Merck & Co., Inc.
Form 10-Q
November 06, 2018

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, 2018
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.
2000 Galloping Hill Road
Kenilworth, N.J. 07033
(908) 740-4000
Incorporated in New Jersey I.R.S. Employer
Identification No. 22-1918501
The number of shares of common stock outstanding as of the close of business on October 31, 2018: 2,600,376,500
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

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,	
	2018	2017	2018	2017
Sales	$10,794	$10,325	$31,296	$29,689
Costs, Expenses and Other				
Materials and production	3,619	3,307	10,220	9,472
Marketing and administrative	2,443	2,459	7,459	7,432
Research and development	2,068	4,413	7,538	8,024
Restructuring costs	171	153	494	470
Other (income) expense, net	(172)	(207)	(512)	(351)
	8,129	10,125	25,199	25,047
Income Before Taxes	2,665	200	6,097	4,642
Taxes on Income	707	251	1,682	1,186
Net Income (Loss)	1,958	(51)	4,415	3,456
Less: Net Income Attributable to Noncontrolling Interests	8	5	22	16
Net Income (Loss) Attributable to Merck & Co., Inc.	$1,950	$(56)	$4,393	$3,440
Basic Earnings (Loss) per Common Share Attributable to Merck & Co., Inc. Common Shareholders	$0.73	$(0.02)	$1.64	$1.26
Earnings (Loss) per Common Share Assuming Dilution Attributable to Merck & Co., Inc. Common Shareholders	$0.73	$(0.02)	$1.63	$1.25

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Net Income (Loss) Attributable to Merck & Co., Inc.	$1,950	$(56)	$4,393	$3,440
Other Comprehensive (Loss) Income Net of Taxes:				
Net unrealized gain (loss) on derivatives, net of reclassifications	27	(66)	223	(441)
Net unrealized gain (loss) on investments, net of reclassifications	40	135	(56)	213
Benefit plan net gain and prior service credit, net of amortization	40	13	106	86
Cumulative translation adjustment	(136)	67	(240)	423
	(29)	149	33	281
Comprehensive Income Attributable to Merck & Co., Inc.	$1,921	$93	$4,426	$3,721

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, 2018	December 31, 2017
Assets		
Current Assets		
Cash and cash equivalents	$7,826	$6,092
Short-term investments	2,459	2,406
Accounts receivable (net of allowance for doubtful accounts of $229 in 2018 and $210 in 2017)	7,374	6,873
Inventories (excludes inventories of $1,294 in 2018 and $1,187 in 2017 classified in Other assets - see Note 7)	5,416	5,096
Other current assets	3,761	4,299
Total current assets	26,836	24,766
Investments	7,606	12,125
Property, Plant and Equipment, at cost, net of accumulated depreciation of $16,568 in 2018 and $16,602 in 2017	12,755	12,439
Goodwill	18,258	18,284
Other Intangibles, Net	12,175	14,183
Other Assets	7,500	6,075
	$85,130	$87,872
Liabilities and Equity		
Current Liabilities		
Loans payable and current portion of long-term debt	$3,656	$3,057
Trade accounts payable	3,091	3,102
Accrued and other current liabilities	9,776	10,427
Income taxes payable	759	708
Dividends payable	1,304	1,320
Total current liabilities	18,586	18,614
Long-Term Debt	19,936	21,353
Deferred Income Taxes	2,065	2,219
Other Noncurrent Liabilities	11,887	11,117
Merck & Co., Inc. Stockholders' Equity		
Common stock, $0.50 par value		
Authorized - 6,500,000,000 shares	1,788	1,788
Issued - 3,577,103,522 shares in 2018 and 2017		
Other paid-in capital	39,762	39,902
Retained earnings	42,189	41,350
Accumulated other comprehensive loss	(5,151)	(4,910)
	78,588	78,130
Less treasury stock, at cost: 918,364,126 shares in 2018 and 880,491,914 shares in 2017	46,166	43,794
Total Merck & Co., Inc. stockholders' equity	32,422	34,336
Noncontrolling Interests	234	233
Total equity	32,656	34,569
	$85,130	$87,872

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,	
	2018	2017
Cash Flows from Operating Activities		
Net income	$4,415	$3,456
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	3,424	3,509
Intangible asset impairment charges	—	376
Charge for future payments related to collaboration license options	650	750
Charge for collaboration termination	420	—
Deferred income taxes	(391)	(601)
Share-based compensation	261	232
Other	585	(31)
Net changes in assets and liabilities	(2,034)	(5,259)
Net Cash Provided by Operating Activities	7,330	2,432
Cash Flows from Investing Activities		
Capital expenditures	(1,686)	(1,173)
Purchases of securities and other investments	(6,899)	(8,397)
Proceeds from sales of securities and other investments	11,243	12,533
Acquisitions, net of cash acquired	(372)	(347)
Other	(150)	121
Net Cash Provided by Investing Activities	2,136	2,737
Cash Flows from Financing Activities		
Net change in short-term borrowings	2,294	1,962
Payments on debt	(3,007)	(301)
Purchases of treasury stock	(3,158)	(2,312)
Dividends paid to stockholders	(3,895)	(3,884)
Proceeds from exercise of stock options	461	481
Other	(289)	(167)
Net Cash Used in Financing Activities	(7,594)	(4,221)
Effect of Exchange Rate Changes on Cash, Cash Equivalents and Restricted Cash	(140)	438
Net Increase in Cash, Cash Equivalents and Restricted Cash	1,732	1,386
Cash, Cash Equivalents and Restricted Cash at Beginning of Year (includes restricted cash of $4 million at January 1, 2018 included in Other Assets)	6,096	6,515
Cash, Cash Equivalents and Restricted Cash at End of Period (includes restricted cash of $2 million at September 30, 2018 included in Other Assets)	$7,828	$7,901

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

Notes to Condensed Consolidated Financial Statements (unaudited)

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, 2018.

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 May 2014, the Financial Accounting Standards Board (FASB) issued amended accounting guidance on revenue recognition (ASU 2014-09) that applies to all contracts with customers. The objective of the new guidance is to improve comparability of revenue recognition practices across entities and to provide more useful information to users of financial statements through improved disclosure requirements. The new standard permits two methods of adoption: retrospectively to each prior reporting period presented (full retrospective method), or retrospectively with the cumulative effect of adopting the guidance being recognized at the date of initial application (modified retrospective method). The new standard was effective as of January 1, 2018 and was adopted using the modified retrospective method. The Company recorded a cumulative-effect adjustment upon adoption increasing Retained earnings by $5 million. See Note 2 for additional information related to the adoption of this standard.

In January 2016, the FASB issued revised guidance for the accounting and reporting of financial instruments (ASU 2016-01) and in 2018 issued related technical corrections (ASU 2018-03). The new guidance requires that equity investments with readily determinable fair values currently classified as available for sale be measured at fair value with changes in fair value recognized in net income. The Company has elected to measure equity investments without readily determinable fair values at cost, less impairment, adjusted for subsequent observable price changes, which will be recognized in net income. The new guidance also changed certain disclosure requirements. ASU 2016-01 was effective as of January 1, 2018 and was adopted using a modified retrospective approach. The Company recorded a cumulative-effect adjustment upon adoption increasing Retained earnings by $8 million. ASU 2018-03 was also adopted as of January 1, 2018 on a prospective basis and did not result in any additional impacts upon adoption.

In October 2016, the FASB issued guidance on the accounting for the income tax consequences of intra-entity transfers of assets other than inventory (ASU 2016-16). The new guidance requires the recognition of the income tax consequences of an intra-entity transfer of an asset (with the exception of inventory) when the intra-entity transfer occurs, replacing the prohibition against doing so. The current exception to defer the recognition of any tax impact on the transfer of inventory within the consolidated entity until it is sold to a third party remains unaffected. The new standard was effective as of January 1, 2018 and was adopted using a modified retrospective approach. The Company recorded a cumulative-effect adjustment upon adoption increasing Retained earnings by $54 million with a corresponding decrease to Deferred Income Taxes.

