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

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the quarterly period ended September 30, 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 New Jersey 07033
(Address of principal executive offices) (zip code)
(Registrant's telephone number, including area code) **(908) 740-4000**

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

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

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

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

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

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

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

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

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

The number of shares of common stock outstanding as of the close of business on October 31, 2019: 2,545,984,142

Table of Contents

Part I - Financial Information

Item 1. Financial Statements

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Sales	$ 12,397	$ 10,794	$ 34,972	$ 31,296
Costs, Expenses and Other				
Cost of sales	3,990	3,619	10,443	10,220
Selling, general and administrative	2,589	2,443	7,726	7,459
Research and development	3,204	2,068	7,324	7,538
Restructuring costs	232	171	444	494
Other (income) expense, net	35	(172)	362	(512)
	10,050	8,129	26,299	25,199
Income Before Taxes	2,347	2,665	8,673	6,097
Taxes on Income	440	707	1,259	1,682
Net Income	1,907	1,958	7,414	4,415
Less: Net Income (Loss) Attributable to Noncontrolling Interests	6	8	(73)	22
Net Income Attributable to Merck & Co., Inc.	$ 1,901	$ 1,950	$ 7,487	$ 4,393
Basic Earnings per Common Share Attributable to Merck & Co., Inc. Common Shareholders	$ 0.74	$ 0.73	$ 2.91	$ 1.64
Earnings per Common Share Assuming Dilution Attributable to Merck & Co., Inc. Common Shareholders	$ 0.74	$ 0.73	$ 2.89	$ 1.63

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Net Income Attributable to Merck & Co., Inc.	$ 1,901	$ 1,950	$ 7,487	$ 4,393
Other Comprehensive (Loss) Income Net of Taxes:				
Net unrealized gain (loss) on derivatives, net of reclassifications	91	27	(9)	223
Net unrealized (loss) gain on investments, net of reclassifications	(17)	40	109	(56)
Benefit plan net gain and prior service credit, net of amortization	15	40	41	106
Cumulative translation adjustment	(117)	(136)	14	(240)
	(28)	(29)	155	33
Comprehensive Income Attributable to Merck & Co., Inc.	$ 1,873	$ 1,921	$ 7,642	$ 4,426

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

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

	September 30, 2019	December 31, 2018
Assets		
Current Assets		
Cash and cash equivalents	$ 7,869	$ 7,965
Short-term investments	149	899
Accounts receivable (net of allowance for doubtful accounts of $116 in 2019 and $119 in 2018)	8,442	7,071
Inventories (excludes inventories of $1,515 in 2019 and $1,417 in 2018 classified in Other assets - see Note 6)	5,855	5,440
Other current assets	3,827	4,500
Total current assets	26,142	25,875
Investments	2,111	6,233
Property, Plant and Equipment, at cost, net of accumulated depreciation of $17,281 in 2019 and $16,324 in 2018	14,287	13,291
Goodwill	19,480	18,253
Other Intangibles, Net	12,307	11,431
Other Assets	9,004	7,554
	$ 83,331	$ 82,637
Liabilities and Equity		
Current Liabilities		
Loans payable and current portion of long-term debt	$ 3,411	$ 5,308
Trade accounts payable	3,198	3,318
Accrued and other current liabilities	11,768	10,151
Income taxes payable	873	1,971
Dividends payable	1,434	1,458
Total current liabilities	20,684	22,206
Long-Term Debt	22,677	19,806
Deferred Income Taxes	1,960	1,702
Other Noncurrent Liabilities	11,085	12,041
Merck & Co., Inc. Stockholders' Equity		
Common stock, $0.50 par value Authorized - 6,500,000,000 shares Issued - 3,577,103,522 shares in 2019 and 2018	1,788	1,788
Other paid-in capital	39,561	38,808
Retained earnings	45,804	42,579
Accumulated other comprehensive loss	(5,390)	(5,545)
	81,763	77,630
Less treasury stock, at cost: 1,026,214,892 shares in 2019 and 984,543,979 shares in 2018	54,925	50,929
Total Merck & Co., Inc. stockholders' equity	26,838	26,701
Noncontrolling Interests	87	181
Total equity	26,925	26,882
	$ 83,331	$ 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)

	Nine Months Ended September 30,	
	2019	2018
Cash Flows from Operating Activities		
Net income	$ 7,414	$ 4,415
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	2,716	3,521
Intangible asset impairment charges	864	—
Charge for acquisition of Peloton Therapeutics, Inc.	982	—
Charge for future payments related to collaboration license options	—	650
Charge for collaboration termination	—	420
Deferred income taxes	(386)	(391)
Share-based compensation	306	261
Other	219	488
Net changes in assets and liabilities	(3,469)	(2,034)
Net Cash Provided by Operating Activities	8,646	7,330
Cash Flows from Investing Activities		
Capital expenditures	(2,336)	(1,686)
Purchases of securities and other investments	(2,380)	(6,899)
Proceeds from sales of securities and other investments	7,459	11,243
Acquisition of Antelliq Corporation, net of cash acquired	(3,620)	—
Acquisition of Peloton Therapeutics, Inc., net of cash acquired	(1,040)	—
Other acquisitions, net of cash acquired	(269)	(372)
Other	320	(150)
Net Cash (Used in) Provided by Investing Activities	(1,866)	2,136
Cash Flows from Financing Activities		
Net change in short-term borrowings	(3,892)	2,294
Payments on debt	—	(3,007)
Proceeds from issuance of debt	4,958	—
Purchases of treasury stock	(3,730)	(3,158)
Dividends paid to stockholders	(4,290)	(3,895)
Proceeds from exercise of stock options	344	461
Other	(240)	(289)
Net Cash Used in Financing Activities	(6,850)	(7,594)
Effect of Exchange Rate Changes on Cash, Cash Equivalents and Restricted Cash	(26)	(140)
Net (Decrease) Increase in Cash, Cash Equivalents and Restricted Cash	(96)	1,732
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 $2 million at September 30, 2019 included in Other Assets)	$ 7,871	$ 7,828

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 Financial Accounting Standards Board (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 are classified as either operating or finance. Operating leases result in straight-line expense in the income statement (similar to previous operating leases), while finance leases result in more expense being recognized in the earlier years of the lease term (similar to previous 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 8). The adoption of the new guidance did not impact the Company's consolidated statements of income or cash flows.

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 Company adopted the new standard in the third quarter of 2019 using prospective application for eligible costs, which were immaterial.

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 continuing to assess the impact of adopting the new standard but does not expect the adoption to have a material impact on its consolidated financial statements, subject to the finalization of its assessment.

In November 2018, the FASB issued new guidance for collaborative arrangements intended to reduce diversity in practice by clarifying whether certain transactions between collaborative arrangement participants should be accounted for under revenue recognition guidance (ASC 606). The 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, Divestitures, Research Collaborations and License Agreements

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

In July 2019, Merck acquired Peloton Therapeutics, Inc. (Peloton), a clinical-stage biopharmaceutical company focused on the development of novel small molecule therapeutic candidates targeting hypoxia-inducible factor-2α (HIF-2α) for the treatment of patients with cancer and other non-oncology diseases. Peloton's lead candidate, MK-6482 (formerly PT2977), is a novel oral

HIF-2α inhibitor in late-stage development for renal cell carcinoma. Merck made an upfront payment of $1.2 billion in cash; additionally, former Peloton shareholders will be eligible to receive $50 million upon U.S. regulatory approval, $50 million upon first commercial sale in the United States, and up to $1.05 billion of sales-based milestones. The transaction was accounted for as an acquisition of an asset. Merck recorded cash of $157 million, deferred tax liabilities of $64 million, and other net liabilities of $6 million at the acquisition date and *Research and development* expenses of $982 million in the third quarter and first nine months of 2019 related to the transaction.

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

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

($ in millions)		April 1, 2019
Cash and cash equivalents	$	31
Accounts receivable		73
Inventories		95
Property, plant and equipment		62
Identifiable intangible assets (useful lives ranging from 18-24 years) [(1)]		2,689
Deferred income tax liabilities		(563)
Other assets and liabilities, net		(81)
Total identifiable net assets		2,306
Goodwill [(2)]		1,345
Consideration transferred	$	3,651

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

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

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

Also in April 2019, Merck acquired Immune Design, a late-stage immunotherapy company employing next-generation *in vivo* approaches to enable the body's immune system to fight disease, for $301 million in cash. The transaction was accounted for as an acquisition of a business. Merck recognized intangible assets for in-process research and development (IPR&D) of $156 million, cash of $83 million and other net assets of $31 million. The excess of the consideration transferred over the fair value of net assets acquired of $31 million was recorded as goodwill that was allocated to the Pharmaceutical segment and is not deductible for tax purposes. The fair values of the identifiable intangible assets related to IPR&D were determined using an income approach. Actual cash flows are likely to be different than those assumed.

In the third quarter of 2018, the Company recorded an aggregate charge of $420 million within *Cost of sales* in conjunction with the termination of a collaboration agreement entered into in 2014 with Samsung Bioepis Co., Ltd. (Samsung) for insulin glargine. The charge reflects a termination payment of $155 million, which represents the reimbursement of all fees previously paid by Samsung to Merck under the agreement, plus interest, as well as the release of Merck's ongoing obligations under the agreement. The charge also included fixed asset abandonment charges of $137 million, inventory write-offs of $122 million, as well as other related costs of $6 million. The termination of this agreement has no impact on the Company's other collaboration with Samsung.

In June 2018, Merck acquired Viralytics Limited (Viralytics), an Australian publicly traded company focused on oncolytic immunotherapy treatments for a range of cancers, for AUD 502 million ($378 million). The transaction provided Merck with full rights to V937 (formerly CVA21), Viralytics's investigational oncolytic immunotherapy. V937 is based on Viralytics's proprietary formulation of an oncolytic virus (Coxsackievirus Type A21) that has been shown to preferentially infect and kill cancer cells. V937 is currently being evaluated in multiple Phase 1 and Phase 2 clinical trials, both as an intratumoral and intravenous agent, including in combination with *Keytruda*. Under a previous agreement between Merck and Viralytics, a study is investigating the use of the *Keytruda* and V937 combination in melanoma, prostate, lung and bladder cancers. The transaction was accounted for as an acquisition of an asset. Merck recorded net assets of $34 million (primarily cash) at the acquisition date and *Research and development* expenses of $344 million in the first nine months of 2018 related to the transaction. There are no future contingent payments associated with the acquisition.

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 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.

In the second quarter of 2019, Merck determined it was probable that annual sales of Lynparza in the future would trigger a $300 million sales-based milestone payment from Merck to AstraZeneca. Accordingly, in the second quarter of 2019, Merck recorded a $300 million liability and a corresponding increase to the intangible asset related to Lynparza and also recognized $52 million of cumulative amortization expense within *Cost of sales*. Prior to 2019, Merck accrued sales-based milestone payments aggregating $700 million related to Lynparza. Of these amounts, $450 million has been paid to AstraZeneca. Potential future sales-based milestone payments of $3.1 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 (EU) 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 June 2019, Lynparza received regulatory approval in the EU as a monotherapy for the maintenance treatment of certain adult patients with *BRCA*-mutated advanced ovarian 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 $1.7 billion remain under the agreement.

The asset balance related to Lynparza (which includes capitalized sales-based and regulatory milestone payments) was $983 million at September 30, 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 financial information related to this collaboration is as follows:

($ in millions)	Three Months Ended September 30, 2019	Three Months Ended September 30, 2018	Nine Months Ended September 30, 2019	Nine Months Ended September 30, 2018
Alliance revenue	$ 123	$ 49	$ 313	$ 125
Cost of sales [1]	28	12	120	48
Selling, general and administrative	36	12	96	28
Research and development	44	47	122	118

($ in millions)	September 30, 2019	December 31, 2018
Receivables from AstraZeneca included in *Other current assets*	$ 119	$ 52
Payables to AstraZeneca included in *Accrued and other current liabilities* [2]	578	405
Payables to AstraZeneca included in *Other Noncurrent Liabilities* [3]	300	250

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

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

[3] *Includes accrued milestone 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 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 related to Lenvima in 2018. Of these amounts, $50 million has been paid to Eisai. 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 $664 million at September 30, 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 financial information related to this collaboration is as follows:

($ in millions)	Three Months Ended September 30, 2019	Three Months Ended September 30, 2018	Nine Months Ended September 30, 2019	Nine Months Ended September 30, 2018
Alliance revenue	$ 109	$ 43	$ 280	$ 78
Cost of sales [1]	23	8	97	9
Selling, general and administrative	21	5	59	7
Research and development [2]	37	36	146	1,473

($ in millions)	September 30, 2019	December 31, 2018
Receivables from Eisai included in *Other current assets*	$ 109	$ 71
Payables to Eisai included in *Accrued and other current liabilities* [3]	692	375
Payables to Eisai included in *Other Noncurrent Liabilities* [3]	125	543

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

[2] *Amount for the first nine months of 2018 includes 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. 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 the second quarter of 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 and also recognized $106 million of cumulative amortization expense within *Cost of sales*. 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 $893 million at September 30, 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 financial information related to this collaboration is as follows:

($ in millions)	Three Months Ended September 30, 2019	Three Months Ended September 30, 2018	Nine Months Ended September 30, 2019	Nine Months Ended September 30, 2018
Net product sales recorded by Merck	$ 57	$ 47	$ 158	$ 138
Merck's profit share from sales in Bayer's marketing territories	50	47	144	100
Total sales	107	94	302	238
Cost of sales [1]	28	29	86	188
Selling, general and administrative	12	11	31	26
Research and development	31	34	94	90

($ in millions)	September 30, 2019	December 31, 2018
Receivables from Bayer included in *Other current assets*	$ 44	$ 32
Payables to Bayer included in *Other Noncurrent Liabilities* [2]	375	375

[1] *Includes amortization of intangible assets.*

[2] *Represents accrued milestone payment.*

4. Restructuring

Merck recently approved a new global restructuring program (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 60% of the cumulative pretax costs will result in cash outlays, primarily related to employee separation expense and facility shut-down costs. Approximately 40% of the cumulative pretax costs will be non-cash, relating primarily to the accelerated depreciation of facilities to be closed or divested. The Company expects to record charges of approximately $750 million in 2019 related to the program. Actions under previous global restructuring programs have been substantially completed.

