenses were $1.9 billion for the first quarter of 2019 compared with $3.2 billion for the first quarter of 2018 . The decline was driven primarily by a $1.4 billion aggregate charge recorded in the first quarter of 2018 related to the formation of an oncology collaboration with Eisai (see Note 3 to the condensed consolidated financial statements). The decline also reflects a reduction in expenses related to a decrease in the estimated fair value measurement of liabilities for contingent consideration and the favorable effect of foreign exchange. Partially offsetting the decline was increased clinical development spending in 2019, in particular for collaborations, and increased investment in discovery, preclinical and early drug development.

R&D expenses are comprised of the costs directly incurred by Merck Research Laboratories (MRL), the Company's research and development division that focuses on human health-related activities, which were $1.4 billion and $1.3 billion in the first quarter of 2019 and 2018 , 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 $545 million and $495 million for the first quarter of 2019 and 2018 , respectively. In addition, R&D expenses include expense or income related to changes in the estimated fair value measurement of liabilities for contingent consideration recorded in connection with business acquisitions. During the first quarter of 2019, the Company recorded a net reduction in expenses of $39 million to decrease the estimated fair value of liabilities for contingent consideration related to the discontinuation or delay of certain programs (see Note 5 to the consolidated financial statements).

*Restructuring Costs*

Merck recently approved a new global restructuring program (the "2019 Restructuring Program") as part of a worldwide initiative focused primarily on further optimizing the Company's manufacturing and supply network, as well as reducing its global real estate footprint. This program is a continuation of the Company's plant rationalization and builds on prior restructuring

programs. The Company will continue to evaluate its global footprint and overall operating model, which could result in the identification of additional actions over time. The actions contemplated under the 2019 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 $800 million to $1.2 billion . The Company expects to record charges of approximately $500 million in 2019 related to the program. The Company anticipates the actions under the 2019 Restructuring Program to result in annual net cost savings of approximately $500 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 $153 million and $95 million for the first quarter of 2019 and 2018 , 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, 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 $187 million and $104 million in the first quarter of 2019 and 2018 , respectively, related to restructuring program activities (see Note 4 to the condensed consolidated financial statements).

*Other (Income) Expense, Net*

Other (income) expense, net was $188 million of expense in the first quarter of 2019 compared with $291 million of income in the first quarter of 2018 . For details on the components of *Other (income) expense, net* , see Note 12 to the condensed consolidated financial statements.

*Segment Profits*

| | Three Months Ended March 31, | |
|---|---|---|
| *($ in millions)* | 2019 | 2018 |
| Pharmaceutical segment profits | $ 6,574 | $ 5,939 |
| Animal Health segment profits | 415 | 413 |
| Other non-reportable segment profits | 2 | 63 |
| Other | (3,924) | (5,070) |
| Income before taxes | $ 3,067 | $ 1,345 |

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 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 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, and restructuring costs. 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 grew 11% in the first quarter of 2019 compared with the first quarter of 2018 driven primarily by higher sales and lower selling and promotional costs. Animal Health segment profits were essentially flat in the first quarter of 2019 compared with the first quarter of 2018 reflecting lower selling and promotional costs, offset by lower sales.

*Taxes on Income*

The effective income tax rates of 6.7% and 44.9% for the first quarter of 2019 and 2018 , 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 quarter of 2019 reflects the favorable impact of a $360 million net tax benefit related to the settlement of certain federal income tax matters (discussed below). The effective income tax rate for the first quarter

of 2018 reflects the unfavorable impact of a $1.4 billion pretax charge recorded in connection with the formation of a collaboration with Eisai for which no tax benefit was recognized.

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 quarter 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 Income and Earnings per Common Share*

Net income attributable to Merck & Co., Inc. was $2.9 billion for the first quarter of 2019 compared with $736 million for the first quarter of 2018 . Earnings per common share assuming dilution attributable to Merck & Co., Inc. common shareholders (EPS) for the first quarter of 2019 were $1.12 compared with $0.27 in the first quarter of 2018 .