In August 2017, the FASB issued new guidance on hedge accounting (ASU 2017-12) that is intended to more closely align hedge accounting with companies' risk management strategies, simplify the application of hedge accounting, and increase transparency as to the scope and results of hedging programs. The new guidance makes more financial and nonfinancial hedging strategies eligible for hedge accounting, amends the presentation and disclosure requirements, and changes how companies assess effectiveness. The Company elected to early adopt this guidance as of January 1, 2018 on a modified retrospective basis. The new guidance was applied to all existing hedges as of the adoption date. For fair value hedges of interest rate risk outstanding as of the date of adoption, the Company recorded a cumulative-effect adjustment upon adoption to the basis adjustment on the hedged item resulting from applying the benchmark component of the coupon guidance. This adjustment decreased Retained earnings by $11 million. Also, in accordance with the transition provisions of ASU 2017-12, the Company was required to eliminate the separate measurement of ineffectiveness for its cash flow hedging instruments existing as of the adoption date through a cumulative-effect adjustment to retained earnings; however, all such amounts were de minimis.

In February 2018, the FASB issued new guidance to address a narrow-scope financial reporting issue that arose as a consequence of the Tax Cuts and Jobs Act of 2017 (TCJA) (ASU 2018-02). Existing guidance requires that deferred tax liabilities and assets be adjusted for a change in tax laws or rates with the effect included in income from continuing operations in the reporting period that includes the enactment date. That guidance is applicable even in situations in which the related income tax effects of items in accumulated other comprehensive income were originally recognized in other comprehensive income (rather than in net income), such as amounts related to benefit plans and hedging activity. As a result, the tax effects of items within accumulated other comprehensive income do not reflect the appropriate tax rate (the difference is referred to as stranded tax effects). The new guidance allows for a reclassification of these amounts to retained earnings thereby eliminating these stranded tax effects. The Company elected to early adopt the new guidance in the first quarter of 2018 and reclassified the stranded income

Notes to Condensed Consolidated Financial Statements (unaudited)

tax effects of the TCJA increasing Accumulated other comprehensive loss in the provisional amount of $266 million with a corresponding increase to Retained earnings (see Note 16). The Company's policy for releasing disproportionate income tax effects from Accumulated other comprehensive loss is to utilize the item-by-item approach.

The impact of adopting the above standards is as follows:

($ in millions)	ASU 2014-09 (Revenue)	ASU 2016-01 (Financial Instruments)	ASU 2016-16 (Intra-Entity Transfers of Assets Other than Inventory)	ASU 2017-12 (Derivatives and Hedging)	ASU 2018-02 (Reclassification of Certain Tax Effects)	Total
Assets - Increase (Decrease)						
Accounts receivable	$ 5					$ 5
Liabilities - Increase (Decrease)						
Income Taxes Payable				(3)		(3)
Debt				14		14
Deferred Income Taxes			(54)			(54)
Equity - Increase (Decrease)						
Retained earnings	5	8	54	(11)	266	322
Accumulated other comprehensive loss		(8)			(266)	(274)

In March 2017, the FASB amended the guidance related to net periodic benefit cost for defined benefit plans that requires entities to (1) disaggregate the current service cost component from the other components of net benefit cost and present it with other employee compensation costs in the income statement within operations if such a subtotal is presented; (2) present the other components of net benefit cost separately in the income statement and outside of income from operations; and (3) only capitalize the service cost component when applicable. The Company adopted the new standard as of January 1, 2018 using a retrospective transition method as to the requirement for separate presentation in the income statement of service costs and other components and a prospective transition method as to the requirement to limit the capitalization of benefit costs to the service cost component. The Company utilized a practical expedient that permits it to use the amounts disclosed in its pension and other postretirement benefit plan note for the prior comparative periods as the estimation basis for applying the retrospective presentation requirements. Upon adoption, net periodic benefit cost (credit) other than service cost was reclassified to Other (income) expense, net from the previous classification within Materials and production costs, Marketing and administrative expenses and Research and development costs (see Note 13).

In August 2016, the FASB issued guidance on the classification of certain cash receipts and payments in the statement of cash flows intended to reduce diversity in practice. The Company adopted the new standard effective as of January 1, 2018 using a retrospective application. There were no changes to the presentation of the Consolidated Statement of Cash Flows in the prior year period as a result of adopting the new standard.

In November 2016, the FASB issued guidance requiring that amounts generally described as restricted cash and restricted cash equivalents be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. The new standard was effective as of January 1, 2018 and was adopted using a retrospective application. The adoption of the new guidance did not have a material effect on the Company's Consolidated Statement of Cash Flows.

In May 2017, the FASB issued guidance clarifying when to account for a change to the terms or conditions of a share-based payment award as a modification. Under the new guidance, modification accounting is required only if the fair value, the vesting conditions, or the classification of the award (as equity or liability) changes as a result of the change in terms or conditions. The Company adopted the new standard effective as of January 1, 2018 and will apply the new guidance to future share-based payment award modifications should they occur.

Recently Issued Accounting Standards Not Yet Adopted

In February 2016, the FASB issued new accounting guidance for the accounting and reporting of leases and subsequently issued several updates to the new guidance. The new guidance requires that lessees recognize a right-of-use asset and a lease liability recorded on the balance sheet for each of its leases (other than leases that meet the definition of a short-term lease). Leases will be classified as either operating or finance. Operating leases will result in straight-line expense in the income statement (similar to current operating leases) while finance leases will result in more expense being recognized in the earlier years of the lease term (similar to current capital leases). The Company will adopt the new standard on January 1, 2019 using a modified retrospective approach. Merck will elect 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 intends to elect available practical expedients. The Company is currently evaluating the impact of adoption on its consolidated financial statements. Merck has

Notes to Condensed Consolidated Financial Statements (unaudited)

selected a lease accounting tool and made significant progress regarding lease data validation for contracts that are in the Company's current lease portfolio. Merck continues to assess the potential impact of embedded leases in certain agreements.

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. The new guidance is to be applied on a modified retrospective basis through a cumulative-effect adjustment directly to retained earnings in the beginning of the period of adoption. The Company is currently evaluating the impact of adoption on its consolidated financial statements.

In January 2017, the FASB issued guidance that provides for the elimination of Step 2 from the goodwill impairment test. Under the new guidance, impairment charges are recognized to the extent the carrying amount of a reporting unit exceeds its fair value with certain limitations. The new guidance is effective for interim and annual periods in 2020. Early adoption is permitted. The Company does not anticipate that the adoption of the new guidance will have a material effect on its consolidated financial statements.

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

2. Summary of Significant Accounting Policies

On January 1, 2018, the Company adopted ASU 2014-09, Revenue from Contracts with Customers, and subsequent amendments (ASC 606 or new guidance), using the modified retrospective method. Merck applied the new guidance to all contracts with customers within the scope of the standard that were in effect on January 1, 2018 and recognized the cumulative effect of initially applying the new guidance as an adjustment to the opening balance of retained earnings (see Note 1). Comparative information for prior periods has not been restated and continues to be reported under the accounting standards in effect for those periods.

The new guidance provides principles that an entity applies to report useful information about the amount, timing, and uncertainty of revenue and cash flows arising from its contracts to provide goods or services to customers. The core principle requires an entity to recognize revenue to depict the transfer of goods or services to customers in an amount that reflects the consideration that it expects to be entitled to in exchange for those goods or services. The new guidance introduces a 5-step model to recognize revenue when or as control is transferred: identify the contract with a customer, identify the performance obligations in the contract, determine the transaction price, allocate the transaction price to the performance obligations in the contract, and recognize revenue when or as the performance obligations are satisfied. The Company's significant accounting policies are detailed in Note 2 to the consolidated financial statements included in Merck's Annual Report on Form 10-K for the year ended December 31, 2017. Changes to the Company's revenue recognition policy as a result of adopting ASC 606 are described below. See Note 17 for disaggregated revenue disclosures.