The Company recorded total pretax costs of $296 million and $169 million in the third quarter of 2019 and 2018, respectively, and $642 million and $508 million for the first nine months 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 September 30, 2019				Nine Months Ended September 30, 2019			
($ in millions)	Separation Costs	Accelerated Depreciation	Other	Total	Separation Costs	Accelerated Depreciation	Other	Total
Cost of sales	$ —	$ 41	$ 21	$ 62	$ —	$ 139	$ 22	$ 161
Selling, general and administrative	—	1	—	1	—	33	—	33
Research and development	—	(1)	2	1	—	1	3	4
Restructuring costs	205	—	27	232	358	—	86	444
	$ 205	$ 41	$ 50	$ 296	$ 358	$ 173	$ 111	$ 642

	Three Months Ended September 30, 2018				Nine Months Ended September 30, 2018			
($ in millions)	Separation Costs	Accelerated Depreciation	Other	Total	Separation Costs	Accelerated Depreciation	Other	Total
Cost of sales	$ —	$ 1	$ 1	$ 2	$ —	$ 1	$ 10	$ 11
Selling, general and administrative	—	—	—	—	—	1	1	2
Research and development	—	(9)	5	(4)	—	(12)	13	1
Restructuring costs	137	—	34	171	392	—	102	494
	$ 137	$ (8)	$ 40	$ 169	$ 392	$ (10)	$ 126	$ 508

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 12) and share-based compensation.

The following table summarizes the charges and spending relating to restructuring program activities for the nine months ended September 30, 2019:

($ in millions)	Separation Costs	Accelerated Depreciation	Other	Total
Restructuring reserves January 1, 2019	$ 443	$ —	$ 91	$ 534
Expense	358	173	111	642
(Payments) receipts, net	(198)	—	(158)	(356)
Non-cash activity	—	(173)	20	(153)
Restructuring reserves September 30, 2019 [(1)]	$ 603	$ —	$ 64	$ 667

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

The fair values of these derivative contracts are recorded as either assets (gain positions) or liabilities (loss positions) in the Condensed Consolidated Balance Sheet. Changes in the fair value of derivative contracts are recorded each period in either current earnings or *Other comprehensive income* (*OCI*), depending on whether the derivative is designated as part of a hedge transaction and, if so, the type of hedge transaction. For derivatives that are designated as cash flow hedges, the unrealized gains or losses on these contracts 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 September 30,		Nine Months Ended September 30,		Three Months Ended September 30,		Nine Months Ended September 30,	
($ in millions)	2019	2018	2019	2018	2019	2018	2019	2018
Net Investment Hedging Relationships								
Foreign exchange contracts	$ 1	$ (10)	$ 8	$ (24)	$ (8)	$ (4)	$ (23)	$ (7)
Euro-denominated notes	(150)	38	(152)	(54)	—	—	—	—

[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 September 30, 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.

($ in millions)	September 30, 2019 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)	September 30, 2019	December 31, 2018	September 30, 2019	December 31, 2018
Balance Sheet Line Item in which Hedged Item is Included				
Loans payable and current portion of long-term debt	$ 1,247	$ —	$ (3)	$ —
Long-Term Debt	3,416	4,560	22	(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:

		September 30, 2019			December 31, 2018		
		Fair Value of Derivative			Fair Value of Derivative		
($ in millions)	Balance Sheet Caption	Asset	Liability	U.S. Dollar Notional	Asset	Liability	U.S. Dollar Notional
Derivatives Designated as Hedging Instruments							
Interest rate swap contracts	Other Assets	$ 22	$ —	$ 3,400	$ —	$ —	$ —
Interest rate swap contracts	Accrued and other current liabilities	—	3	1,250	—	—	—
Interest rate swap contracts	Other Noncurrent Liabilities	—	—	—	—	81	4,650
Foreign exchange contracts	Other current assets	252	—	7,144	263	—	6,222
Foreign exchange contracts	Other Assets	56	—	2,073	75	—	2,655
Foreign exchange contracts	Accrued and other current liabilities	—	6	775	—	7	774
Foreign exchange contracts	Other Noncurrent Liabilities	—	1	9	—	1	89
		$ 330	$ 10	$ 14,651	$ 338	$ 89	$ 14,390
Derivatives Not Designated as Hedging Instruments							
Foreign exchange contracts	Other current assets	$ 153	$ —	$ 6,802	$ 116	$ —	$ 5,430
Foreign exchange contracts	Accrued and other current liabilities	—	100	6,906	—	71	9,922
		$ 153	$ 100	$ 13,708	$ 116	$ 71	$ 15,352
		$ 483	$ 110	$ 28,359	$ 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:

	September 30, 2019		December 31, 2018	
($ in millions)	Asset	Liability	Asset	Liability
Gross amounts recognized in the condensed consolidated balance sheet	$ 483	$ 110	$ 454	$ 160
Gross amounts subject to offset in master netting arrangements not offset in the condensed consolidated balance sheet	(73)	(73)	(121)	(121)
Cash collateral received	(133)	—	(107)	—
Net amounts	$ 277	$ 37	$ 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)		Sales		Other (income) expense, net [1]		Other comprehensive income (loss)	
	Three Months Ended September 30,		Three Months Ended September 30,		Three Months Ended September 30,		Nine Months Ended September 30,		Nine Months Ended September 30,		Nine Months Ended September 30,	
($ in millions)	2019	2018	2019	2018	2019	2018	2019	2018	2019	2018	2019	2018
Financial Statement Line Items in which Effects of Fair Value or Cash Flow Hedges are Recorded	$ 12,397	$ 10,794	$ 35	$ (172)	$ (28)	$ (29)	$ 34,972	$ 31,296	$ 362	$ (512)	$ 155	$ 33
(Gain) loss on fair value hedging relationships												
Interest rate swap contracts												
Hedged items	—	—	13	(9)	—	—	—	—	101	(86)	—	—
Derivatives designated as hedging instruments	—	—	(6)	15	—	—	—	—	(74)	100	—	—
Impact of cash flow hedging relationships												
Foreign exchange contracts												
Amount of income (loss) recognized in *OCI* on derivatives	—	—	—	—	186	29	—	—	—	—	183	113
Increase (decrease) in *Sales* as a result of *AOCI* reclassifications	70	(6)	—	—	(70)	6	189	(172)	—	—	(189)	172
Interest rate contracts												
Amount of gain recognized in *Other (income) expense, net* on derivatives	—	—	(1)	(1)	—	—	—	—	(3)	(3)	—	—
Amount of loss recognized in *OCI* on derivatives	—	—	—	—	(1)	(1)	—	—	—	—	(6)	(3)

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

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

		Amount of Derivative Pretax (Gain) Loss Recognized in Income			
		Three Months Ended September 30,		Nine Months Ended September 30,	
($ in millions)	Income Statement Caption	2019	2018	2019	2018
Derivatives Not Designated as Hedging Instruments					
Foreign exchange contracts [1]	Other (income) expense, net	$ (8)	$ (57)	$ 112	$ (224)
Foreign exchange contracts [2]	Sales	(11)	—	(7)	(5)

[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 September 30, 2019, the Company estimates $174 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:

	September 30, 2019				December 31, 2018			
		Gross Unrealized				Gross Unrealized		
($ in millions)	Amortized Cost	Gains	Losses	Fair Value	Amortized Cost	Gains	Losses	Fair Value
Corporate notes and bonds	$ 1,260	$ 24	$ —	$ 1,284	$ 4,985	$ 3	$ (68)	$ 4,920
Asset-backed securities	434	3	—	437	1,285	1	(11)	1,275
U.S. government and agency securities	358	4	—	362	895	2	(5)	892
Foreign government bonds	32	—	—	32	167	—	(1)	166
Mortgage-backed securities	—	—	—	—	8	—	—	8
Total debt securities	$ 2,084	$ 31	$ —	$ 2,115	$ 7,340	$ 6	$ (85)	$ 7,261
Publicly traded equity securities [(1)]				691				456
Total debt and publicly traded equity securities				$ 2,806				$ 7,717

[(1)] *Unrealized net losses (gains) recognized in* Other (income) expense, net *on equity securities still held at September 30, 2019 were $25 million and $(10) million, for the third quarter of 2019 and 2018, respectively, and were $(41) million and $(60) million for the first nine months of 2019 and 2018, respectively.*

At September 30, 2019, the Company also had $393 million of equity investments without readily determinable fair values included in *Other Assets*. During the first nine months of 2019, the Company recognized unrealized gains of $4 million on certain of these equity investments recorded in *Other (income) expense, net* based on favorable observable price changes from transactions involving similar investments of the same investee. In addition, during the first nine months of 2019, the Company recognized unrealized losses of $12 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 $172 million and $21 million, respectively.

Available-for-sale debt securities included in *Short-term investments* totaled $129 million at September 30, 2019. Of the remaining debt securities, $1.8 billion mature within five years. At September 30, 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)	September 30, 2019				December 31, 2018			
Assets								
Investments								
Corporate notes and bonds	$ —	$ 1,284	$ —	$ 1,284	$ —	$ 4,835	$ —	$ 4,835
Asset-backed securities [1]	—	437	—	437	—	1,253	—	1,253
U.S. government and agency securities	—	301	—	301	—	731	—	731
Foreign government bonds	—	32	—	32	—	166	—	166
Publicly traded equity securities	206	—	—	206	147	—	—	147
	206	2,054	—	2,260	147	6,985	—	7,132
Other assets [2]								
U.S. government and agency securities	61	—	—	61	55	106	—	161
Corporate notes and bonds	—	—	—	—	—	85	—	85
Mortgage-backed securities	—	—	—	—	—	8	—	8
Asset-backed securities [1]	—	—	—	—	—	22	—	22
Publicly traded equity securities	485	—	—	485	309	—	—	309
	546	—	—	546	364	221	—	585
Derivative assets [3]								
Forward exchange contracts	—	259	—	259	—	241	—	241
Purchased currency options	—	202	—	202	—	213	—	213
Interest rate swaps	—	22	—	22	—	—	—	—
	—	483	—	483	—	454	—	454
Total assets	$ 752	$ 2,537	$ —	$ 3,289	$ 511	$ 7,660	$ —	$ 8,171
Liabilities								
Other liabilities								
Contingent consideration	$ —	$ —	$ 755	$ 755	$ —	$ —	$ 788	$ 788
Derivative liabilities [3]								
Forward exchange contracts	—	105	—	105	—	74	—	74
Interest rate swaps	—	3	—	3	—	81	—	81
Written currency options	—	2	—	2	—	5	—	5
	—	110	—	110	—	160	—	160
Total liabilities	$ —	$ 110	$ 755	$ 865	$ —	$ 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 nine months of 2019. As of September 30, 2019, *Cash and cash equivalents* of $7.9 billion included $7.1 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:

	Nine Months Ended September 30,	
($ in millions)	2019	2018
Fair value January 1	$ 788	$ 935
Changes in estimated fair value [(1)]	52	144
Additions	—	8
Payments	(85)	(235)
Fair value September 30 [(2)]	$ 755	$ 852

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

[(2)] *Balance at September 30, 2019 includes $112 million recorded as a current liability for amounts expected to be paid within the next 12 months.*

The payments of contingent consideration in both periods include payments related to liabilities recorded in connection with the 2016 termination of the Sanofi-Pasteur MSD joint venture. The payments of contingent consideration in the first nine months of 2018 also include $175 million related to the achievement of a clinical development milestone for MK-7264 (gefapixant), a program obtained in connection with the acquisition of Afferent Pharmaceuticals.