*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. Senior management's annual compensation is derived in part using non-GAAP income and non-GAAP EPS. 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 March 31, | |
|---|---|---|
| *($ in millions except per share amounts)* | 2019 | 2018 |
| Income before taxes as reported under GAAP | $ 3,067 | $ 1,345 |
| Increase (decrease) for excluded items: | | |
| Acquisition and divestiture-related costs | 548 | 733 |
| Restructuring costs | 187 | 104 |
| Other items: | | |
| Aggregate charge related to the formation of a collaboration with Eisai | — | 1,400 |
| Other | — | (22) |
| Non-GAAP income before taxes | 3,802 | 3,560 |
| Taxes on income as reported under GAAP | 205 | 604 |
| Estimated tax benefit on excluded items [(1)] | 129 | 107 |
| 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 | 627 | 711 |
| Non-GAAP net income | 3,175 | 2,849 |
| Less: Net (loss) income attributable to noncontrolling interests as reported under GAAP | (53) | 5 |
| Acquisition and divestiture-related costs attributable to noncontrolling interests | 53 | — |
| Non-GAAP net income attributable to noncontrolling interests | — | 5 |
| Non-GAAP net income attributable to Merck & Co., Inc. | $ 3,175 | $ 2,844 |
| EPS assuming dilution as reported under GAAP | $ 1.12 | $ 0.27 |
| EPS difference [(2)] | 0.10 | 0.78 |
| Non-GAAP EPS assuming dilution | $ 1.22 | $ 1.05 |

[(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.*

[(2)] *Represents the difference between calculated GAAP EPS and calculated non-GAAP EPS, which may be different than the amount calculated by dividing the impact of the excluded items by the weighted-average shares for the applicable period.*

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, 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, and typically 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. Excluded from non-GAAP income and non-GAAP EPS in 2018 is a charge related to the formation of a collaboration with Eisai (see Note 3 to the condensed consolidated financial statements).

**Research and Development Update**

*Keytruda* is an anti-PD-1 therapy approved in the United States in 11 different tumor types. *Keytruda* is also approved in many international markets. These approvals were the result of a broad clinical development program that currently consists of more than 1,000 clinical trials, including more than 600 trials that combine *Keytruda* with other cancer treatments. These studies encompass more than 30 cancer types including: bladder, cervical, colorectal, cutaneous squamous cell, esophageal, gastric, HNSCC, hepatocellular, Hodgkin lymphoma, non-Hodgkin lymphoma, melanoma, mesothelioma, nasopharyngeal, NSCLC, ovarian, PMBCL, prostate, renal, small-cell lung and triple-negative breast, many of which are currently in Phase 3 clinical development. Further trials are being planned for other cancers.

*Keytruda* , in combination with Inlyta (axitinib), a tyrosine kinase inhibitor, is under review in the EU for the first-line treatment of patients with advanced renal cell carcinoma. *Keytruda* was approved for this indication by the FDA in April 2019 based on findings from the pivotal Phase 3 KEYNOTE-426 trial, which demonstrated significant improvements in OS, PFS and ORR compared to sunitinib.

*Keytruda* is also under review in the EU as monotherapy for the first-line treatment of patients with stage III NSCLC who are not candidates for surgical resection or definitive chemoradiation, or metastatic NSCLC, and whose tumors express PD-L1 (TPS ≥1%) with no EGFR or ALK genomic tumor aberrations. *Keytruda* was approved for this indication by the FDA in April 2019 based on results from the Phase 3 KEYNOTE-042 trial, in which OS was sequentially tested as part of a pre-specified analysis plan. In the trial, *Keytruda* monotherapy demonstrated a statistically significant improvement in OS compared with chemotherapy alone in patients whose tumors expressed PD-L1 with a TPS ≥50%, with a TPS ≥20%, and then in the entire study population (TPS ≥1%).

In February 2019, the FDA accepted and granted Priority Review for a supplemental BLA for *Keytruda* as monotherapy for the treatment of patients with advanced small-cell lung cancer (SCLC) whose disease has progressed after two or more lines of prior therapy. This supplemental BLA, which is seeking accelerated approval for this new indication, is based on data from the SCLC cohorts of the Phase 2 KEYNOTE-158 and Phase 1b KEYNOTE-028 trials. The FDA set a PDUFA date of June 17, 2019. *Keytruda* is also being studied in combination with chemotherapy in the ongoing Phase 3 KEYNOTE-604 study in patients with newly diagnosed extensive stage SCLC.

In February 2019, the FDA accepted a supplemental BLA for *Keytruda* as monotherapy or in combination with platinum and 5-fluorouracil chemotherapy for the first-line treatment of patients with recurrent or metastatic HNSCC. This supplemental BLA is based in part on data from the pivotal Phase 3 KEYNOTE-048 trial where *Keytruda* demonstrated a significant improvement in OS compared with the standard of care, as monotherapy in patients whose tumors expressed PD-L1 with Combined Positive Score (CPS)≥20 and CPS≥1 and in combination with chemotherapy in the total patient population. These data were presented at the European Society for Medical Oncology 2018 Congress. The FDA granted Priority Review to the supplemental BLA and set

a PDUFA date of June 10, 2019. A corresponding application is also under review in the EU. KEYNOTE-048 serves as the confirmatory trial for KEYNOTE-012, a Phase 1b study which supported the previous accelerated approval for *Keytruda* as monotherapy for the treatment of patients with recurrent or metastatic HNSCC with disease progression on or after platinum-containing chemotherapy.