Revenue Recognition — Recognition of revenue requires evidence of a contract, probable collection of sales proceeds and completion of substantially all performance obligations. Merck acts as the principal in substantially all of its customer arrangements and therefore records revenue on a gross basis. The majority of the Company's contracts related to the Pharmaceutical and Animal Health segments have a single performance obligation - the promise to transfer goods. Shipping is considered immaterial in the context of the overall customer arrangement and damages or loss of goods in transit are rare. Therefore, shipping is not deemed a separately recognized performance obligation. The vast majority of revenues from sales of products are recognized at a point in time when control of the goods is transferred to the customer, which the Company has determined is when title and risks and rewards of ownership

transfer to the customer and the Company is entitled to payment. Certain Merck entities, including U.S. entities, have contract terms under which control of the goods passes to the customer upon shipment; however, either pursuant to the terms of the contract or as a business practice, Merck retains responsibility for goods lost or damaged in transit. Prior to the adoption of the new standard, Merck would recognize revenue for these entities upon delivery of the goods. Under the new guidance, the Company is now recognizing revenue at time of shipment for these entities.

For businesses within the Company's Healthcare Services segment and certain services in the Animal Health segment, revenue is recognized over time, generally ratably over the contract term as services are provided.

Notes to Condensed Consolidated Financial Statements (unaudited)

Merck's payment terms for U.S. pharmaceutical customers are typically net 36 days from receipt of invoice and for U.S. animal health customers are typically net 30 days from receipt of invoice; however, certain products, including Keytruda, have longer payment terms up to 90 days. Outside of the United States, payment terms are typically 30 days to 90 days although certain markets have longer payment terms.

The nature of the Company's business gives rise to several types of variable consideration including discounts and returns, which are estimated at the time of sale generally using the expected value method, although the most likely amount method is also used for certain types of variable consideration. In the United States, sales discounts are issued to customers at the point-of-sale, through an intermediary wholesaler (known as chargebacks), or in the form of rebates. Additionally, sales are generally made with a limited right of return under certain conditions. Revenues are recorded net of provisions for sales discounts and returns, which are established at the time of sale. In addition, revenues are recorded net of time value of money discounts if collection of accounts receivable is expected to be in excess of one year.

The provision for aggregate customer discounts covers chargebacks and rebates. Chargebacks are discounts that occur when a contracted customer purchases through an intermediary wholesaler. The contracted customer generally purchases product from the wholesaler at its contracted price plus a mark-up. The wholesaler, in turn, charges the Company back for the difference between the price initially paid by the wholesaler and the contract price paid to the wholesaler by the customer. The provision for chargebacks is based on expected sell-through levels by the Company's wholesale customers to contracted customers, as well as estimated wholesaler inventory levels. Rebates are amounts 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. The provision for rebates is based on expected patient usage, as well as inventory levels in the distribution channel to determine the contractual obligation to the benefit providers. The Company uses historical customer segment utilization mix, sales forecasts, changes to product mix and price, inventory levels in the distribution channel, government pricing calculations and prior payment history in order to estimate the expected provision. Amounts accrued for aggregate customer discounts are evaluated on a quarterly basis through comparison of information provided by the wholesalers, health maintenance organizations, pharmacy benefit managers, federal and state agencies, and other customers to the amounts accrued. These discounts, in the aggregate, reduced U.S. sales by $2.6 billion and $2.9 billion in the third quarter of 2018 and 2017, respectively, and by $7.7 billion and $8.2 billion for the first nine months of 2018 and 2017, respectively.

Outside of the United States, variable consideration in the form of discounts and rebates are a combination of commercially-driven discounts in highly competitive product classes, discounts required to gain or maintain reimbursement, or legislatively mandated rebates. In certain European countries, legislatively mandated rebates are calculated based on an estimate of the government's total unbudgeted spending and the Company's specific payback obligation. Rebates may also be required based on specific product sales thresholds. The Company applies an estimated factor against its actual invoiced sales to represent the expected level of future discount or rebate obligations associated with the sale.

The Company maintains a returns policy that allows its U.S. pharmaceutical customers to return product within a specified period prior to and subsequent to the expiration date (generally, three to six months before and 12 months after product expiration). The estimate of the provision for returns is based upon historical experience with actual returns. Additionally, the Company considers factors such as levels of inventory in the distribution channel, product dating and expiration period, whether products have been discontinued, entrance in the market of generic competition, changes in formularies or launch of over-the-counter products, among others. Outside of the United States, returns are only allowed on a limited basis in certain countries.

The following table provides the effects of adopting ASC 606 on the Consolidated Statement of Income:

	Three Months Ended September 30, 2018			Nine Months Ended September 30, 2018		
($ in millions)	As Reported	Effects of Adopting ASC 606	Amounts Without Adoption	As Reported	Effects of Adopting ASC 606	Amounts Without Adoption

			of ASC 606			of ASC 606
Sales	$10,794	$ (1)	$ 10,793	$31,296	$ (30)	$ 31,266
Materials and production	3,619	(1)	3,618	10,220	(18)	10,202
Income before taxes	2,665	—	2,665	6,097	(12)	6,085
Taxes on income	707	—	707	1,682	(3)	1,679
Net income attributable to Merck & Co., Inc.	1,950	—	1,950	4,393	(9)	4,384

Notes to Condensed Consolidated Financial Statements (unaudited)

The following table provides the effects of adopting ASC 606 on the Consolidated Balance Sheet:

	September 30, 2018		
($ in millions)	As Reported	Effects of Adopting ASC 606	Amounts Without Adoption of ASC 606
Assets			
Accounts receivable	$7,374	$ (45)	$ 7,329
Inventories	5,416	19	5,435
Liabilities			
Accrued and other current liabilities	9,776	(6)	9,770
Income taxes payable	759	(5)	754
Equity			
Retained earnings	42,189	(15)	42,174

3. Acquisitions, Divestitures, Research Collaborations and License Agreements

The Company continues to pursue the acquisition of businesses and 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 the third quarter of 2018, the Company recorded an aggregate charge of $420 million within Materials and production costs in conjunction with the termination of a collaboration agreement entered into in 2014 with Samsung Bioepis Co., Ltd. (Samsung) for insulin glargine. The aggregate 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 aggregate 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 Cavatak (V937, formerly CVA21), Viralytics's investigational oncolytic immunotherapy. Cavatak 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. Cavatak 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, Merck's anti-PD-1 (programmed death receptor-1) therapy. Under a previous agreement between Merck and Viralytics, a study is investigating the use of the Keytruda and Cavatak 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 for the first nine months of 2018 related to the transaction. There are no future contingent payments associated with the acquisition.

In April 2018, Merck sold C3i Solutions, a multi-channel customer engagement services provider which was part of the Healthcare Services segment, to HCL Technologies Limited for $65 million. The transaction resulted in a loss of $11 million recorded in Other (income) expense, net.

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 4).

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 (see Note 4).