Other Fair Value Measurements

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

The estimated fair value of loans payable and long-term debt (including current portion) at September 30, 2019, was $28.7 billion compared with a carrying value of $26.1 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 $133 million and $107 million at September 30, 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 September 30, 2019 or December 31, 2018.

6. Inventories

Inventories consisted of:

($ in millions)	September 30, 2019	December 31, 2018
Finished goods	$ 1,698	$ 1,658
Raw materials and work in process	5,526	5,004
Supplies	213	194
Total (approximates current cost)	7,437	6,856
(Decrease) increase to LIFO costs	(67)	1
	$ 7,370	$ 6,857
Recognized as:		
Inventories	$ 5,855	$ 5,440
Other assets	1,515	1,417

Amounts recognized as *Other Assets* are comprised almost entirely of raw materials and work in process inventories. At September 30, 2019 and December 31, 2018, these amounts included $1.4 billion of inventories not expected to be sold within one year. In addition, these amounts included $138 million and $7 million at September 30, 2019 and December 31, 2018, respectively, of inventories produced in preparation for product launches.

7. Other Intangibles

In connection with business acquisitions, the Company measures the fair value of marketed products and research and development pipeline programs and capitalizes these amounts. See Note 2 for information on intangible assets acquired as a result of business acquisitions in the first nine months of 2019 and 2018.

During the third quarter and first nine months of 2019, the Company recorded $612 million and $693 million, respectively, of intangible asset impairment charges related to marketed products within *Cost of sales*. During the third quarter of 2019, the Company recorded an impairment charge of $612 million related to *Sivextro* (tedizolid phosphate), a product for the treatment of acute bacterial skin and skin structure infections caused by designated susceptible Gram-positive organisms. In the third quarter of 2019, as part of a reorganization and reprioritization of its internal sales force, the Company made the decision to cease promotion of *Sivextro* in the U.S. market by the end of 2019. This decision resulted in reduced cash flow projections for *Sivextro*, which indicated that the *Sivextro* intangible asset value was not fully recoverable on an undiscounted cash flows basis. The Company utilized market participant assumptions to determine its best estimate of the fair value of the intangible asset related to *Sivextro* that, when compared with its related carrying value, resulted in the impairment charge noted above. The remaining intangible asset value for *Sivextro* was $175 million at September 30, 2019.

8. 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 used the net proceeds from the offering of $5.0 billion for general corporate purposes, including the repayment of outstanding commercial paper borrowings.

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 $79 million and $244 million for the third quarter and first nine months of 2019, respectively. Cash paid for amounts included in the measurement of operating lease liabilities was $71 million and $209 million for the third quarter and first nine months of 2019, respectively.

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

($ in millions)		September 30, 2019
Assets		
Other Assets [(1)]	$	1,085
Liabilities		
Accrued and other current liabilities	$	241
Other Noncurrent Liabilities		779
	$	1,020
Weighted-average remaining lease term (years)		7.5
Weighted-average discount rate		3.3%

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

Maturities of operating leases liabilities are as follows:

($ in millions)		September 30, 2019
2019 (excluding the nine months ended September 30, 2019)	$	71
2020		235
2021		189
2022		155
2023		127
Thereafter		374
Total lease payments		1,151
Less: imputed interest		(131)
	$	1,020

As of September 30, 2019, the Company had entered into additional real estate operating leases that had not yet commenced. The obligations associated with these leases totaled $444 million, of which $221 million relates to a lease that will commence in April 2020 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.

9. Contingencies

The Company is involved in various claims and legal proceedings of a nature considered normal to its business, including product liability, intellectual property, and commercial litigation, as well as certain additional matters including governmental and environmental matters. In the opinion of the Company, it is unlikely that the resolution of these matters will be material to the Company's financial 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 September 30, 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*.

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. On May 20, 2019, the Supreme Court issued its opinion and decided that the Third Circuit had incorrectly concluded that the issue of preemption should be resolved by a jury, and accordingly vacated the judgment of the Third Circuit and remanded the proceedings back to the Third Circuit to address the issue in a manner consistent with the Supreme Court's opinion. The Third Circuit requested, by August 6, 2019, ten-page letters from each side addressing two specific issues central to the appeal. Both sides submitted their letter briefs and await a decision from the Third Circuit.

Accordingly, as of September 30, 2019, 11 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 Third Circuit of the appeal of the Femur Fracture MDL court's preemption order.

As of September 30, 2019, approximately 2,520 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 September 30, 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 September 30, 2019, Merck is aware of approximately 1,370 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 September 30, 2019, six product users have claims pending against Merck in state courts other than California, including Illinois. In June 2017, the Illinois trial court denied Merck's motion for summary judgment based on federal preemption. Merck appealed, and the Illinois appellate court affirmed in December 2018. Merck filed a petition for leave to appeal to the Illinois Supreme Court in February 2019. In April 2019, the Illinois Supreme Court stayed consideration of the pending petition to appeal until the United States Supreme Court issued its opinion in *Merck Sharp & Dohme Corp. v. Albrecht* (relating to the *Fosamax* matter discussed above). Merck filed the opinion in *Albrecht* with the Illinois Supreme Court in June 2019. The petition for leave to appeal was decided on September 25, 2019, in which the Illinois Supreme Court directed the intermediate appellate court to reconsider its earlier ruling.

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.

Governmental Proceedings

As previously disclosed, in July 2017, Merck received a subpoena from the California Department of Insurance (DOI) pursuant to an investigation of whether, prior to Merck's acquisition of the company, Cubist Pharmaceuticals unlawfully induced the presentation of false claims for *Cubicin* to private insurers under the California Insurance Code False Claims Act. By letter dated August 12, 2019, the DOI advised Merck that it was withdrawing the subpoena and closing its investigation.

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

As previously disclosed, from time to time, the Company receives inquiries and is the subject of preliminary investigation activities from competition and other governmental authorities in markets outside the United States. These authorities may include regulators, administrative authorities, and law enforcement and other similar officials, and these preliminary investigation activities may include site visits, formal or informal requests or demands for documents or materials, inquiries or interviews and similar matters. Certain of these preliminary inquiries or activities may lead to the commencement of formal proceedings. Should those proceedings be determined adversely to the Company, monetary fines and/or remedial undertakings may be required.

Commercial and Other Litigation

Zetia *Antitrust Litigation*

As previously disclosed, Merck, MSD, Schering Corporation and MSP Singapore Company LLC (collectively, the Merck Defendants) are defendants in putative class action and opt-out lawsuits filed in 2018 on behalf of direct and indirect purchasers of *Zetia* alleging violations of federal and state antitrust laws, as well as other state statutory and common law causes of action. The cases have been consolidated for pretrial purposes in a federal multidistrict litigation before Judge Rebecca Beach Smith in the Eastern District of Virginia. In December 2018, the court denied the Merck Defendants' motions to dismiss or stay the direct purchaser putative class actions pending bilateral arbitration. On August 9, 2019, the district court adopted in full the report and recommendation of the magistrate judge, thereby granting in part and denying in part Merck Defendants' motions to dismiss on non-arbitration issues. In addition, on June 27, 2019, the representatives of the putative direct purchaser class filed an amended complaint, and on August 1, 2019, retailer opt-out plaintiffs filed an amended complaint. The Merck Defendants moved to dismiss the new allegations in both complaints. On October 15, 2019, the magistrate judge issued a report and recommendation recommending that the district judge grant the motions in their entirety. Trial is currently scheduled to begin on October 14, 2020.

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. On October 28, 2019, the Third Circuit vacated the district court's order and remanded for limited discovery on the issue of arbitrability, after which MSD may file a renewed motion to compel arbitration.

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.

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. The Company filed a patent infringement lawsuit against Mylan Pharmaceuticals Inc. and Mylan Inc. (Mylan) in the Northern District of West Virginia. The Judicial Panel of Multidistrict Litigation entered an order transferring the Company's lawsuit against Mylan to the U.S. District Court for the District of Delaware for coordinated and consolidated pretrial proceedings with the other cases pending in that district. The U.S. District Court for the District of Delaware has scheduled the lawsuits for a single 3-day trial on invalidity issues in October 2021. The Court will schedule separate 1-day trials on infringement issues if necessary. In October 2019, Mylan filed a petition for *Inter Partes* Review (IPR) at the United States Patent and Trademark Office (USPTO) seeking invalidity of the 2026 patent. The USPTO has six months from filing to determine whether it will institute the requested IPR proceeding.

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 September 30, 2019 and December 31, 2018 of approximately $260 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.

10. Equity

	Three Months Ended September 30,								
	Common Stock		Other Paid-In Capital	Retained Earnings	Accumulated Other Comprehensive Loss	Treasury Stock		Non-controlling Interests	Total
($ and shares in millions except per share amounts)	Shares	Par Value				Shares	Cost		
Balance at July 1, 2018	3,577	$ 1,788	$ 39,741	$ 41,523	$ (5,122)	907	$ (45,401)	$ 237	$ 32,766
Net income attributable to Merck & Co., Inc.	—	—	—	1,950	—	—	—	—	1,950
Other comprehensive loss, net of taxes	—	—	—	—	(29)	—	—	—	(29)
Cash dividends declared on common stock ($0.48 per share)	—	—	—	(1,284)	—	—	—	—	(1,284)
Treasury stock shares purchased	—	—	—	—	—	16	(996)	—	(996)
Share-based compensation plans and other	—	—	21	—	—	(5)	231	—	252
Net income attributable to noncontrolling interests	—	—	—	—	—	—	—	8	8
Distributions attributable to noncontrolling interests	—	—	—	—	—	—	—	(11)	(11)
Balance at September 30, 2018	3,577	$ 1,788	$ 39,762	$ 42,189	$ (5,151)	918	$ (46,166)	$ 234	$ 32,656
Balance at July 1, 2019	3,577	$ 1,788	$ 39,484	$ 45,295	$ (5,362)	1,010	$ (53,570)	$ 102	$ 27,737
Net income attributable to Merck & Co., Inc.	—	—	—	1,901	—	—	—	—	1,901
Other comprehensive loss, net of taxes	—	—	—	—	(28)	—	—	—	(28)
Cash dividends declared on common stock ($0.55 per share)	—	—	—	(1,392)	—	—	—	—	(1,392)
Treasury stock shares purchased	—	—	—	—	—	17	(1,405)	—	(1,405)
Share-based compensation plans and other	—	—	77	—	—	(1)	50	—	127
Net income attributable to noncontrolling interests	—	—	—	—	—	—	—	6	6
Distributions attributable to noncontrolling interests	—	—	—	—	—	—	—	(21)	(21)
Balance at September 30, 2019	3,577	$ 1,788	$ 39,561	$ 45,804	$ (5,390)	1,026	$ (54,925)	$ 87	$ 26,925

	Nine Months Ended September 30,							
	Common Stock		Other Paid-In Capital	Retained Earnings	Accumulated Other Comprehensive Loss	Treasury Stock		Non-controlling Interests	Total
($ and shares in millions except per share amounts)	Shares	Par Value				Shares	Cost		
Balance at January 1, 2018	3,577	$ 1,788	$ 39,902	$ 41,350	$ (4,910)	880	$ (43,794)	$ 233	$ 34,569
Net income attributable to Merck & Co., Inc.	—	—	—	4,393	—	—	—	—	4,393
Adoption of new accounting standards	—	—	—	322	(274)	—	—	—	48
Other comprehensive income, net of taxes	—	—	—	—	33	—	—	—	33
Cash dividends declared on common stock ($1.44 per share)	—	—	—	(3,876)	—	—	—	—	(3,876)
Treasury stock shares purchased	—	—	—	—	—	53	(3,158)	—	(3,158)
Share-based compensation plans and other	—	—	(140)	—	—	(15)	786	—	646
Net income attributable to noncontrolling interests	—	—	—	—	—	—	—	22	22
Distributions attributable to noncontrolling interests	—	—	—	—	—	—	—	(21)	(21)
Balance at September 30, 2018	3,577	$ 1,788	$ 39,762	$ 42,189	$ (5,151)	918	$ (46,166)	$ 234	$ 32,656
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.	—	—	—	7,487	—	—	—	—	7,487
Other comprehensive income, net of taxes	—	—	—	—	155	—	—	—	155
Cash dividends declared on common stock ($1.65 per share)	—	—	—	(4,262)	—	—	—	—	(4,262)
Treasury stock shares purchased	—	—	1,000	—	—	54	(4,730)	—	(3,730)
Share-based compensation plans and other	—	—	(247)	—	—	(13)	734	—	487
Net loss attributable to noncontrolling interests	—	—	—	—	—	—	—	(73)	(73)
Distributions attributable to noncontrolling interests	—	—	—	—	—	—	—	(21)	(21)
Balance at September 30, 2019	3,577	$ 1,788	$ 39,561	$ 45,804	$ (5,390)	1,026	$ (54,925)	$ 87	$ 26,925

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 was reflected as an increase to treasury stock and an increase to other-paid-in capital in the first nine months of 2019.