In April 2019, Merck announced topline findings from the final analysis of the pivotal Phase 3 KEYNOTE-062 trial evaluating *Keytruda* as monotherapy and in combination with chemotherapy (cisplatin and either 5-fluorouracil or capecitabine) for the first-line treatment of advanced gastric or gastroesophageal junction adenocarcinoma. In the monotherapy arm of the study, *Keytruda* met a primary endpoint by demonstrating noninferiority to chemotherapy, the current standard of care, for OS in the entire intention-to-treat population of patients whose tumors expressed PD-L1 (CPS ≥1). In the combination arm of KEYNOTE-062, *Keytruda* plus chemotherapy was not found to be superior for OS (CPS ≥1 or CPS ≥10) or PFS (CPS ≥1) compared with chemotherapy alone. Results will be presented during an oral session at the 2019 Annual Meeting of the American Society of Clinical Oncology and will be discussed with regulatory authorities. In September 2017, the FDA approved *Keytruda* as a third-line treatment for previously treated patients with recurrent locally advanced or metastatic gastric or gastroesophageal junction cancer whose tumors express PD-L1 (CPS ≥1) as determined by an FDA-approved test, with disease progression on or after two or more prior lines of therapy including fluoropyrimidine- and platinum-containing chemotherapy and if appropriate, HER2/neu-targeted therapy. KEYNOTE-062 was a potential confirmatory trial for this accelerated, third-line approval. In addition to KEYNOTE-062, additional first-line, Phase 3 studies in Merck's gastric clinical program include KEYNOTE-811 and KEYNOTE-859, as well as KEYNOTE-585 in the neoadjuvant and adjuvant treatment setting.

In addition, *Keytruda* has received Breakthrough Therapy designation from the FDA for the treatment of high-risk, early-stage triple-negative breast cancer in combination with neoadjuvant 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.

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

In April 2019, the Committee for Medicinal Products for Human Use of the European Medicines Agency adopted a positive opinion, recommending Lynparza as a first-line maintenance treatment in patients with *BRCA* -mutated advanced ovarian cancer who are in complete or partial response following first-line standard platinum-based chemotherapy. This recommendation was based on positive results from the pivotal Phase 3 SOLO-1 trial. The trial showed a statistically-significant and clinically-meaningful improvement in PFS for Lynparza compared to placebo, reducing the risk of disease progression or death by 70%.

In March 2019, Merck and AstraZeneca announced positive results from the Phase 3 POLO trial. POLO is a randomized, double-blinded, placebo-controlled trial exploring the efficacy of Lynparza tablets as first-line maintenance monotherapy in patients with germline *BRCA* -mutated (g *BRCA* m) metastatic adenocarcinoma of the pancreas (pancreatic cancer) whose disease has not progressed on platinum-based chemotherapy. Results from the trial showed a statistically-significant and clinically-meaningful improvement in PFS with Lynparza versus placebo. Merck and AstraZeneca plan to present the full results from the trial at the 2019 Annual Meeting of the American Society of Clinical Oncology.