In March 2017, Merck acquired a controlling interest in Vallée S.A. (Vallée), a leading privately held producer of animal health products in Brazil. Vallée has an extensive portfolio of products spanning parasiticides, anti-infectives and vaccines that include products for livestock, horses, and companion animals. Under the terms of the agreement, Merck acquired 93.5% of the shares of Vallée for $358 million. Of the total purchase price, $176 million was placed into escrow pending resolution of certain contingent items. The transaction was accounted for as an acquisition of a business. Merck recognized intangible assets of $297 million related to currently marketed products, net deferred tax liabilities of $102 million, other net assets of $32 million and noncontrolling interest of $25 million. In addition, the Company recorded liabilities of $37 million for contingencies identified at

Notes to Condensed Consolidated Financial Statements (unaudited) (continued)

the acquisition date and corresponding indemnification assets of $37 million, representing the amounts to be reimbursed to Merck if and when the contingent liabilities are paid. The excess of the consideration transferred over the fair value of net assets acquired of $156 million was recorded as goodwill. The goodwill was allocated to the Animal Health segment and is not deductible for tax purposes. The estimated fair values of identifiable intangible assets related to currently marketed products were determined using an income approach. The probability-adjusted future net cash flows of each product were discounted to present value utilizing a discount rate of 15.5%. Actual cash flows are likely to be different than those assumed. The intangible assets related to currently marketed products are being amortized over their estimated useful lives of 15 years. In the fourth quarter of 2017, Merck acquired an additional 4.5% interest in Vallée for $18 million, which reduced the noncontrolling interest related to Vallée.

4. Collaborative Arrangements

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

AstraZeneca

In July 2017, Merck and 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 currently 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 expenses. Reimbursements received from AstraZeneca for research and development expenses are recognized as reductions to Research and development costs.

As part of the agreement, Merck made an upfront payment to AstraZeneca of $1.6 billion and is making payments totaling $750 million over a multi-year period for certain license options ($250 million of which was paid in 2017). The Company recorded an aggregate charge of $2.35 billion in Research and development expenses in 2017 related to the upfront payment and future license options payments. In addition, the agreement provides for additional contingent payments from Merck to AstraZeneca related to the successful achievement of regulatory and sales-based milestones.

In the second quarter of 2018, Merck determined it was probable that annual sales of Lynparza in the future would trigger a $200 million sales-based milestone payment from Merck to AstraZeneca. Accordingly, in the second quarter of 2018, Merck recorded a $200 million noncurrent liability and a corresponding intangible asset and also recognized $17 million of cumulative amortization expense within Materials and production costs. Merck previously accrued a $150 million sales-based milestone in the first quarter of 2018 (along with $9 million of cumulative amortization expense) and a $100 million sales-based milestone in 2017 (which was paid in 2018). The remaining $3.65 billion of potential future sales-based milestone payments have not yet been accrued as they are not deemed by the Company to be probable at this time.

In January 2018, Lynparza received approval in the United States for the treatment of certain patients with metastatic breast cancer, triggering a $70 million capitalized milestone payment from Merck to AstraZeneca. Potential future

regulatory milestone payments of $1.93 billion remain under the agreement.

The asset balance related to Lynparza (which includes capitalized sales-based and regulatory milestone payments) was $468 million at September 30, 2018 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.

Notes to Condensed Consolidated Financial Statements (unaudited) (continued)

Summarized information related to this collaboration is as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
($ in millions)	2018	2017	2018	2017
Alliance revenues	$ 49	$ 5	$ 125	$ 5
Materials and production [1]	12	—	48	—
Marketing and administrative	12	—	28	—
Research and development [2]	47	2,377	118	2,377

($ in millions)	September 30, 2018	December 31, 2017
Receivables from AstraZeneca	$ 46	$ 12
Payables to AstraZeneca [3]	892	643

[1] Represents amortization of capitalized milestone payments.

[2] Amounts for the third quarter and first nine months of 2017 include $2.35 billion related to the upfront payment and future license option payments.

[3] Includes accrued milestone and license option payments.

Eisai

In March 2018, Merck and Eisai announced a strategic collaboration for the worldwide co-development and co-commercialization of Lenvima, an orally available tyrosine kinase inhibitor discovered by Eisai. Under the agreement, Merck and Eisai will develop and commercialize Lenvima jointly, both as monotherapy and in combination with Merck's anti-PD-1 therapy, Keytruda. Eisai records Lenvima product sales globally (Eisai is the principal on Lenvima sales transactions), and Merck and Eisai share gross profits equally. Merck records its share of Lenvima product sales, net of cost of sales and commercialization costs, as alliance revenue. Expenses incurred during co-development, including for studies evaluating Lenvima as monotherapy, are shared equally by the two companies and reflected in Research and development expenses. Under the agreement, Merck made upfront payments to Eisai of $750 million and will make payments of up to $650 million for certain option rights through 2021 ($325 million in January 2019 or earlier in certain circumstances, $200 million in January 2020 and $125 million in January 2021). The Company recorded an aggregate charge of $1.4 billion in Research and development expenses in the first nine months of 2018 related to the upfront payments and future option payments. In addition, the agreement provides for Eisai to receive up to $385 million associated with the achievement of certain clinical and regulatory milestones and up to $3.97 billion for the achievement of milestones associated with sales of Lenvima.

In the third quarter of 2018, Merck determined it was probable that annual sales of Lenvima in the future would trigger a $50 million sales-based milestone payment from Merck to Eisai. Accordingly, in the third quarter of 2018, Merck recorded a $50 million noncurrent liability and a corresponding intangible asset. The remaining $3.92 billion of potential future sales-based milestone payments have not yet been accrued as they are not deemed by the Company to be probable at this time.

Lenvima was approved for the treatment of patients with unresectable hepatocellular carcinoma in Japan in March 2018, in the United States and European Union in August 2018, and in China in September 2018, triggering capitalized milestone payments of $25 million, $125 million, $50 million, and $25 million, respectively, to Eisai. Potential future regulatory milestone payments of $160 million remain under the agreement.

The asset balance related to Lenvima (which includes capitalized sales-based and regulatory milestones payments) was $266 million at September 30, 2018 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.

Notes to Condensed Consolidated Financial Statements (unaudited) (continued)

Summarized information related to this collaboration is as follows:

($ in millions)	Three Months Ended September 30, 2018	Nine Months Ended September 30, 2018
Alliance revenues	$ 43	$ 78
Materials and production [1]	8	9
Marketing and administrative	5	7
Research and development [2]	36	1,473

($ in millions)	September 30, 2018
Receivables from Eisai	$ 42
Payables to Eisai [3]	733

[1] Represents amortization of capitalized milestone payments.
[2] Amount for the first nine months of 2018 includes $1.4 billion related to the upfront payment and future license option payments.
[3] Includes accrued milestone and license option payments.

Bayer AG

In 2014, the Company entered into a worldwide clinical development collaboration with Bayer AG (Bayer) to market and develop soluble guanylate cyclase (sGC) modulators including Bayer's Adempas, which is approved to treat pulmonary arterial hypertension and chronic thromboembolic pulmonary hypertension. The two companies have implemented a joint development and commercialization strategy. The collaboration also includes clinical development of Bayer's vericiguat, which is in Phase 3 trials for worsening heart failure, as well as opt-in rights for other early-stage sGC compounds in development by Bayer. Merck in turn made available its early-stage sGC compounds under similar terms. Under the agreement, Bayer leads commercialization of Adempas in the Americas, while Merck leads commercialization in the rest of the world. For vericiguat and other potential opt-in products, Bayer will lead commercialization in the rest of world and Merck will lead in the Americas. For all products and candidates included in the agreement, both companies will share in development costs and profits on sales and will have the right to co-promote in territories where they are not the lead. In 2016, Merck began promoting and distributing Adempas in Europe. Transition from Bayer in other Merck territories, including Japan, continued in 2017. Revenue from Adempas includes sales in Merck's marketing territories, as well as Merck's share of profits from the sale of Adempas in Bayer's marketing territories.

In the 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, in the second quarter of 2018, Merck recorded a $375 million noncurrent liability and a corresponding intangible asset and also recognized $106 million of cumulative amortization expense within Materials and production costs. In 2017, annual worldwide sales of Adempas exceeded $500 million triggering a $350 million milestone payment from Merck to Bayer, which was accrued for in 2016 when Merck deemed the payment to be probable. The milestone was paid in the first quarter of 2018. There is an additional $400 million potential future sales-based milestone payment that has not yet been accrued as it is not deemed by the Company to be probable at this time.