11. 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 September 30,		Nine Months Ended September 30,	
($ in millions)	2019	2018	2019	2018
Pretax share-based compensation expense	$ 101	$ 91	$ 306	$ 261
Income tax benefit	(14)	(14)	(42)	(42)
Total share-based compensation expense, net of taxes	$ 87	$ 77	$ 264	$ 219

During the first nine months of 2019, the Company granted 5 million RSUs with a weighted-average grant date fair value of $80.03 per RSU and during the first nine months of 2018 granted 7 million RSUs with a weighted-average grant date fair

value of $58.19 per RSU. During the first nine months of 2019, the Company granted 609 thousand PSUs with a weighted-average grant date fair value of $90.50 per PSU and during the first nine months of 2018 granted 855 thousand PSUs with a weighted-average grant date fair value of $56.70 per PSU.

During the first nine months of 2019, the Company granted 3 million stock options with a weighted-average exercise price of $80.05 per option and during the first nine months of 2018 granted 3 million stock options with a weighted-average exercise price of $57.72 per option. The weighted-average fair value of options granted during the first nine months of 2019 and 2018 was $10.63 and $8.19 per option, respectively, and was determined using the following assumptions:

	Nine Months Ended September 30,	
	2019	2018
Expected dividend yield	3.2%	3.4%
Risk-free interest rate	2.4%	2.8%
Expected volatility	18.7%	19.1%
Expected life (years)	5.9	6.1

At September 30, 2019, there was $691 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 2.0 years. For segment reporting, share-based compensation costs are unallocated expenses.

12. 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 September 30,				Nine Months Ended September 30,			
	2019		2018		2019		2018	
($ in millions)	U.S.	International	U.S.	International	U.S.	International	U.S.	International
Service cost	$ 76	$ 58	$ 77	$ 56	$ 221	$ 178	$ 245	$ 181
Interest cost	115	44	109	43	343	133	324	134
Expected return on plan assets	(202)	(106)	(209)	(106)	(613)	(320)	(634)	(326)
Amortization of unrecognized prior service credit	(12)	(3)	(12)	(3)	(37)	(9)	(37)	(10)
Net loss amortization	43	16	63	21	113	47	174	64
Termination benefits	3	—	1	—	7	1	18	—
Curtailments	5	—	3	—	6	—	7	(1)
Settlements	—	—	—	—	—	—	1	3
	$ 28	$ 9	$ 32	$ 11	$ 40	$ 30	$ 98	$ 45

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
($ in millions)	2019	2018	2019	2018
Service cost	$ 12	$ 15	$ 36	$ 43
Interest cost	17	17	52	52
Expected return on plan assets	(18)	(21)	(54)	(63)
Amortization of unrecognized prior service credit	(20)	(21)	(59)	(63)
Net loss amortization	(3)	—	(7)	1
Termination benefits	1	—	1	2
Curtailments	(3)	(1)	(4)	(7)
	$ (14)	$ (11)	$ (35)	$ (35)

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 13), 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.

13. Other (Income) Expense, Net

Other (income) expense, net, consisted of:

	Three Months Ended September 30,		Nine Months Ended September 30,	
($ in millions)	2019	2018	2019	2018
Interest income	$ (61)	$ (92)	$ (225)	$ (257)
Interest expense	231	190	674	569
Exchange losses	38	42	166	119
Income from investments in equity securities, net [(1)]	(16)	(198)	(50)	(376)
Net periodic defined benefit plan (credit) cost other than service cost	(128)	(119)	(409)	(384)
Other, net	(29)	5	206	(183)
	$ 35	$ (172)	$ 362	$ (512)

[(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 the first nine months of 2019 reflect losses on forward exchange contracts related to the acquisition of Antelliq.

Other, net (as reflected in the table above) in the first nine months of 2019 includes $162 million of goodwill impairment charges related to certain businesses in the Healthcare Services segment. Other, net in the first nine months of 2018 includes a $115 million gain on the settlement of certain patent litigation and $84 million of income related to AstraZeneca's option exercise associated with AstraZeneca LP.

Interest paid for the nine months ended September 30, 2019 and 2018 was $629 million and $535 million, respectively.

14. Taxes on Income

The effective income tax rates of 18.7% and 26.5% for the third quarter of 2019 and 2018, respectively, and 14.5% and 27.6% for the first nine months 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. The effective income tax rates in the third quarter and first nine months of 2019 also reflect the unfavorable impact of a charge for the acquisition of Peloton for which no tax benefit was recognized and the favorable impact of product mix on the estimated full-year tax rate. In addition, the effective income tax rate for the first nine months 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 nine months of 2018 reflects the unfavorable impact of a 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 nine months of 2019. This net benefit reflects reductions in reserves for unrecognized tax benefits for tax positions relating to the years that were under examination, partially offset by additional reserves for tax positions not previously reserved for.

15. Earnings Per Share

The calculations of earnings per share are as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
($ and shares in millions except per share amounts)	2019	2018	2019	2018
Net income attributable to Merck & Co., Inc.	$ 1,901	$ 1,950	$ 7,487	$ 4,393
Average common shares outstanding	2,558	2,662	2,572	2,680
Common shares issuable [(1)]	14	16	15	14
Average common shares outstanding assuming dilution	2,572	2,678	2,587	2,694
Basic earnings per common share attributable to Merck & Co., Inc. common shareholders	$ 0.74	$ 0.73	$ 2.91	$ 1.64
Earnings per common share assuming dilution attributable to Merck & Co., Inc. common shareholders	$ 0.74	$ 0.73	$ 2.89	$ 1.63

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

For the third quarter of 2019 and 2018, 3 million and 2 million, respectively, and for the first nine months of 2019 and 2018, 2 million and 7 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.

16. Other Comprehensive Income (Loss)

Changes in *AOCI* by component are as follows:

	Three Months Ended September 30,				
($ in millions)	Derivatives	Investments	Employee Benefit Plans	Cumulative Translation Adjustment	Accumulated Other Comprehensive Income (Loss)
Balance July 1, 2018, net of taxes	$ 65	$ (164)	$ (3,065)	$ (1,958)	$ (5,122)
Other comprehensive income (loss) before reclassification adjustments, pretax	29	8	—	(147)	(110)
Tax	(6)	—	—	11	5
Other comprehensive income (loss) before reclassification adjustments, net of taxes	23	8	—	(136)	(105)
Reclassification adjustments, pretax	5 [(1)]	32 [(2)]	47 [(3)]	—	84
Tax	(1)	—	(7)	—	(8)
Reclassification adjustments, net of taxes	4	32	40	—	76
Other comprehensive income (loss), net of taxes	27	40	40	(136)	(29)
Balance September 30, 2018, net of taxes	$ 92	$ (124)	$ (3,025)	$ (2,094)	$ (5,151)
Balance July 1, 2019, net of taxes	$ 66	$ 48	$ (3,530)	$ (1,946)	$ (5,362)
Other comprehensive income (loss) before reclassification adjustments, pretax	186	8	(4)	(84)	106
Tax	(39)	—	—	(33)	(72)
Other comprehensive income (loss) before reclassification adjustments, net of taxes	147	8	(4)	(117)	34
Reclassification adjustments, pretax	(71) [(1)]	(25) [(2)]	21 [(3)]	—	(75)
Tax	15	—	(2)	—	13
Reclassification adjustments, net of taxes	(56)	(25)	19	—	(62)
Other comprehensive income (loss), net of taxes	91	(17)	15	(117)	(28)
Balance September 30, 2019, net of taxes	$ 157	$ 31	$ (3,515)	$ (2,063)	$ (5,390)

	Nine Months Ended September 30,				
($ 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	113	(125)	(2)	(129)	(143)
Tax	(24)	1	4	(111)	(130)
Other comprehensive income (loss) before reclassification adjustments, net of taxes	89	(124)	2	(240)	(273)
Reclassification adjustments, pretax	169 (1)	68 (2)	128 (3)	—	365
Tax	(35)	—	(24)	—	(59)
Reclassification adjustments, net of taxes	134	68	104	—	306
Other comprehensive income (loss), net of taxes	223	(56)	106	(240)	33
Adoption of ASU 2018-02	(23)	1	(344)	100	(266)
Adoption of ASU 2016-01	—	(8)	—	—	(8)
Balance September 30, 2018, net of taxes	$ 92	$ (124)	$ (3,025)	$ (2,094)	$ (5,151)
Balance January 1, 2019, net of taxes	$ 166	$ (78)	$ (3,556)	$ (2,077)	$ (5,545)
Other comprehensive income (loss) before reclassification adjustments, pretax	183	139	(5)	47	364
Tax	(38)	—	6	(33)	(65)
Other comprehensive income (loss) before reclassification adjustments, net of taxes	145	139	1	14	299
Reclassification adjustments, pretax	(195) (1)	(30) (2)	49 (3)	—	(176)
Tax	41	—	(9)	—	32
Reclassification adjustments, net of taxes	(154)	(30)	40	—	(144)
Other comprehensive income (loss), net of taxes	(9)	109	41	14	155
Balance September 30, 2019, net of taxes	$ 157	$ 31	$ (3,515)	$ (2,063)	$ (5,390)

(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 12).*

17. 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 September 30,						Nine Months Ended September 30,					
	2019			2018			2019			2018		
($ in millions)	U.S.	Int'l	Total	U.S.	Int'l	Total	U.S.	Int'l	Total	U.S.	Int'l	Total
Pharmaceutical:												
Oncology												
Keytruda	$ 1,743	$ 1,327	$ 3,070	$ 1,109	$ 780	$ 1,889	$ 4,525	$ 3,448	$ 7,973	$ 2,906	$ 2,114	$ 5,020
Emend	42	56	98	71	52	123	173	163	336	239	157	396
Alliance revenue - Lynparza	71	53	123	33	15	49	186	126	313	88	37	125
Alliance revenue - Lenvima	65	44	109	30	13	43	169	112	280	49	29	78
Vaccines												
Gardasil/Gardasil 9	761	558	1,320	740	308	1,048	1,579	1,464	3,044	1,422	894	2,317
ProQuad/M-M-R II*/Varivax*	482	141	623	429	96	525	1,325	469	1,794	1,097	246	1,343
Pneumovax 23	179	58	237	160	54	214	428	164	592	394	192	586
RotaTeq	102	78	180	134	57	191	360	203	564	384	156	540
Vaqta	36	26	62	36	30	66	103	65	167	95	72	167
Hospital Acute Care												
Bridion	133	151	284	96	120	217	381	437	817	272	389	661
Noxafil	77	100	177	89	99	188	268	291	560	257	294	551
Cubicin	14	38	52	55	40	95	78	129	207	150	137	287
Primaxin	2	75	77	1	71	72	2	204	207	6	206	212
Invanz	(1)	58	57	74	62	137	30	176	206	252	185	437
Cancidas	—	62	62	2	77	79	5	187	191	10	247	257
Immunology												
Simponi	—	203	203	—	210	210	—	625	625	—	673	673
Remicade	—	101	101	—	135	135	—	322	322	—	459	459
Neuroscience												
Belsomra	23	57	80	23	43	66	68	155	223	76	115	191
Virology												
Isentress/Isentress HD	102	149	250	123	151	275	304	449	752	383	477	860
Zepatier	24	59	83	18	86	104	96	208	304	8	339	347
Cardiovascular												
Zetia	5	142	147	9	157	165	11	432	443	34	662	696
Vytorin	5	52	57	—	92	92	11	219	231	11	402	414
Atozet	—	97	97	—	84	84	—	283	283	—	258	258
Adempas	—	107	107	—	94	94	—	302	302	—	238	238
Diabetes												
Januvia	367	440	807	498	429	927	1,223	1,317	2,539	1,466	1,291	2,756
Janumet	129	375	503	225	339	563	462	1,105	1,567	625	1,067	1,693
Women's Health												
NuvaRing	202	39	241	193	41	234	593	107	700	550	135	686
Implanon/Nexplanon	136	62	199	133	53	186	421	160	581	375	160	535
Diversified Brands												
Singulair	11	140	152	5	156	161	24	479	503	16	505	521
Cozaar/Hyzaar	6	110	116	4	99	103	16	313	329	18	330	348
Nasonex	4	55	58	7	64	71	2	224	226	8	266	274
Arcoxia	—	72	72	—	83	83	—	221	221	—	249	249
Follistim AQ	27	35	62	26	34	60	80	102	182	83	115	198
Other pharmaceutical *(1)*	385	842	1,229	326	786	1,109	1,142	2,492	3,634	932	2,557	3,486
Total Pharmaceutical segment sales	5,132	5,962	11,095	4,649	5,010	9,658	14,065	17,153	31,218	12,206	15,653	27,859
Animal Health:												
Livestock	144	582	726	153	508	660	406	1,601	2,007	383	1,563	1,946
Companion Animals	193	203	396	153	207	361	560	704	1,264	541	689	1,230
Total Animal Health segment sales	337	785	1,122	306	715	1,021	966	2,305	3,271	924	2,252	3,176

Other segment sales [2]	46	—	46	55	—	55	133	1	133	194	1	195
Total segment sales	5,515	6,747	12,263	5,010	5,725	10,734	15,164	19,459	34,622	13,324	17,906	31,230
Other [3]	10	125	134	20	39	60	19	330	350	101	(35)	66
	$ 5,525	$ 6,872	$ 12,397	$ 5,030	$ 5,764	$ 10,794	$ 15,183	$ 19,789	$ 34,972	$ 13,425	$ 17,871	$ 31,296

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 $3.0 billion and $2.6 billion for the three months ended September 30, 2019 and 2018, respectively, and by $8.6 billion and $7.7 billion for the nine months ended September 30, 2019 and 2018, respectively.