The chart below reflects the Company's research pipeline as of May 1, 2019. 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 certain other indications) 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**<br>MK-3475 *Keytruda*<br>Advanced Solid Tumors<br>Prostate<br>MK-7902 Lenvima *(1)*<br>Biliary Tract<br>V937 *Cavatak*<br>Melanoma<br>MK-7690 *(2)*<br>Colorectal<br>MK-7339 Lynparza *(1)*<br>Advanced Solid Tumors<br>**Cytomegalovirus**<br>V160<br>**Diabetes Mellitus**<br>MK-8521 *(3)*<br>**HIV-1 Infection**<br>MK-8591<br>**Pediatric Neurofibromatosis Type 1**<br>MK-5618 (selumetinib) *(1)(4)*<br>**Respiratory Syncytial Virus**<br>MK-1654<br>**Schizophrenia**<br>MK-8189 | **Cancer**<br>MK-3475 *Keytruda*<br>Breast (October 2015)<br>Cervical (October 2018) (EU)<br>Colorectal (November 2015)<br>Cutaneous Squamous Cell (April 2019)<br>Esophageal (December 2015)<br>Gastric (May 2015) (EU)<br>Hepatocellular (May 2016) (EU)<br>Mesothelioma (May 2018)<br>Nasopharyngeal (April 2016)<br>Ovarian (December 2018)<br>Small-Cell Lung (May 2017) (EU)<br>MK-7902 Lenvima *(1)(2)*<br>Endometrial (June 2018)<br>Melanoma (March 2019)<br>Non-Small-Cell Lung (March 2019)<br>MK-7339 Lynparza *(1)*<br>Pancreatic (December 2014)<br>Prostate (April 2017)<br>**Cough**<br>MK-7264 (gefapixant) (March 2018)<br>**Heart Failure**<br>MK-1242 (vericiguat) (September 2016) *(1)*<br>**Pneumoconjugate Vaccine**<br>V114 (June 2018) | **New Molecular Entities/Vaccines**<br>**Bacterial Infection**<br>MK-7655A (relebactam+imipenem/cilastatin) (U.S.)(EU)<br>**Ebola Vaccine**<br>V920 (U.S.) *(5)* (EU)<br><br>**Certain Supplemental Filings**<br>**Cancer**<br>MK-3475 *Keytruda*<br>• First-Line Advanced Renal Cell Carcinoma (KEYNOTE-426) (EU)<br>• First-Line Metastatic Non-Small-Cell Lung Cancer (KEYNOTE-042) (EU)<br>• Third-Line Advanced Small-Cell Lung Cancer (KEYNOTE-158) (U.S.)<br>• First-Line Head and Neck Cancer (KEYNOTE-048) (U.S.)(EU)<br>MK-7339 Lynparza *(1)*<br>• First-line Advanced Ovarian Cancer (EU)<br>**HABP/VABP** *(6)*<br>MK-7625A *Zerbaxa* (U.S.)<br><br>**Footnotes:**<br>*(1)* Being developed in a collaboration.<br>*(2)* Being developed in combination with *Keytruda* .<br>*(3)* Development is currently on hold.<br>*(4)* This is a registrational study.<br>*(5)* Rolling submission.<br>*(6)* HABP - Hospital-Acquired Bacterial Pneumonia / VABP -Ventilator-Associated Bacterial Pneumonia |

## Liquidity and Capital Resources

| *($ in millions)* | March 31, 2019 | December 31, 2018 |
|---|---|---|
| Cash and investments | $ 14,419 | $ 15,097 |
| Working capital | 6,808 | 3,669 |
| Total debt to total liabilities and equity | 31.4% | 30.4% |

Cash provided by operating activities was $1.3 billion in the first three months of 2019 compared with $1.2 billion in the first three months of 2018 . Cash provided by operating activities in the first three months of 2019 reflects the receipt of $424 million from AstraZeneca related to the conclusion of the Company's relationship with AstraZeneca LP, as well as $1.4 billion of tax payments and a $325 million option payment to Eisai (see Note 3 to the condensed consolidated financial statements). Cash provided by operating activities in the first three months of 2018 reflects $750 million of upfront payments made by the Company related to the formation of a collaboration with Eisai (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 provided by investing activities was $368 million in the first three months of 2019 compared with a use of cash in investing activities of $197 million in the first three months of 2018 . The change was driven primarily by lower purchases of securities and other investments in 2019, as well as a $350 million milestone payment in 2018 related to a collaboration with Bayer (see Note 3 to the condensed consolidated financial statements), partially offset by higher capital expenditures in 2019.

Cash used in financing activities was $1.6 billion in the first three months of 2019 compared with $2.7 billion in the first three months of 2018 . The lower use of cash in financing activities was driven primarily by proceeds from the issuance of debt (see below) and lower payments on debt, partially offset by the repayment of short-term borrowings, higher purchases of treasury stock, and higher dividends paid to shareholders.

Capital expenditures totaled $595 million and $450 million for the first three months of 2019 and 2018 , respectively.

Dividends paid to stockholders were $1.4 billion and $1.3 billion for the first three months of 2019 and 2018 , respectively. In January 2019, the Board of Directors declared a quarterly dividend of $0.55 per share on the Company's outstanding common stock for the second quarter that was paid in April 2019.

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 intends to use the net proceeds from the offering of $5.0 billion for general corporate purposes, including the repayment of outstanding commercial paper borrowings and other indebtedness with upcoming maturities.

In October 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 three months of 2019 , the Company purchased $1.1 billion ( 14 million shares) for its treasury under a previously authorized share repurchase program. As of March 31, 2019 , the Company's remaining share repurchase authorization was $10.9 billion . In October 2018, the Company entered into accelerated share repurchase (ASR) agreements as discussed below.