The intangible asset balance related to Adempas (which includes the remaining acquired intangible asset balance, as well as capitalized sales-based milestones payments) was $1.1 billion at September 30, 2018 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.

Notes to Condensed Consolidated Financial Statements (unaudited) (continued)

Summarized information related to this collaboration is as follows:

($ in millions)	Three Months Ended September 30, 2018	2017	Nine Months Ended September 30, 2018	2017
Net product sales recorded by Merck	$ 47	$ 38	$138	$ 105
Merck's profit share from sales in Bayer's marketing territories	47	32	100	116
Total sales	94	70	238	221
Materials and production [1]	29	25	188	73
Marketing and administrative	11	6	26	18
Research and development	34	27	90	78

($ in millions)	September 30, 2018	December 31, 2017
Receivables from Bayer	$36	$ 33
Payables to Bayer [2]	375	352

[1] Includes amortization of intangible assets.

[2] Includes accrued milestone payments.

5. Restructuring

In 2010 and 2013, the Company commenced actions under global restructuring programs designed to streamline its cost structure. The actions under these programs include the elimination of positions in sales, administrative and headquarters organizations, as well as the sale or closure of certain manufacturing and research and development sites and the consolidation of office facilities. The Company also continues to reduce its global real estate footprint and improve the efficiency of its manufacturing and supply network.

The Company recorded total pretax costs of $169 million and $180 million in the third quarter of 2018 and 2017, respectively, and $508 million and $605 million for the first nine months of 2018 and 2017, respectively, related to restructuring program activities. Since inception of the programs through September 30, 2018, Merck has recorded total pretax accumulated costs of approximately $14.0 billion and eliminated approximately 45,220 positions comprised of employee separations, as well as the elimination of contractors and vacant positions. The Company estimates that approximately two-thirds of the cumulative pretax costs are cash outlays, primarily related to employee separation expense. Approximately one-third of the cumulative pretax costs are non-cash, relating primarily to the accelerated depreciation of facilities to be closed or divested. While the Company has substantially completed the actions under these programs, approximately $50 million of additional pretax costs are expected to be incurred in the fourth quarter of 2018 relating to anticipated employee separations and remaining asset-related costs.

For segment reporting, restructuring charges are unallocated expenses.

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

($ in millions)	Three Months Ended September 30, 2018 Separation Costs	Accelerated Depreciation	Other	Total	Nine Months Ended September 30, 2018 Separation Costs	Accelerated Depreciation	Other	Total
Materials and production	$—	$ 1	$ 1	$2	$—	$ 1	$ 10	$11
Marketing 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

($ in millions)	Three Months Ended September 30, 2017				Nine Months Ended September 30, 2017			
	Separation Costs	Accelerated Depreciation	Other	Total	Separation Costs	Accelerated Depreciation	Other	Total
Materials and production	$—	$ 5	$ 20	$25	$—	$ 52	$69	$121
Marketing and administrative	—	—	—	—	—	2	1	3
Research and development	—	1	1	2	—	7	4	11
Restructuring costs	100	—	53	153	302	—	168	470
	$100	$ 6	$ 74	$180	$302	$ 61	$242	$605

Notes to Condensed Consolidated Financial Statements (unaudited) (continued)

Separation costs are associated with actual headcount reductions, as well as those headcount reductions which were probable and could be reasonably estimated. In the third quarter of 2018 and 2017, approximately 525 positions and 205 positions, respectively, and for the first nine months of 2018 and 2017, 1,870 positions and 1,225 positions, respectively, were eliminated under restructuring program activities.

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 of the sites have and will continue to operate up through the respective closure dates and, since future undiscounted cash flows were 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 2018 and 2017 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, 2018:

($ in millions)	Separation Costs	Accelerated Depreciation	Other	Total
Restructuring reserves January 1, 2018	$ 619	$ —	$128	$747
Expense	392	(10)	126	508
(Payments) receipts, net	(535)	—	(170)	(705)
Non-cash activity	—	10	13	23
Restructuring reserves September 30, 2018 [1]	$ 476	$ —	$97	$573

[1] The remaining cash outlays are expected to be substantially completed by the end of 2020.

6. Financial Instruments

Derivative Instruments and Hedging Activities

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

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

Foreign Currency Risk Management

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

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

The fair values of these derivative contracts are recorded as either assets (gain positions) or liabilities (loss positions) in the Condensed Consolidated Balance Sheet. Changes in the fair value of derivative contracts are recorded each period in either current earnings or Other comprehensive income (OCI), depending on whether the derivative is designated as part of a hedge transaction and, if so, the type of hedge transaction. For derivatives that are designated as cash flow hedges, the unrealized gains or losses on these contracts is recorded in Accumulated other comprehensive income (AOCI) and reclassified into Sales when the hedged anticipated revenue is recognized. For those derivatives which are not designated as cash flow hedges, but serve as economic

Notes to Condensed Consolidated Financial Statements (unaudited) (continued)

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. In accordance with the new guidance adopted on January 1, 2018 (see Note 1), the Company has elected to recognize 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)	2018	2017	2018	2017	2018	2017	2018	2017

Net Investment Hedging Relationships								
Foreign exchange contracts	$(10)	$ —	$ (24)	$ —	$(4)	$ —	$ (7)	$ —
Euro-denominated notes	38	128	(54)	467	—	—	—	—

(1) No amounts were reclassified from AOCI into income related to the sale of a subsidiary.

Interest Rate Risk Management

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

In May 2018, four interest rate swaps with notional amounts of $250 million each matured. These swaps effectively converted the Company's $1.0 billion, 1.30% fixed-rate notes due 2018 to variable rate debt. At September 30, 2018, the Company was a party to 22 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.

Notes to Condensed Consolidated Financial Statements (unaudited) (continued)

($ in millions)	September 30, 2018 Par Value of Debt	Number of Interest Rate Swaps Held	Total Swap Notional Amount
5.00% notes due 2019	1,250	3	550
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:

($ in millions)	Carrying Amount of Hedged Liabilities		Cumulative Amount of Fair Value Hedging Adjustment Increase (Decrease) Included in the Carrying Amount	
	September 30, 2018	December 31, 2017	September 30, 2018	December 31, 2017
Balance Sheet Line Item in which Hedged Item is Included				
Loans payable and current portion of long-term debt	$553	$ 983	$ 3	$ (17)
Long-Term Debt [1]	4,503	5,146	(138)	(41)

[1] Amounts include hedging adjustment gains related to discontinued hedging relationships of $6 million and $11 million at September 30, 2018 and December 31, 2017, respectively.