Consolidated sales by geographic area where derived are as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
($ in millions)	2019	2018	2019	2018
United States	$ 5,525	$ 5,030	$ 15,183	$ 13,425
Europe, Middle East and Africa	3,189	2,884	9,452	9,218
Japan	919	761	2,639	2,353
China	914	512	2,423	1,556
Asia Pacific (other than Japan and China)	756	666	2,217	2,210
Latin America	671	622	1,889	1,748
Other	423	319	1,169	786
	$ 12,397	$ 10,794	$ 34,972	$ 31,296

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
($ in millions)	2019	2018	2019	2018
Segment profits:				
Pharmaceutical segment	$ 7,747	$ 6,621	$ 21,437	$ 18,535
Animal Health segment	423	409	1,243	1,273
Other segments	(2)	5	(2)	94
Total segment profits	8,168	7,035	22,678	19,902
Other profits (losses)	101	55	226	(35)
Unallocated:				
Interest income	61	92	225	257
Interest expense	(231)	(190)	(674)	(569)
Depreciation and amortization	(382)	(324)	(1,169)	(1,006)
Research and development	(3,110)	(1,997)	(7,045)	(7,304)
Amortization of purchase accounting adjustments	(329)	(679)	(1,105)	(2,144)
Restructuring costs	(232)	(171)	(444)	(494)
Charge related to termination of collaboration agreement with Samsung	—	(420)	—	(420)
Other unallocated, net	(1,699)	(736)	(4,019)	(2,090)
	$ 2,347	$ 2,665	$ 8,673	$ 6,097

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. Also excluded from the determination of segment profits are costs related to restructuring activities, as well as the amortization of purchase accounting adjustments.

Other profits are primarily comprised of miscellaneous corporate profits, as well as operating profits related to third-party manufacturing sales.

Other unallocated, net, includes expenses from corporate and manufacturing cost centers, goodwill and other intangible asset impairment charges, gains or losses on sales of businesses, expense or income related to changes in the estimated fair value measurement of liabilities for contingent consideration, and other miscellaneous income or expense items.

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

Recent Developments

Business Developments

In April 2019, Merck acquired Antelliq Corporation (Antelliq), a leader in digital animal identification, traceability and monitoring solutions. These solutions help veterinarians, farmers and pet owners gather critical data to improve management, health and well-being of livestock and pets. Merck paid $2.3 billion to acquire all outstanding shares of Antelliq and spent $1.3 billion to repay Antelliq's debt (see Note 2 to the condensed consolidated financial statements).

Also in April 2019, Merck acquired Immune Design, a late-stage immunotherapy company employing next-generation *in vivo* approaches to enable the body's immune system to fight disease, for $301 million in cash (see Note 2 to the condensed consolidated financial statements).

In July 2019, Merck acquired Peloton Therapeutics, Inc. (Peloton), a clinical-stage biopharmaceutical company focused on the development of novel small molecule therapeutic candidates targeting hypoxia-inducible factor-2α (HIF-2α) for the treatment of patients with cancer and other non-oncology diseases. Peloton's lead candidate, MK-6482 (formerly PT2977), is a novel oral HIF-2α inhibitor in late-stage development for renal cell carcinoma. Merck made an upfront payment of $1.2 billion in cash; additionally, former Peloton shareholders will be eligible to receive up to an additional $1.15 billion contingent upon successful achievement of future regulatory and sales-based milestones (see Note 2 to the condensed consolidated financial statements).

Restructuring Program

Merck recently approved a new global restructuring program (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 $750 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 nine months 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 in the future.

Operating Results

Sales

Worldwide sales were $12.4 billion for the third quarter of 2019, an increase of 15% compared with the third quarter of 2018 including a 1% unfavorable effect from foreign exchange. Global sales were $35.0 billion for the first nine months of 2019, an increase of 12% compared with the same period of 2018 including a 2% unfavorable effect from foreign exchange. Sales growth in both periods was driven primarily by higher sales in the oncology franchise reflecting strong growth of *Keytruda* (pembrolizumab), as well as increased alliance revenue from Lenvima (lenvatinib) and Lynparza (olaparib). Also contributing to revenue growth in the third quarter and first nine months of 2019 were 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 combined sales of pediatric vaccines *ProQuad* (Measles, Mumps, Rubella and Varicella Virus Vaccine Live), *M-M-R* II (Measles, Mumps and Rubella Virus Vaccine Live) and *Varivax* (Varicella Virus Vaccine Live). Higher sales of certain hospital acute care products, including *Bridion* (sugammadex) Injection, as well as higher sales of animal health products also drove revenue growth in the third quarter and first nine months of 2019.

Sales growth in both periods was partially offset by the ongoing effects of generic competition for cardiovascular products *Zetia* (ezetimibe) and *Vytorin* (ezetimibe and simvastatin), hospital acute care product *Invanz* (ertapenem sodium), and biosimilar competition for immunology product *Remicade* (infliximab). Lower sales of diabetes products *Januvia* (sitagliptin) and

Janumet (sitagliptin/metformin HCl) also partially offset revenue growth in the quarter and year-to-date period. Additionally, sales growth in the first nine months of 2019 was partially offset by lower sales of products within the diversified brands franchise. The diversified brands franchise includes certain products that are approaching the expiration of their marketing exclusivity or that are no longer protected by patents in developed markets.

International sales represented 55% and 57% of total sales in the third quarter and first nine months of 2019, respectively. Performance in international markets was led by China, which had total sales of $914 million and $2.4 billion in the third quarter and first nine months of 2019, respectively, representing growth rates of 79% and 56%, respectively, compared with the same prior year periods. Foreign exchange unfavorably affected sales performance in China by 6% and 8% in the third quarter and first nine months of 2019, respectively.

See Note 17 to the consolidated financial statements for details on sales of the Company's products.

Pharmaceutical Segment

Oncology

Keytruda is an anti-PD-1 therapy that has been approved for the treatment of multiple malignancies including cervical cancer, classical Hodgkin lymphoma (cHL), esophageal cancer, gastric or gastroesophageal junction adenocarcinoma, head and neck squamous cell carcinoma (HNSCC), hepatocellular carcinoma, non-small-cell lung cancer (NSCLC), small-cell lung cancer (SCLC), melanoma, Merkel cell carcinoma, microsatellite instability-high (MSI-H) or mismatch repair deficient cancer, primary mediastinal large B-cell lymphoma (PMBCL), renal cell carcinoma, and urothelial carcinoma. The *Keytruda* clinical development program includes studies across a broad range of cancer types (see "Research and Development" below).

In July 2019, the U.S. Food and Drug Administration (FDA) approved *Keytruda* as monotherapy for the treatment of patients with recurrent locally advanced or metastatic squamous cell carcinoma of the esophagus whose tumors express PD-L1 (Combined Positive Score [CPS] ≥10) as determined by an FDA-approved test, with disease progression after one or more prior lines of systemic therapy based on the results of the KEYNOTE-181 and KEYNOTE-180 trials.

In June 2019, the FDA approved *Keytruda* as monotherapy or in combination with chemotherapy for the first-line treatment of patients with metastatic or unresectable, recurrent HNSCC based on results from the pivotal Phase 3 KEYNOTE-048 trial. *Keytruda* was initially approved for the treatment of certain patients with recurrent or metastatic HNSCC under the FDA's accelerated approval process based on data from the Phase 1b KEYNOTE-012 trial. In accordance with the accelerated approval process, continued approval was contingent upon verification and description of clinical benefit, which has now been demonstrated in KEYNOTE-048 and has resulted in the FDA converting the accelerated approval to a full (regular) approval.

Also in June 2019, the FDA approved *Keytruda* as monotherapy for the treatment of patients with metastatic SCLC with disease progression on or after platinum-based chemotherapy and at least one other prior line of therapy based on pooled data from the KEYNOTE-158 (cohort G) and KEYNOTE-028 (cohort C1) clinical trials.

In April 2019, the 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, based on findings from the pivotal Phase 3 KEYNOTE-426 trial. *Keytruda* was approved for this indication in the EU in September 2019.

Also in April 2019, the FDA approved an expanded label for *Keytruda* as monotherapy for the first-line treatment of patients with NSCLC expressing PD-L1 (Tumor Proportion Score [TPS] ≥1%) as determined by an FDA-approved test, with no EGFR or ALK genomic tumor aberrations, and is stage III where patients are not candidates for surgical resection or definitive chemoradiation, or metastatic. The approval was based on results from the Phase 3 KEYNOTE-042 trial.

Additionally, in April 2019, Merck announced that *Keytruda* was approved by China's National Medical Products Administration (NMPA) 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 October 2019, Merck announced that *Keytruda* was approved by the NMPA as monotherapy for the first-line treatment of patients with locally advanced or metastatic NSCLC whose tumors express PD-L1 as determined by a NMPA-approved test, with no EGFR or ALK genomic tumor aberrations, based on the results from the Phase 3 KEYNOTE-042 trial, including data from an extension of the global study in Chinese patients. *Keytruda* is the first anti-PD-1 therapy approved in China as both monotherapy and in combination with chemotherapy for the first-line treatment of appropriate patients with NSCLC.

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 based on data from the Phase 3 KEYNOTE-407 trial. *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 European Union (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 $3.1 billion in the third quarter of 2019 and $8.0 billion in the first nine months of 2019, representing growth of 62% and 59%, respectively, compared with the same periods of 2018. Foreign exchange unfavorably affected global sales performance by 2% and 4% in the third quarter and first nine months of 2019, respectively. Sales growth in both periods 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 in combination with chemotherapy for either nonsquamous or squamous NSCLC, along with uptake in the recently launched renal cell carcinoma and adjuvant melanoma indications. Other indications contributing to U.S. sales growth include HNSCC, bladder cancer, melanoma, and MSI-H cancer. *Keytruda* sales growth in international markets was driven primarily by increased use in the treatment of NSCLC particularly in Europe, Japan and China.

Global sales of *Emend* (aprepitant), for the prevention of chemotherapy-induced and post-operative nausea and vomiting, were $98 million in the third quarter of 2019 and $336 million for the first nine months of 2019, declines of 20% and 15%, respectively, compared with the same periods of 2018. Foreign exchange unfavorably affected global sales performance by 1% and 2% in the third quarter and first nine months of 2019, respectively. The sales declines primarily reflect lower demand in the United States due to competition, including recent generic competition for *Emend* for Injection upon U.S. patent expiry in September 2019. The patent that provided U.S. market exclusivity for *Emend* expired in 2015 and the patent that provided market exclusivity in most major European markets expired in May 2019. Additionally, the patent that provides market exclusivity for *Emend* for Injection in major European markets expires in February 2020 (although six-month pediatric exclusivity may extend this date). The Company anticipates that sales of *Emend* for Injection in these markets will decline significantly after the patent expires.

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 $123 million in the third quarter of 2019 compared with $49 million in the third quarter of 2018 and $313 million for the first nine months of 2019 compared with $125 million for the first nine months of 2018. The increase in alliance revenue reflects expanded use in the treatment of ovarian and breast cancer in the United States, Europe, Japan and China. Lynparza received approval for the treatment of certain types of ovarian cancer in the United States in December 2018 and in the EU in June 2019 (which triggered a $30 million milestone payment from Merck to AstraZeneca) based on the results of the Phase 3 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 related to Lenvima of $109 million and $43 million in the third quarter of 2019 and 2018, respectively, and $280 million and $78 million for the first nine months of 2019 and 2018, respectively. Lenvima sales in 2019 reflect strong performance in hepatocellular carcinoma following recent worldwide launches. In September 2019, Merck and Eisai announced that the FDA approved the combination of *Keytruda* plus Lenvima for the treatment of patients with advanced endometrial carcinoma that is not MSI-H or mismatch repair deficient, who have disease progression following prior systemic therapy, and are not candidates for curative surgery or radiation. This marks the first U.S. approval for the combination of *Keytruda* plus Lenvima.