On October 25, 2018, the Company entered into ASR agreements with two third-party financial institutions (Dealers). Under the ASR agreements, Merck agreed to purchase $5 billion of Merck's common stock, in total, with an initial delivery of 56.7 million shares of Merck's common stock, based on the then-current market price, made by the Dealers to Merck, and payments of $5 billion made by Merck to the Dealers on October 29, 2018, which were funded with existing cash and investments, as well as short-term borrowings. Upon settlement of the ASR agreements in April 2019, Merck received an additional 7.7 million shares as determined by the average daily volume weighted-average price of Merck's common stock during the term of the ASR program, less a negotiated discount, bringing the total shares received by Merck under this program to 64.4 million .

The Company has a $6.0 billion credit facility that matures in June 2023. 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, 2018 included in Merck's Form 10-K filed on February 27, 2019. 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, 2018 . See Note 1 to the condensed consolidated financial statements for information on the adoption of new accounting standards during 2019 .

**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 for the period covered by this Form 10–Q. Based on this assessment, the Company's Chief Executive Officer and Chief Financial Officer have concluded that as of March 31, 2019 , the Company's disclosure controls and procedures are effective. For the period covered by this report, there have been no changes in internal control over financial reporting that have 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

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, 2018 , as filed on February 27, 2019, 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 2. Unregistered Sales of Equity Securities and Use of Proceeds

Issuer purchases of equity securities for the three months ended March 31, 2019 were as follows:

ISSUER PURCHASES OF EQUITY SECURITIES

| | | | *($ in millions)* |
|---|---|---|---|
| Period | Total Number of Shares Purchased [1] | Average Price Paid Per Share | Approximate Dollar Value of Shares That May Yet Be Purchased Under the Plans or Programs [1] |
| January 1 - January 31 | 11,990,506 | $74.83 | $11,052 |
| February 1 - February 28 | 2,470,576 | $77.93 | $10,860 |
| March 1 - March 31 | — | — | $10,860 |
| Total | 14,461,082 | $75.36 | $10,860 |

[1] *Shares purchased during the period were made as part of a plan approved by the Board of Directors in November 2017 to purchase up to $10 billion of Merck's common stock for its treasury. In October 2018, the Board of Directors authorized an additional $10 billion of treasury stock purchases with no time limit for completion.*

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 | — | The following materials from Merck & Co., Inc.'s Quarterly Report on Form 10-Q for the quarter ended March 31, 2019, formatted in XBRL (Extensible Business Reporting Language): (i) the Condensed Consolidated Statement of Income, (ii) the Condensed Consolidated Statement of Comprehensive Income, (iii) the Condensed Consolidated Balance Sheet, (iv) the Condensed Consolidated Statement of Cash Flows, and (v) Notes to the Condensed Consolidated Financial Statements. |

Signatures

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

MERCK & CO., INC.

Date: May 8, 2019

/s/ Jennifer Zachary

JENNIFER ZACHARY

Executive Vice President and General Counsel

Date: May 8, 2019

/s/ Rita A. Karachun

RITA A. KARACHUN

Senior Vice President Finance - Global Controller

EXHIBIT INDEX

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Exhibit 31.1

**CERTIFICATION**

I, Kenneth C. Frazier, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: May 8, 2019

By: /s/ Kenneth C. Frazier

KENNETH C. FRAZIER
Chairman, President and Chief Executive Officer

Exhibit 31.2

**CERTIFICATION**

I, Robert M. Davis, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: May 8, 2019

By: /s/ Robert M. Davis

ROBERT M. DAVIS
Executive Vice President, Global Services
and Chief Financial Officer

Exhibit 32.1

**Section 1350**
**Certification of Chief Executive Officer**

Pursuant to 18 U.S.C. Section 1350, the undersigned officer of Merck & Co., Inc. (the "Company"), hereby certifies that the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2019 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: May 8, 2019

/s/ Kenneth C. Frazier

Name: KENNETH C. FRAZIER
Title: Chairman, President and Chief Executive Officer

Exhibit 32.2

**Section 1350**
**Certification of Chief Financial Officer**

Pursuant to 18 U.S.C. Section 1350, the undersigned officer of Merck & Co., Inc. (the "Company"), hereby certifies that the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2019 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: May 8, 2019

/s/ Robert M. Davis

Name: ROBERT M. DAVIS
Title: Executive Vice President, Global Services and Chief Financial Officer