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, 2018			December 31, 2017		
($ in millions)	Balance Sheet Caption	Fair Value of Derivative Asset	Fair Value of Derivative Liability	U.S. Dollar Notional	Fair Value of Derivative Asset	Fair Value of Derivative Liability	U.S. Dollar Notional
Derivatives Designated as Hedging Instruments							
Interest rate swap contracts	Other assets	$—	$ —	$ —	$ 2	$ —	$ 550
Interest rate swap contracts	Accrued and other current liabilities	—	2	550	—	3	1,000
Interest rate swap contracts	Other noncurrent liabilities	—	138	4,650	—	52	4,650
Foreign exchange contracts	Other current assets	175	—	6,115	51	—	4,216

Foreign exchange contracts	Other assets	85	—	2,682	38	—	1,936
Foreign exchange contracts	Accrued and other current liabilities	—	5	657	—	71	2,014
Foreign exchange contracts	Other noncurrent liabilities	—	1	66	—	1	20
		$ 260	$ 146	$ 14,720	$ 91	$ 127	$ 14,386
Derivatives Not Designated as Hedging Instruments							
Foreign exchange contracts	Other current assets	$ 127	$ —	$ 6,531	$ 39	$ —	$ 3,778
Foreign exchange contracts	Accrued and other current liabilities	—	58	5,298	—	90	7,431
		$ 127	$ 58	$ 11,829	$ 39	$ 90	$ 11,209
		$ 387	$ 204	$ 26,549	$ 130	$ 217	$ 25,595

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:

Notes to Condensed Consolidated Financial Statements (unaudited) (continued)

	September 30, 2018		December 31, 2017	
($ in millions)	Asset	Liability	Asset	Liability
Gross amounts recognized in the consolidated balance sheet	$387	$ 204	$130	$ 217
Gross amount subject to offset in master netting arrangements not offset in the consolidated balance sheet	(135)	(135)	(94)	(94)
Cash collateral received	(54)	—	(3)	—
Net amounts	$198	$ 69	$33	$ 123

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)	2018	2017	2018	2017	2018	2017	2018	2017	2018	2017	2018	2017
Financial Statement Line Items in which Effects of Fair Value or Cash Flow Hedges are Recorded	$10,794	$10,325	$(172)	(207)	$(29)	$149	31,296	$29,689	$(512)	$(351)	$33	$281
(Gain) loss on fair value hedging relationships												
Interest rate swap contracts												
Hedged items	—	—	(9)	(9)	—	—	—	—	(86)	(5)	—	—
Derivatives designated as hedging instruments	—	—	15	2	—	—	—	—	100	(25)	—	—
Impact of cash flow hedging relationships												
Foreign exchange contracts												
Amount of gain (loss) recognized in OCI on derivatives	—	—	—	—	29	(88)	—	—	—	—	113	(520)
(Decrease) increase in Sales as a result of AOCI reclassifications	(6)	13	—	—	6	(13)	(172)	157	—	—	172	(157)

[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	2018	2017	2018	2017
Derivatives Not Designated as Hedging Instruments					
Foreign exchange contracts [1]	Other (income) expense, net	$(57)	$119	$(224)	$ 70
Foreign exchange contracts [2]	Sales	—	—	(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, 2018, the Company estimates $75 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.

Notes to Condensed Consolidated Financial Statements (unaudited) (continued)

Investments in Debt and Equity Securities

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

	September 30, 2018				December 31, 2017			
($ in millions)	Fair Value	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses
Corporate notes and bonds	$6,866	$ 6,952	$ 2	$ (88)	$9,806	$ 9,837	$ 9	$ (40)
U.S. government and agency securities	1,431	1,448	—	(17)	2,042	2,059	—	(17)
Asset-backed securities	1,288	1,300	1	(13)	1,542	1,548	1	(7)
Foreign government bonds	538	546	—	(8)	733	739	—	(6)
Mortgage-backed securities	23	24	—	(1)	626	634	1	(9)
Commercial paper	30	30	—	—	159	159	—	—
Total debt securities	$10,176	$ 10,300	$ 3	$ (127)	$14,908	$ 14,976	$ 11	$ (79)
Publicly traded equity securities [1]	378				275	265	16	(6)
Total debt and publicly traded equity securities	$10,554				$15,183	$ 15,241	$ 27	$ (85)

[1] Pursuant to the adoption of ASU 2016-01 (see Note 1), beginning on January 1, 2018, changes in the fair value of publicly traded equity securities are recognized in net income. Unrealized net gains of $10 million and $60 million, respectively, were recognized in Other (income) expense, net during the third quarter and first nine months of 2018 on equity securities still held at September 30, 2018.

At September 30, 2018, the Company also had $749 million of equity investments without readily determinable fair values included in Other Assets. During the first nine months of 2018, the Company recognized unrealized gains of $199 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 2018, the Company recognized unrealized losses of $25 million in Other (income) expense, net related to certain of these investments based on unfavorable observable price changes.

Available-for-sale debt securities included in Short-term investments totaled $2.4 billion at September 30, 2018. Of the remaining debt securities, $7.1 billion mature within five years. At September 30, 2018 and December 31, 2017, 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.

Notes to Condensed Consolidated Financial Statements (unaudited) (continued)

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, 2018				December 31, 2017			
Assets								
Investments								
Corporate notes and bonds	$—	$ 6,765	$ —	$6,765	$—	$ 9,678	$ —	$9,678
Asset-backed securities [1]	—	1,271	—	1,271	—	1,476	—	1,476
U.S. government and agency securities	—	1,265	—	1,265	68	1,767	—	1,835
Foreign government bonds	—	538	—	538	—	732	—	732
Commercial paper	—	30	—	30	—	159	—	159
Mortgage-backed securities	—	—	—	—	—	547	—	547
Publicly traded equity securities	196	—	—	196	104	—	—	104
	196	9,869	—	10,065	172	14,359	—	14,531
Other assets [2]								
U.S. government and agency securities	54	112	—	166	—	207	—	207
Corporate notes and bonds	—	101	—	101	—	128	—	128
Mortgage-backed securities	—	23	—	23	—	79	—	79
Asset-backed securities [1]	—	17	—	17	—	66	—	66
Foreign government bonds	—	—	—	—	—	1	—	1
Publicly traded equity securities	182	—	—	182	171	—	—	171
	236	253	—	489	171	481	—	652
Derivative assets [3]								
Forward exchange contracts	—	233	—	233	—	48	—	48
Purchased currency options	—	154	—	154	—	80	—	80
Interest rate swaps	—	—	—	—	—	2	—	2
	—	387	—	387	—	130	—	130
Total assets	$432	$ 10,509	$ —	$10,941	$343	$ 14,970	$ —	$15,313
Liabilities								
Other liabilities								
Contingent consideration	$—	$ —	$ 852	$852	$—	$ —	$ 935	$935
Derivative liabilities [3]								
Interest rate swaps	—	140	—	140	—	55	—	55
Forward exchange contracts	—	60	—	60	—	162	—	162
Written currency options	—	4	—	4	—	—	—	—
	—	204	—	204	—	217	—	217
Total liabilities	$—	$ 204	$ 852	$1,056	$—	$ 217	$ 935	$1,152

[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 2018. As of September 30, 2018, Cash and cash equivalents of $7.8 billion included $7.1 billion of cash equivalents (which would be considered Level 2 in the fair value hierarchy).

Notes to Condensed Consolidated Financial Statements (unaudited) (continued)

Contingent Consideration

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

	Nine Months Ended September 30,	
($ in millions)	2018	2017
Fair value January 1	$935	$891
Changes in estimated fair value [1]	144	151
Additions	8	3
Payments	(235)	(100)
Fair value September 30 [2]	$852	$945

[1] Recorded in Research and development expenses, Materials and production costs and Other (income) expense, net. Includes cumulative translation adjustments.

[2] Balance at September 30, 2018 includes $95 million recorded as a current liability for amounts expected to be paid within the next 12 months.

The payments of contingent consideration in the first nine months of 2018 include $175 million related to the achievement of a clinical milestone in connection with the 2016 acquisition of Afferent Pharmaceuticals. The remaining payments in 2018 relate 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 2017 relate to the achievement of a clinical milestone in connection with the 2016 acquisition of IOmet Pharma Ltd.

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, 2018, was $24.0 billion compared with a carrying value of $23.6 billion and at December 31, 2017, was $25.6 billion compared with a carrying value of $24.4 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. At September 30, 2018, the Company's total net accounts receivable outstanding for more than one year were approximately $40 million. 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. As of September 30, 2018 and December 31, 2017, the Company had received cash collateral of $54 million and $3 million, respectively, from various counterparties and the obligation to return such collateral is recorded in Accrued and other current liabilities. The Company had not advanced any cash collateral to counterparties as of September 30,

2018 or December 31, 2017.