Vaccines

Worldwide sales of *Gardasil/Gardasil* 9, vaccines to help prevent certain cancers and other diseases caused by certain types of HPV, were $1.3 billion in the third quarter of 2019 and $3.0 billion for the first nine months of 2019, increases of 26% and 31% compared with the same periods of 2018. Foreign exchange unfavorably affected global sales performance by 1% and 3% in the third quarter and first nine months of 2019, respectively. Sales growth in both periods was driven primarily by higher demand in the Asia Pacific region, particularly in China, as well as higher sales in the United States reflecting higher pricing and demand that was partially offset by public sector buying patterns. Higher demand in Europe reflecting increased vaccination rates for both boys and girls also contributed to sales growth in the quarter and year-to-date period.

In October 2019, the Company borrowed doses of *Gardasil* 9 from the U.S. Centers for Disease Control and Prevention (CDC) Pediatric Vaccine Stockpile. These doses will be allocated to support routine vaccination in the United States and will allow the Company to manufacture doses for other parts of the world, including regions where some of the most vulnerable populations live. The borrowing will reduce sales in the fourth quarter of 2019 by approximately $120 million and the Company will recognize a corresponding liability.

Global sales of *ProQuad*, a pediatric combination vaccine to help protect against measles, mumps, rubella and varicella, were $232 million in the third quarter of 2019, an increase of 24% compared with $186 million in the third quarter of 2018. Worldwide sales of *ProQuad* were $588 million in the first nine months of 2019, an increase of 29% compared with $455 million

in the first nine months of 2018. Foreign exchange unfavorably affected global sales performance by 1% and 2% in the third quarter and first nine months of 2019, respectively. Sales growth in both periods 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 $121 million for the third quarter of 2019, essentially flat compared with the third quarter of 2018 including a 1% unfavorable effect from foreign exchange. Higher demand in the United States due to measles outbreaks, as well as higher pricing, was offset by private-sector buy-out. Global sales of *M-M-R* II were $443 million in the first nine months of 2019, an increase of 43% compared with $310 million in the first nine months of 2018. Foreign exchange unfavorably affected global sales performance by 1% in the first nine months of 2018. Sales growth in the year-to-date period was driven primarily by higher sales in the United Sates reflecting increased demand, as well as higher pricing.

Global sales of *Varivax*, a vaccine to help prevent chickenpox (varicella), were $270 million for the third quarter of 2019, an increase of 25% compared with $217 million for the third quarter of 2018. Worldwide sales of *Varivax* were $763 million in the first nine months of 2019, an increase of 32% compared with $578 million in the first nine months of 2018. Foreign exchange unfavorably affected global sales performance by 3% in the first nine months of 2019. Sales growth in both periods reflects government tenders in Latin America, as well as volume growth and higher pricing in the United States.

Worldwide sales of *RotaTeq* (Rotavirus Vaccine, Live Oral, Pentavalent), a vaccine to help protect against rotavirus gastroenteritis in infants and children, were $180 million in the third quarter of 2019, a decline of 5% compared with the third quarter of 2018, reflecting lower sales in the United States due to public sector buying patterns, partially offset by continued uptake from the launch in China. Global sales of *RotaTeq* were $564 million for the first nine months of 2019, an increase of 4% compared with the same period of 2018 including a 2% unfavorable effect from foreign exchange. Sales growth in the year-to-date period was driven primarily by continued uptake from the launch in China, partially offset by lower sales in the United States due to public sector buying patterns and lower volumes in Latin America.

Hospital Acute Care

Worldwide sales of *Bridion*, for the reversal of two types of neuromuscular blocking agents used during surgery, were $284 million in the third quarter of 2019 and $817 million for the first nine months of 2019, increases of 31% and 24%, respectively, compared with the same periods of 2018. Foreign exchange unfavorably affected global sales performance by 1% and 3% in the third quarter and first nine months of 2019, respectively. Sales growth in both periods was driven by higher demand globally, particularly in the United States.

Worldwide sales of *Noxafil* (posaconazole), for the prevention of invasive fungal infections, were $177 million in the third quarter of 2019, a decline of 6% compared with the third quarter of 2018 including a 2% unfavorable effect from foreign exchange. The patent that provided U.S. market exclusivity for *Noxafil* expired in July 2019; accordingly, the Company anticipates a significant decline in U.S. sales of *Noxafil* in future periods. 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 *Noxafil* were $560 million for the first nine months of 2019, an increase of 1% compared with the same period of 2018 including a 4% unfavorable effect from foreign exchange.

Global sales of *Invanz*, for the treatment of certain infections, were $57 million in the third quarter of 2019 and $206 million for the first nine months of 2019, declines of 58% and 53%, respectively, compared with the same periods of 2018. Foreign exchange unfavorably affected global sales performance by 1% and 3% in the third quarter and first nine months of 2019, respectively. The sales decline in both periods was driven by generic competition in the United States. The patent that provided U.S. market exclusivity for *Invanz* expired in 2017. Accordingly, the Company is experiencing a significant decline in U.S. *Invanz* sales and expects the decline to continue.

In June 2019, the FDA approved a supplemental New Drug Application (NDA) for the use of *Zerbaxa* (ceftolozane and tazobactam) for the treatment of patients 18 years and older with hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP) caused by certain susceptible Gram-negative microorganisms based on the results of the pivotal Phase 3 ASPECT-NP trial. In August 2019, the EC approved *Zerbaxa* for the treatment of hospital-acquired pneumonia, including ventilator-associated pneumonia, in adults based on the results of the ASPECT-NP trial. *Zerbaxa* was previously approved in the United States and EU for the treatment of certain adult patients with complicated urinary tract infections, including pyelonephritis, and complicated intra-abdominal infections.

In July 2019, the FDA approved *Recarbrio* (imipenem, cilastatin, and relebactam) for injection, a new combination antibacterial for the treatment of complicated urinary tract infections, including pyelonephritis, caused by certain Gram-negative microorganisms in patients 18 years of age and older who have limited or no alternative treatment options. Merck anticipates making *Recarbrio* available in early 2020. In September 2019, Merck announced that the pivotal Phase 3 *Recarbrio* RESTORE-IMI 2 trial met its primary endpoint. The trial investigated the efficacy and safety of *Recarbrio* for use in adult patients with HABP and VABP. Results from the trial showed *Recarbrio* met both the primary and key secondary endpoints of statistical non-inferiority

compared to piperacillin/tazobactam in Day 28 all-cause mortality and clinical response at early follow up, respectively, in the modified intent-to-treat population. Merck plans to present the full data from the trial at a scientific congress in 2020. Relebactam (the beta lactamase inhibitor component of *Recarbrio*) has received the FDA's Qualified Infectious Disease Product (QIDP) designation and Fast Track status for the treatment of HABP/VABP.

In October 2019, the FDA accepted for priority review an NDA for *Dificid* (fidaxomicin) for oral suspension, and a supplemental NDA for a new indication for use of *Dificid* tablets and oral suspension for the treatment of *Clostridium* (also known as *Clostridioides*) *difficile* infections in children aged six months or older. The Prescription Drug User Fee Act (PDUFA), or target action, date for both applications is set for January 24, 2020. The investigational pediatric indication for *Dificid* was granted Orphan Drug Designation in 2010.

Immunology

Sales of *Simponi* (golimumab), a once-monthly subcutaneous treatment for certain inflammatory diseases (marketed by the Company in Europe, Russia and Turkey), were $203 million in the third quarter of 2019 and $625 million for the first nine months of 2019, declines of 3% and 7%, respectively, compared with the same periods of 2018. Foreign exchange unfavorably affected sales performance by 4% and 6% in the third quarter and first nine months of 2019, respectively. Sales of *Simponi* are being unfavorably affected by the 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 $101 million in the third quarter of 2019 and $322 million for the first nine months of 2019, declines of 25% and 30%, respectively, compared with the same periods of 2018. Foreign exchange unfavorably affected sales performance by 2% and 5% in the third quarter and first nine months of 2019, respectively. 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 combined sales of *Isentress/Isentress HD* (raltegravir), an HIV integrase inhibitor for use in combination with other antiretroviral agents for the treatment of HIV-1 infection, were $250 million in the third quarter of 2019 and $752 million for the first nine months of 2019, declines of 9% and 13%, respectively, compared with the same periods of 2018. Foreign exchange unfavorably affected global sales performance by 3% and 6% in the third quarter and first nine months of 2019, respectively. The sales declines were driven primarily by lower demand in the United States and Europe due to competitive pressure.

In September 2019, the FDA approved supplemental NDAs for *Pifeltro* (doravirine) (in combination with other antiretroviral agents) and *Delstrigo* (doravirine/lamivudine/tenofovir disoproxil fumarate) (as a complete regimen) that expand their indications to include adult patients with HIV-1 infection who are virologically suppressed on a stable antiretroviral regimen with no history of treatment failure and no known substitutions associated with resistance to *Pifeltro* or the individual components of *Delstrigo*.

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 $332 million in the third quarter of 2019 and $1.1 billion for the first nine months of 2019, declines of 6% and 26%, respectively, compared with the same periods of 2018. Foreign exchange unfavorably affected global sales performance by 2% and 4% in the third quarter and first nine months of 2019, respectively. The sales declines were driven primarily by lower sales in Europe. The EU patents for *Ezetrol* and *Inegy* expired in April 2018 and April 2019, respectively. 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. The sales declines were also attributable to loss of exclusivity in Australia. These declines were partially offset by volume growth of *Rosuzet* and *Atozet* in certain ex-U.S. markets.

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 $107 million in the third quarter of 2019 and $302 million for the first nine months of 2019, increases of 14% and 27%, respectively, compared with the same periods of 2018. Foreign exchange unfavorably affected global sales performance by 1% and 3% in the third quarter and first nine months of 2019, respectively. Sales growth in both periods was driven both by higher profit sharing from Bayer and higher sales of Adempas in Merck's marketing territories.

Diabetes

Worldwide combined sales of *Januvia* and *Janumet*, medicines that help lower blood sugar levels in adults with type 2 diabetes, were $1.3 billion in the third quarter of 2019 and $4.1 billion for the first nine months of 2019, declines of 12% and 8%, respectively, compared with the same periods of 2018. Foreign exchange unfavorably affected global sales performance by 1% and 3% in the third quarter and first nine months of 2019, respectively. The sales decline in both periods 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 $241 million in the third quarter of 2019 and $700 million for the first nine months of 2019, increases of 3% and 2%, respectively, compared with the same periods of 2018 including a 1% unfavorable effect from foreign exchange in both periods. 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 $1.1 billion for the third quarter of 2019, growth of 10% compared with the third quarter of 2018 including a 2% unfavorable effect from foreign exchange. Sales growth in the third quarter was primarily driven by higher sales of livestock products as a result of the Antelliq acquisition, as well as higher sales of companion animal products, primarily the *Bravecto* (fluralaner) line of products for parasitic control. Worldwide sales of Animal Health products totaled $3.3 billion for the first nine months of 2019, an increase of 3% compared with the first nine months of 2018 including a 5% unfavorable effect from foreign exchange. Revenue growth in the year-to-date period was driven by higher sales of livestock products due to the Antelliq acquisition, as well as higher demand for poultry and swine products. Higher demand for companion animal products, primarily the *Bravecto* line of products, also contributed to sales growth in the year-to-date period.

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 $4.0 billion for the third quarter of 2019, an increase of 10% compared with the third quarter of 2018, and were $10.4 billion for the first nine months of 2019, an increase of 2% compared with the same period of 2018. Costs in the third quarter of 2019 and 2018 include $320 million and $679 million, respectively, and for the first nine months of 2019 and 2018 include $1.1 billion and $2.1 billion, 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 amounts capitalized in connection with collaborations of $79 million and $49 million in the third quarter of 2019 and 2018, respectively, and $301 million and $244 million for the first nine months of 2019 and 2018, respectively. These amounts include catch-up amortization from the accrual of sales-based milestones that were deemed by the Company to be probable in each period (see Note 3 to the condensed consolidated financial statements). In addition, cost of sales in the third quarter and first nine months of 2019 include $612 million and $693 million, respectively, of intangible asset impairment charges related to marketed products and other intangibles recorded in connection with business acquisitions (see Note 7 to the condensed consolidated financial statements). The Company may recognize additional non-cash impairment charges in the future related to intangible assets that were measured at fair value and capitalized in connection with business acquisitions and such charges could be material. Additionally, costs in the third quarter and first nine months of 2018 include a $420 million charge related to the termination of a collaboration agreement with Samsung Bioepis Co., Ltd. (Samsung) for insulin glargine (see Note 3 to the condensed consolidated financial statements). Also included in cost of sales are expenses associated with restructuring activities which amounted to $62 million and $2 million in the third quarter of 2019 and 2018, respectively, and $161 million and $11 million for the first nine months 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 67.8% in the third quarter of 2019 compared with 66.5% in the third quarter of 2018 and was 70.1% in the first nine months of 2019 compared with 67.3% for the first nine months of 2018. Gross margin includes the amortization and impairment of intangible assets related to business acquisitions and restructuring costs as noted above, which unfavorably affected gross margin by 8.1 percentage points in the third quarter of 2019 compared with 6.3 percentage points in the third quarter of 2018 and by 5.6 percentage points in the first nine months of 2019 compared with 6.9 percentage points in the first nine months of 2018. The gross margin improvement in both periods reflects the charge recorded in 2018 in connection with the termination of the collaboration agreement with Samsung (noted above), as well as the favorable effects of product mix, partially offset by

higher amortization of unfavorable manufacturing variances, increased amortization of amounts capitalized in connection with collaborations, as well as manufacturing facility start-up costs.