Notes to Condensed Consolidated Financial Statements (unaudited) (continued)

7. Inventories

Inventories consisted of:

($ in millions)	September 30, 2018	December 31, 2017
Finished goods	$ 1,585	$ 1,334
Raw materials and work in process	4,933	4,703
Supplies	202	201
Total (approximates current cost)	6,720	6,238
(Decrease) increase to LIFO costs	(10)	45
	$ 6,710	$ 6,283
Recognized as:		
Inventories	$ 5,416	$ 5,096
Other assets	1,294	1,187

Amounts recognized as Other assets are comprised almost entirely of raw materials and work in process inventories. At September 30, 2018 and December 31, 2017, these amounts included $1.3 billion and $1.1 billion, respectively, of inventories not expected to be sold within one year. In addition, these amounts included $3 million and $80 million at September 30, 2018 and December 31, 2017, respectively, of inventories produced in preparation for product launches.

8. Other Intangibles

In connection with acquisitions, the Company measures the fair value of research and development pipeline programs and marketed products and capitalizes these amounts. See Note 3 for information on intangible assets acquired as a result of business acquisitions in the first nine months of 2018 and 2017.

During the third quarter and first nine months of 2017, the Company recorded $245 million and $253 million, respectively, of IPR&D impairment charges within Research and development expenses. In the third quarter of 2017, Merck made a strategic decision to discontinue the development of the investigational combination regimens MK-3682B (grazoprevir/ruzasvir/uprifosbuvir) and MK-3682C (ruzasvir/uprifosbuvir) for the treatment of chronic hepatitis C virus (HCV) infection. This decision was made based on a review of available Phase 2 efficacy data and in consideration of the evolving marketplace and the growing number of treatment options available for patients with chronic HCV infection, including Zepatier, which is marketed by the Company for the treatment of adult patients with chronic HCV infection. As a result of this decision, the Company recorded an IPR&D impairment charge of $240 million in the third quarter and first nine months of 2017 to write-off the remaining intangible asset related to uprifosbuvir.

Also, during the first nine months of 2017, the Company recorded an intangible asset impairment charge of $47 million within Materials and production costs related to Intron A, a treatment for certain types of cancers. Sales of Intron A were being adversely affected by the availability of new therapeutic options. Sales of Intron A in the United States eroded more rapidly than previously anticipated by the Company, which led to changes in the cash flow assumptions for Intron A. These revisions to cash flows indicated that the Intron A 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 Intron A that, when compared with its related carrying value, resulted in the impairment charge noted above.

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, 2018, approximately 3,955 cases are filed and pending against Merck in either federal or state court. In four of these actions, plaintiffs allege, among other things, that they have suffered osteonecrosis of the jaw (ONJ), generally subsequent to invasive dental procedures, such as tooth extraction or dental implants and/or delayed healing, in association with the use of Fosamax. In addition, plaintiffs in approximately 3,950 of these actions generally allege that they sustained femur fractures and/or other bone injuries (Femur Fractures) in association with the use of Fosamax.

Cases Alleging ONJ and/or Other Jaw Related Injuries

In August 2006, the Judicial Panel on Multidistrict Litigation (JPML) ordered that certain Fosamax product liability cases pending in federal courts nationwide should be transferred and consolidated into one multidistrict litigation (Fosamax ONJ MDL) for coordinated pre-trial proceedings. In 2014, Merck settled approximately 95% of the ONJ cases pending in the Fosamax ONJ MDL and in state courts for a payment of $27.3 million. The escrow agent under the agreement has been making settlement payments to qualifying plaintiffs. The ONJ Master Settlement Agreement has no effect on the cases alleging Femur Fractures discussed below. The Fosamax ONJ MDL was closed in June 2018.

Cases Alleging Femur Fractures

In March 2011, Merck submitted a Motion to Transfer to the JPML seeking to have all federal cases alleging Femur Fractures consolidated into one multidistrict litigation for coordinated pre-trial proceedings. All federal cases involving allegations of Femur Fracture have been or will be transferred to a multidistrict litigation in the District of New Jersey (Femur Fracture MDL). In the only bellwether case tried to date in the Femur Fracture MDL, Glynn v. Merck, the jury returned a verdict in Merck's favor. In addition, in June 2013, the Femur Fracture MDL court granted Merck's motion for judgment as a matter of law in the Glynn case and held that the plaintiff's failure to warn claim was preempted by federal law.

In August 2013, the Femur Fracture MDL court entered an order requiring plaintiffs in the Femur Fracture MDL to show cause why those cases asserting claims for a femur fracture injury that took place prior to September 14, 2010, should not be dismissed based on the court's preemption decision in the Glynn case. Pursuant to the show cause order, in March 2014, the Femur Fracture MDL court dismissed with prejudice approximately 650 cases on preemption grounds. Plaintiffs in approximately 515 of those cases appealed that decision to the U.S. Court of Appeals for the Third Circuit (Third Circuit). In March 2017, the Third Circuit issued a decision reversing the Femur Fracture MDL court's preemption ruling and remanding the appealed cases back to the Femur Fracture MDL court. Merck filed a petition for a writ of certiorari to the U.S. Supreme Court in August 2017 seeking review of the Third Circuit's decision. In December 2017, the Supreme Court invited the Solicitor General to file a brief in the case expressing the views of the United States, and in May 2018, the Solicitor General submitted a brief stating that the Third Circuit's decision was wrongly decided and recommended that the Supreme Court grant Merck's cert petition. The Supreme Court granted Merck's petition in June 2018, and final decision on the Femur Fracture MDL court's preemption ruling is now pending before the Supreme Court.

Accordingly, as of September 30, 2018, three cases were actively pending in the Femur Fracture MDL, and approximately 1,055 cases have either been dismissed without prejudice or administratively closed pending final resolution by the Supreme Court of the appeal of the Femur Fracture MDL court's preemption order.

As of September 30, 2018, approximately 2,610 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 30 cases to be reviewed through fact discovery. Two additional groups of 50 cases each to be reviewed through fact discovery were selected in November 2013 and March 2014, respectively. A further group of 25 cases to be reviewed through fact discovery was selected by Merck in July 2015, and Merck has continued to select additional cases to be reviewed through fact discovery from 2016 to the present.

Notes to Condensed Consolidated Financial Statements (unaudited) (continued)

As of September 30, 2018, 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. In March 2014, the court directed that a group of 10 discovery pool cases be reviewed through fact discovery and subsequently scheduled the Galper v. Merck case, which plaintiffs selected, as the first trial. The Galper trial began in February 2015 and the jury returned a verdict in Merck's favor in April 2015, and plaintiff appealed that verdict to the California appellate court. In April 2017, the California appellate court issued a decision affirming the lower court's judgment in favor of Merck. The next Femur Fracture trial in California that was scheduled to begin in April 2016 was stayed at plaintiffs' request and a new trial date has not been set.

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

Discovery is ongoing in the Femur Fracture MDL and in state courts where Femur Fracture cases are pending and the Company 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, 2018, Merck is aware of approximately 1,285 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, and in November 2017, the U.S. Court of Appeals for the Ninth Circuit reversed and remanded for further discovery, which is ongoing. The appeal in California State Court was argued on October 4, 2018.

As of September 30, 2018, eight 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 has appealed, and oral argument is scheduled for November 14, 2018.

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.

Propecia/Proscar

As previously disclosed, Merck is a defendant in product liability lawsuits in the United States involving Propecia and/or Proscar. The lawsuits were filed in various federal courts and in state court in New Jersey. The federal lawsuits were then consolidated for pretrial purposes in a federal multidistrict litigation before Judge Brian Cogan of the Eastern District of New York. The matters pending in state court in New Jersey were consolidated before Judge Hyland in Middlesex County (NJ Coordinated Proceedings). There is one matter pending in state court in California and one matter pending in state court in Massachusetts.