Selling, General and Administrative

Selling, general and administrative (SG&A) expenses were $2.6 billion in the third quarter of 2019, an increase of 6% compared with the third quarter of 2018, reflecting higher promotional and administrative costs primarily in support of strategic brands, and higher acquisition and divestiture-related costs, partially offset by the favorable effect of foreign exchange. Acquisition and divestiture-related costs consist of integration, transaction, and certain other costs related to business acquisitions and divestitures. SG&A expenses were $7.7 billion for the first nine months of 2019, an increase of 4% compared with the same period of 2018, driven by higher administrative costs, acquisition and divestiture-related costs (primarily related to the acquisition of Antelliq), and restructuring costs, partially offset by the favorable effect of foreign exchange and lower selling and promotional costs. SG&A expenses in the first nine months of 2019 include restructuring costs of $33 million related primarily to accelerated depreciation for facilities to be closed or divested.

Research and Development

Research and development (R&D) expenses increased 55% in the third quarter of 2019 to $3.2 billion driven primarily by a $982 million charge related to the acquisition of Peloton (see Note 2 to the condensed consolidated financial statements), as well as higher expenses related to clinical development and increased investment in discovery research and early drug development. R&D expenses were $7.3 billion in the first nine months of 2019, a decline of 3% compared with the same period of 2018. The decline was driven primarily by a $1.4 billion charge recorded in 2018 related to the formation of an oncology collaboration with Eisai (see Note 3 to the condensed consolidated financial statements) and a $344 million charge in 2018 related to the acquisition of Viralytics Limited (Viralytics) (see Note 2 to the condensed consolidated financial statements). Partially offsetting the decline was the charge in 2019 relating to the acquisition of Peloton as noted above, as well as higher expenses related to clinical development and increased investment in discovery research and early drug development.

R&D expenses are comprised of the costs directly incurred by Merck Research Laboratories (MRL), the Company's research and development division that focuses on human health-related activities, which were $1.6 billion and $1.4 billion in the third quarter of 2019 and 2018, respectively, and were $4.4 billion and $4.1 billion in the first nine months 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 $655 million and $630 million for the third quarter of 2019 and 2018, respectively, and were $1.9 billion and $1.7 billion in the first nine months 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 nine months of 2019, the Company recorded a net reduction in expenses of $36 million to decrease the estimated fair value of liabilities for contingent consideration related to the discontinuation or delay of certain programs.

Restructuring Costs

Merck recently approved a new global restructuring program (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 $750 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 $232 million and $171 million for the third quarter of 2019 and 2018, respectively, and $444 million and $494 million for the first nine months 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 $296 million and $169 million in the third quarter of 2019 and 2018, respectively, and $642 million and $508 million for the first nine months 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 $35 million of expense in the third quarter of 2019 compared with $172 million of income in the third quarter of 2018 and was $362 million of expense in the first nine months of 2019 compared with $512 million of income for the first nine months of 2018. For details on the components of *Other (income) expense, net*, see Note 13 to the condensed consolidated financial statements.

Segment Profits

	Three Months Ended September 30,		Nine Months Ended September 30,	
($ in millions)	2019	2018	2019	2018
Pharmaceutical segment profits	$ 7,747	$ 6,621	$ 21,437	$ 18,535
Animal Health segment profits	423	409	1,243	1,273
Other non-reportable segment profits	(2)	5	(2)	94
Other	(5,821)	(4,370)	(14,005)	(13,805)
Income before taxes	$ 2,347	$ 2,665	$ 8,673	$ 6,097

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 costs related to restructuring activities and acquisition and divestiture-related costs, including the amortization of purchase accounting adjustments, intangible asset impairment charges and changes in the estimated fair value measurement of liabilities for contingent consideration. Additionally, segment profits do not reflect other expenses from corporate and manufacturing cost centers and other miscellaneous income or expense. These unallocated items are reflected in "Other" in the above table. Also included in "Other" are miscellaneous corporate profits (losses), as well as operating profits (losses) related to third-party manufacturing sales.

Pharmaceutical segment profits grew 17% in the third quarter of 2019 and 16% in the first nine months of 2019 compared with the same periods of 2018 driven primarily by higher sales. In the year-to-date period lower selling and promotional costs also contributed to the increase in Pharmaceutical segment profits. Animal Health segment profits grew 4% in the third quarter of 2019 compared with the third quarter of 2018 reflecting higher sales driven by the Antelliq acquisition, partially offset by the unfavorable effect of foreign exchange and higher selling and administrative costs. Animal Health segment profits declined 2% in the first nine months of 2019 compared with the corresponding period of 2018 largely reflecting the unfavorable effect of foreign exchange and higher selling costs, partially offset by higher sales driven primarily by the Antelliq acquisition.

Taxes on Income

The effective income tax rates of 18.7% and 26.5% for the third quarter of 2019 and 2018, respectively, and 14.5% and 27.6% for the first nine months 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. The effective income tax rates in the third quarter and first nine months of 2019 also reflect the unfavorable impact of a charge for the acquisition of Peloton for which no tax benefit was recognized and the favorable impact of product mix on the estimated full-year tax rate. In addition, the effective income tax rate for the first nine months 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 nine months of 2018 reflects the unfavorable impact of a 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 nine months of 2019. This net benefit reflects reductions in reserves for unrecognized tax benefits for tax positions relating to the years that were under examination, partially offset by additional reserves for tax positions not previously reserved for.

Net Income (Loss) Attributable to Noncontrolling Interests

Net income (loss) attributable to noncontrolling interests was $6 million for the third quarter of 2019 compared with $8 million for the third quarter of 2018 and was $(73) million for the first nine months of 2019 compared with $22 million for the first nine months of 2018. The losses in the first nine months of 2019 primarily reflect the portion of goodwill impairment charges related to certain businesses in the Healthcare Services segment that are attributable to noncontrolling interests.

Net Income and Earnings per Common Share

Net income attributable to Merck & Co., Inc. was $1.9 billion for the third quarter of 2019 compared with $2.0 billion for the third quarter of 2018 and was $7.5 billion for the first nine months of 2019 compared with $4.4 billion for the first nine months of 2018. Earnings per common share assuming dilution attributable to Merck & Co., Inc. common shareholders (EPS) for the third quarter of 2019 were $0.74 compared with $0.73 in the third quarter of 2018 and were $2.89 for the first nine months of 2019 compared with $1.63 for the first nine months 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 September 30,		Nine Months Ended September 30,	
($ in millions except per share amounts)	2019	2018	2019	2018
Income before taxes as reported under GAAP	$ 2,347	$ 2,665	$ 8,673	$ 6,097
Increase (decrease) for excluded items:				
Acquisition and divestiture-related costs	975	677	2,183	2,265
Restructuring costs	296	169	642	508
Other items:				
Charge for the acquisition of Peloton	982	—	982	—
Charge related to the termination of a collaboration with Samsung	—	420	—	420
Charge related to the formation of a collaboration with Eisai	—	—	—	1,400
Charge for the acquisition of Viralytics	—	—	—	344
Other	—	—	48	(54)
Non-GAAP income before taxes	4,600	3,931	12,528	10,980
Taxes on income as reported under GAAP	440	707	1,259	1,682
Estimated tax benefit on excluded items [(1)]	281	38	555	400
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	721	745	2,107	2,082
Non-GAAP net income	3,879	3,186	10,421	8,898
Net income (loss) attributable to noncontrolling interests as reported under GAAP	6	8	(73)	22
Acquisition and divestiture-related costs attributable to noncontrolling interests	—	—	89	—
Non-GAAP net income attributable to noncontrolling interests	6	8	16	22
Non-GAAP net income attributable to Merck & Co., Inc.	$ 3,873	$ 3,178	$ 10,405	$ 8,876
EPS assuming dilution as reported under GAAP	$ 0.74	$ 0.73	$ 2.89	$ 1.63
EPS difference [(2)]	0.77	0.46	1.13	1.66
Non-GAAP EPS assuming dilution	$ 1.51	$ 1.19	$ 4.02	$ 3.29

[(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 charge for the acquisition of Peloton (see Note 2 to the condensed consolidated financial statements), a net tax benefit related to the settlement of certain federal income tax matters (see Note 14 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 for the termination of a collaboration agreement

with Samsung for insulin glargine (see Note 2 to the condensed consolidated financial statements), a charge related to the formation of a collaboration with Eisai (see Note 3 to the condensed consolidated financial statements), and a charge for the acquisition of Viralytics (see Note 2 to the condensed consolidated financial statements).

Research and Development Update

Keytruda is an anti-PD-1 therapy approved for the treatment of many cancers. 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: biliary tract, bladder, cervical, colorectal, cutaneous squamous cell, endometrial, 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 is 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 *Keytruda* monotherapy demonstrated a statistically significant improvement in overall survival (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 October 2019, the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) adopted a positive opinion recommending approval of two regimens of *Keytruda*, as monotherapy or in combination with chemotherapy for the first-line treatment of patients with metastatic or unresectable HNSCC. This recommendation is based 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 CPS≥20 and CPS≥1 and in combination with chemotherapy. The CHMP's recommendation will now be reviewed by the EC for marketing authorization in the EU, and a final decision is expected in the fourth quarter of 2019. *Keytruda* was approved for these indications by the FDA in June 2019.

Keytruda is also under review in the EU as monotherapy for the second-line treatment of advanced or metastatic esophageal or esophagogastric junction carcinoma, based on the results of the Phase 3 KEYNOTE-181 trial. In July 2019, the FDA approved *Keytruda* as monotherapy for the treatment of patients with recurrent locally advanced or metastatic squamous cell carcinoma of the esophagus with disease progression after one or more prior lines of systemic therapy and whose tumor express PD-L1 (CPS≥10). In October 2019, Merck announced a similar indication was approved in China.

In July 2019, the FDA accepted for review six supplemental Biologics License Applications (BLAs) to update the dosing frequency for *Keytruda* to include an every-six-weeks (Q6W) dosing schedule option for certain monotherapy indications. Merck is seeking FDA approval of a 400 mg Q6W dose infused over 30 minutes for *Keytruda* monotherapy indications in melanoma, cHL, PMBCL, gastric cancer, hepatocellular carcinoma, and Merkel cell carcinoma. If approved by the FDA, the Q6W dose would be available for use in adults in addition to the currently approved dose of *Keytruda* 200 mg every three weeks (Q3W) infused over 30 minutes. The FDA set a PDUFA date of February 18, 2020. In the EU, 400 mg Q6W dosing for all approved *Keytruda* monotherapy indications was approved by the EC in March 2019.

In October 2019, the FDA accepted a sBLA seeking use of *Keytruda* for the treatment of patients with recurrent and/or metastatic cutaneous squamous cell carcinoma (cSCC) that is not curable by surgery or radiation. The FDA set a PDUFA date of June 29, 2020.

In June 2019, Merck announced full results from the pivotal Phase 3 KEYNOTE-062 trial evaluating *Keytruda* as monotherapy and in combination with chemotherapy 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 patients whose tumors expressed PD-L1 (CPS ≥1). In the combination arm of KEYNOTE-062, *Keytruda* plus chemotherapy was not found to be statistically superior for OS (CPS ≥1 or CPS ≥10) or progression-free survival (PFS) (CPS ≥1) compared with chemotherapy alone. Results were presented at the 2019 American Society of Clinical Oncology (ASCO) Annual Meeting. 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. 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* received Breakthrough Therapy designation from the FDA for the treatment of high-risk, early-stage triple-negative breast cancer (TNBC) 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. Additionally, the FDA recently granted Breakthrough Therapy designation for *Keytruda* in combination with Lenvima for the potential first-line treatment of patients with advanced unresectable hepatocellular carcinoma not amenable to locoregional treatment. Lenvima is being developed as part of a collaboration with Eisai (see Note 3 to the condensed consolidated financial statements).

In September 2019, Merck announced results from the pivotal neoadjuvant/adjuvant Phase 3 KEYNOTE-522 trial in patients with early-stage TNBC. The trial investigated a regimen of neoadjuvant *Keytruda* plus chemotherapy, followed by adjuvant *Keytruda* as monotherapy (the *Keytruda* regimen) compared with a regimen of neoadjuvant chemotherapy followed by adjuvant placebo (the chemotherapy-placebo regimen). Interim findings were presented at the European Society for Medical Oncology (ESMO) 2019 Congress. In the neoadjuvant phase, *Keytruda* plus chemotherapy resulted in a statistically significant increase in pathological complete response (pCR) versus chemotherapy from 51.2% with neoadjuvant chemotherapy to 64.8% for neoadjuvant *Keytruda* plus chemotherapy, in patients with early-stage TNBC. The improvement seen when adding *Keytruda* to neoadjuvant chemotherapy was observed regardless of PD-L1 expression. In the other dual primary endpoint of event-free-survival (EFS), with a median follow-up of 15.5 months, the *Keytruda* regimen reduced the risk of progression in the neoadjuvant phase and recurrence in the adjuvant phase by 37% - a favorable trend for EFS - compared with the chemotherapy-placebo regimen. As previously announced, Merck plans to share early interim analysis data from KEYNOTE-522 with regulatory authorities.

In May 2019, Merck announced that the Phase 3 KEYNOTE-119 trial evaluating *Keytruda* as monotherapy for the second- or third-line treatment of patients with metastatic TNBC did not meet its pre-specified primary endpoint of superior OS compared to chemotherapy. Other endpoints were not formally tested per the study protocol because the primary endpoint of OS was not met. Results will be presented at an upcoming medical meeting. The *Keytruda* breast cancer clinical development program encompasses several internal and external collaborative studies, including three ongoing registration-enabling studies in TNBC: KEYNOTE-355, KEYNOTE-242, and KEYNOTE-522 (discussed above).

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).

Lynparza tablets are under review in the United States and in the EU as a first-line maintenance monotherapy for patients with germline *BRCA*-mutated metastatic pancreatic cancer whose disease had not progressed following platinum-based chemotherapy based on the results from the Phase 3 POLO trial. Results from 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 47%. The results of the trial were presented at the 2019 ASCO Annual Meeting and published online simultaneously in the *New England Journal of Medicine*. A decision by the FDA is expected in the fourth quarter of 2019 and a decision from the EMA is expected in the second half of 2020.

Also in June 2019, Merck and AstraZeneca presented full results from the Phase 3 SOLO-3 trial which evaluated Lynparza, compared to chemotherapy, for the treatment of platinum-sensitive relapsed patients with germline *BRCA*1/2-mutated (g*BRCA*m) advanced ovarian cancer, who have received two or more prior lines of chemotherapy. The results from the trial showed a statistically-significant and clinically-meaningful improvement in objective response rate (ORR) in the Lynparza arm compared to the chemotherapy arm. The key secondary endpoint of PFS was also significantly increased in the Lynparza arm compared to the chemotherapy arm. The results were presented at the 2019 ASCO Annual Meeting.

In September 2019, Merck and AstraZeneca announced detailed positive results from the Phase 3 PAOLA-1 trial showing Lynparza added to bevacizumab demonstrated a statistically significant and clinically meaningful improvement in PFS in women with newly-diagnosed advanced ovarian cancer who had a complete or partial response to first-line treatment with platinum-based chemotherapy and bevacizumab. The results were presented at the ESMO 2019 Congress.

Also in September 2019, Merck and AstraZeneca presented detailed results from the Phase 3 PROfound trial in patients with metastatic castration-resistant prostate cancer (mCRPC) who have a mutation in their homologous recombination repair (HRR) genes and whose disease had progressed on prior treatment with new hormonal agent treatments (e.g. abiraterone or enzalutamide). The trial was designed to analyze men with mCRPC harboring HRR-mutated (HRRm) genes in two cohorts: the primary endpoint was in those with mutations in *BRCA*1/2 or *ATM* genes and then, if Lynparza showed clinical benefit, a formal analysis was performed of the overall trial population of men with HRRm genes (*BRCA*1/2, *ATM*, *CDK*12 and 11 other HRRm genes). Results showed a statistically-significant and clinically-meaningful improvement with Lynparza in the primary endpoint of radiographic progression-free survival (rPFS) in *BRCA*1/2 or *ATM*-mutated tumors reducing the risk of disease progression or death by a median of 7.4 months versus 3.6 months for those receiving abiraterone or enzalutamide. Lynparza reduced the risk of disease progression or death by 66% for these men. The trial also met the key secondary endpoint of rPFS in the overall HRRm population, where Lynparza reduced the risk of disease progression or death by 51% and improved rPFS to a median of 5.8 months vs. 3.5 months for those receiving abiraterone or enzalutamide. The results were presented at the ESMO 2019 Congress.

In October 2019, the CHMP of the EMA adopted a positive opinion recommending a conditional marketing authorization for V920 Ebola Zaire vaccine (rVSVΔG-ZEBOV-GP, live). If affirmed by the EC, the vaccine will be authorized under the brand

name *Ervebo* and indicated for active immunization of individuals 18 years of age or older to protect against Ebola Virus Disease caused by *Zaire ebola virus*. V920 is also under review in the United States. In September 2019, the FDA accepted the BLA and granted priority review for V920. In 2018, Merck started the submission of a rolling BLA to the FDA pursuant to the FDA's Breakthrough Therapy designation for V920. The PDUFA date for the BLA is March 14, 2020. In parallel, and in close collaboration with FDA and EMA, submissions have also been made to the World Health Organization (WHO) to achieve prequalification status and to African health authorities in collaboration with the African Vaccine Regulatory Forum.

The chart below reflects the Company's research pipeline as of November 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 additional claims, line extensions or formulations for in-line products are not shown.

Phase 2	Phase 3 (Phase 3 entry date)	Under Review
Cancer MK-3475 *Keytruda* Advanced Solid Tumors MK-6482 Renal Cell MK-7123*(1)* Solid Tumors MK-7339 Lynparza*(2)* Advanced Solid Tumors MK-7690 (vicriviroc)*(1)* Colorectal MK-7902 Lenvima*(2)* Biliary Tract V937 Melanoma **Cytomegalovirus** V160 **HIV-1 Infection** MK-8591 (islatravir) **Pediatric Neurofibromatosis Type 1** MK-5618 (selumetinib)*(2)* **Respiratory Syncytial Virus** MK-1654 **Schizophrenia** MK-8189	**Cancer** MK-3475 *Keytruda* Biliary Tract (September 2019) Breast (October 2015) Cervical (October 2018) (EU) Colorectal (November 2015) Cutaneous Squamous Cell (August 2019) (EU) Endometrial (August 2019) (EU) Gastric (May 2015) (EU) Hepatocellular (May 2016) (EU) Mesothelioma (May 2018) Nasopharyngeal (April 2016) Ovarian (December 2018) Prostate (May 2019) Small-Cell Lung (May 2017) (EU) MK-7339 Lynparza*(2)* Non-Small-Cell Lung (June 2019) Prostate (April 2017) MK-7902 Lenvima*(1)(2)* Bladder (May 2019) Endometrial (June 2018) (EU) Melanoma (March 2019) Non-Small-Cell Lung (March 2019) **Cough** MK-7264 (gefapixant) (March 2018) **Heart Failure** MK-1242 (vericiguat) (September 2016)*(2)* **Pneumoconjugate Vaccine** V114 (June 2018)	**New Molecular Entities/Vaccines** **Bacterial Infection** MK-7655A (relebactam+imipenem/cilastatin) (EU) **Ebola Vaccine** V920 (U.S.)(EU) **Certain Supplemental Filings** **Cancer** MK-3475 *Keytruda* • First-Line Metastatic Non-Small-Cell Lung Cancer (KEYNOTE-042) (EU) • First-Line Head and Neck Cancer (KEYNOTE-048) (EU) • Recurrent Locally Advanced or Metastatic Esophageal Cancer (KEYNOTE-180/KEYNOTE-181) (EU) • Recurrent and/or Metastatic Cutaneous Squamous Cell Carcinoma (KEYNOTE-629) (U.S.) • Alternative Dosing Regimen (Q6W) (U.S.) MK-7339 Lynparza*(2)* • First-Line g*BRCA*m Metastatic Pancreatic Cancer (POLO) (U.S.)(EU) **Footnotes:** *(1)* Being developed in combination with *Keytruda*. *(2)* Being developed in a collaboration.

Liquidity and Capital Resources

($ in millions)	September 30, 2019	December 31, 2018
Cash and investments	$ 10,129	$ 15,097
Working capital	5,458	3,669
Total debt to total liabilities and equity	31.3%	30.4%

Cash provided by operating activities was $8.6 billion in the first nine months of 2019 compared with $7.3 billion in the first nine months of 2018, reflecting stronger operating performance. Cash provided by operating activities continues to be the Company's primary source of funds to finance operating needs, capital expenditures, treasury stock purchases and dividends paid to shareholders.

Cash used in investing activities was $1.9 billion in the first nine months of 2019 compared with cash provided by investing activities of $2.1 billion in the first nine months of 2018. The change was driven primarily by the acquisitions of Antelliq and Peloton in 2019, lower proceeds from the sales of securities and other investments and higher capital expenditures, partially

offset by lower purchases of securities and other investments, 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).

Cash used in financing activities was $6.9 billion in the first nine months of 2019 compared with $7.6 billion in the first nine 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 $2.3 billion and $1.7 billion for the first nine months of 2019 and 2018, respectively. The increase reflects investment in new capital projects focused primarily on increasing manufacturing capacity across Merck's key businesses.

Dividends paid to stockholders were $4.3 billion and $3.9 billion for the first nine months of 2019 and 2018, respectively. In May 2019, the Board of Directors declared a quarterly dividend of $0.55 per share on the Company's common stock for the third quarter that was paid in July 2019. In July 2019, the Board of Directors declared a quarterly dividend of $0.55 per share on the Company's common stock for the fourth quarter that was paid in October 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 used the net proceeds from the offering of $5.0 billion for general corporate purposes, including the repayment of outstanding commercial paper borrowings.

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 nine months of 2019, the Company purchased $3.7 billion (47 million shares) for its treasury under this and a previously authorized share repurchase program. In addition, the Company received 7.7 million shares in settlement of accelerated share repurchase (ASR) agreements as discussed below. As of September 30, 2019, the Company's remaining share repurchase authorization was $8.2 billion.

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 2024. The facility provides backup liquidity for the Company's commercial paper borrowing facility and is to be used for general corporate purposes. The Company has not drawn funding from this facility.

Critical Accounting Policies

The Company's significant accounting policies, which include management's best estimates and judgments, are included in Note 2 to the consolidated financial statements for the year ended December 31, 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. Based on their evaluation, the Company's Chief Executive Officer and Chief Financial Officer have concluded that as of September 30, 2019, the Company's disclosure controls and procedures are effective. For the third quarter of 2019, there were no changes in internal control over financial reporting that materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

CAUTIONARY FACTORS THAT MAY AFFECT FUTURE RESULTS

This report and other written reports and oral statements made from time to time by the Company may contain so-called "forward-looking statements," all of which are based on management's current expectations and are subject to risks and uncertainties which may cause results to differ materially from those set forth in the statements. One can identify these forward-looking statements by their use of words such as "anticipates," "expects," "plans," "will," "estimates," "forecasts," "projects" and other words of similar meaning, or negative variations of any of the foregoing. One can also identify them by the fact that they do not relate strictly to historical or current facts. These statements are likely to address the Company's growth strategy, financial results, product development, product approvals, product potential and development programs. One must carefully consider any such statement and should understand that many factors could cause actual results to differ materially from the Company's forward-looking statements. These factors include inaccurate assumptions and a broad variety of other risks and uncertainties, including 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 9 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 September 30, 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)]
July 1 - July 31	6,611,817	$82.73	$9,078
August 1 - August 31	5,871,331	$84.90	$8,579
September 1 - September 30	4,276,118	$84.17	$8,219
Total	16,759,266	$83.86	$8,219

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

Item 6. Exhibits

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

EXHIBIT INDEX

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

Signatures

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

MERCK & CO., INC.

Date: November 5, 2019

/s/ Jennifer Zachary

JENNIFER ZACHARY

Executive Vice President and General Counsel

Date: November 5, 2019

/s/ Rita A. Karachun

RITA A. KARACHUN

Senior Vice President Finance - Global Controller

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: November 5, 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: November 5, 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 September 30, 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: November 5, 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 September 30, 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: November 5, 2019

/s/ Robert M. Davis

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