As previously disclosed, on April 9, 2018, Merck and the Plaintiffs' Executive Committee in the MDL and the Plaintiffs' Liaison Counsel in the NJ Coordinated Proceedings entered into an agreement to resolve the above mentioned Propecia/Proscar lawsuits for an aggregate amount of $4.3 million. The settlement was subject to certain contingencies, including 95% plaintiff participation and a per plaintiff clawback if the participation rate was less than 100%. The contingencies were satisfied and the settlement agreement has been finalized. After the settlement, fewer than 40 cases will remain pending in the United States.

The Company intends to defend against any remaining unsettled lawsuits.

Governmental Proceedings

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

As previously disclosed, from time to time, the Company receives inquiries and is the subject of preliminary investigation activities from competition and other governmental authorities in markets outside the United States. These authorities may include regulators, administrative authorities, and law enforcement and other similar officials, and these preliminary investigation activities may include site visits, formal or informal requests or demands for

documents or materials, inquiries or interviews and similar matters. Certain of these preliminary inquiries or activities may lead to the commencement of formal proceedings. Should those proceedings be determined adversely to the Company, monetary fines and/or remedial undertakings may be required.

Notes to Condensed Consolidated Financial Statements (unaudited) (continued)

Patent Litigation

From time to time, generic manufacturers of pharmaceutical products file abbreviated New Drug Applications with the U.S. Food and Drug Administration (FDA) seeking to market generic forms of the Company's products prior to the expiration of relevant patents owned by the Company. To protect its patent rights, the Company may file patent infringement lawsuits against such generic companies. Similar lawsuits defending the Company's patent rights may exist in other countries. The Company intends to vigorously defend its patents, which it believes are valid, against infringement by companies attempting to market products prior to the expiration of such patents. As with any litigation, there can be no assurance of the outcomes, which, if adverse, could result in significantly shortened periods of exclusivity for these products and, with respect to products acquired through acquisitions, potentially significant intangible asset impairment charges.

Inegy — The patents protecting Inegy in Europe have expired but supplemental protection certificates (SPCs) have been granted to the Company in many European countries that will expire in April 2019. There are multiple challenges to the SPCs related to Inegy throughout Europe and generic products have been launched in France, Italy, Ireland, Spain, Portugal, and the Netherlands and may launch in Germany. The Company has filed for preliminary injunctions in many countries that are still pending decision. Preliminary injunctions have been granted in Belgium, the Czech Republic, Germany, Greece, Portugal, Norway and Slovakia. Preliminary injunctions have been denied or revoked in France, Germany, Belgium, Ireland, the Netherlands and Spain. The Company is appealing those decisions. The Company has filed and will continue to file actions for patent infringement seeking damages against those companies that launch generic products before April 2019.

Noxafil — In August 2015, the Company filed a lawsuit against Actavis Laboratories Fl, Inc. (Actavis) in the United States in respect of that company's application to the FDA seeking pre-patent expiry approval to sell a generic version of Noxafil. In October 2017, the district court held the patent valid and infringed. Actavis appealed this decision. While the appeal was pending, the parties reached a settlement, subject to certain terms of the agreement being met, whereby Actavis can launch its generic version prior to expiry of the patent and pediatric exclusivity under certain conditions. In March 2016, the Company filed a lawsuit against Roxane Laboratories, Inc. (Roxane) in the United States in respect of that company's application to the FDA seeking pre-patent expiry approval to sell a generic version of Noxafil. In November 2017, the parties reached a settlement whereby Roxane can launch its generic version prior to expiry of the patent under certain conditions. In February 2016, the Company filed a lawsuit against Par Sterile Products LLC, Par Pharmaceutical, Inc., Par Pharmaceutical Companies, Inc. and Par Pharmaceutical Holdings, Inc. (collectively, Par) in the United States in respect of that company's application to the FDA seeking pre-patent expiry approval to sell a generic version of Noxafil injection. In October 2016, the parties reached a settlement whereby Par can launch its generic version in January 2023, or earlier under certain conditions. In February 2018, the Company filed a lawsuit against Fresenius Kabi USA, LLC., in the United States in respect of that company's application to the FDA seeking pre-patent expiry approval to sell a generic version of Noxafil. In March 2018, the Company filed a lawsuit against Mylan Laboratories Limited in the United States in respect of that company's application to the FDA seeking pre-patent expiry approval to sell a generic version of Noxafil.

Nasonex — Nasonex lost market exclusivity in the United States in 2016. Prior to that, in April 2015, the Company filed a patent infringement lawsuit against Apotex Inc. and Apotex Corp. (Apotex) in respect of Apotex's marketed product that the Company believed was infringing. In January 2018, the Company and Apotex settled this matter with Apotex agreeing to pay the Company $115 million plus certain other consideration.

Gilead Patent Litigation and Opposition

In August 2013, Gilead Sciences, Inc. (Gilead) filed a lawsuit in the U.S. District Court for the Northern District of California seeking a declaration that two Company patents were invalid and not infringed by the sale of their two sofosbuvir containing products, Sovaldi and Harvoni. The Company filed a counterclaim that the sale of these products did infringe these two patents and sought a reasonable royalty for the past, present and future sales of these products. In March 2016, at the conclusion of a jury trial, the patents were found to be not invalid and infringed. The jury awarded the Company $200 million as a royalty for sales of these products up to December 2015. After the conclusion of the jury trial, the court held a bench trial on the equitable defenses raised by Gilead. In June 2016, the court found for Gilead and determined that Merck could not collect the jury award and that the patents were

unenforceable with respect to Gilead. The Company appealed the court's decision. Gilead also asked the court to overturn the jury's decision on validity. The court held a hearing on Gilead's motion in August 2016, and the court subsequently rejected Gilead's request, which Gilead appealed. In April 2018, the appeals court affirmed the decisions that both patents were unenforceable against Gilead. In September 2018, Merck filed a petition for a writ of certiorari to the U.S. Supreme Court seeking review of the appellate decision.

The Company, through its Idenix Pharmaceuticals, Inc. subsidiary, has pending litigation against Gilead in the United States, Germany and France based on different patent estates that would also be infringed by Gilead's sales of these two products. Gilead opposed the European patent at the European Patent Office (EPO). Trial in the United States was held in December 2016 and the jury returned a verdict for the Company, awarding damages of $2.54 billion. The Company submitted post-trial motions, including on the issues of enhanced damages and future royalties. Gilead submitted post-trial motions for judgment as a matter of law. A hearing on the motions was held in September 2017. Also, in September 2017, the court denied the Company's motion on

Notes to Condensed Consolidated Financial Statements (unaudited) (continued)

enhanced damages, granted its motion on prejudgment interest and deferred its motion on future royalties. In February 2018, the court granted Gilead's motion for judgment as a matter of law and found the patent was invalid for a lack of enablement. The Company appealed this decision. The EPO opposition division revoked the European patent, and the Company appealed this decision. The cases in France and Germany have been stayed pending the final decision of the EPO.

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, 2018 and December 31, 2017 of approximately $150 million and $160 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,								
($ and shares in millions)	Common Stock Shares	Common Stock Par Value	Other Paid-In Capital	Retained Earnings	Accumulated Other Comprehensive Loss	Treasury Stock Shares	Treasury Stock Cost	Non-Controlling Interests	Total
Balance at July 1, 2017	3,577	$ 1,788	$39,776	$45,046	$ (5,094)	850	$(42,053)	$ 249	$39,712
Net loss attributable to Merck & Co., Inc.	—	—	—	(56)	—	—	—	—	(56)
Other comprehensive income, net of taxes	—	—	—	—	149	—	—	—	149
Cash dividends declared on common stock ($0.47 per share)	—	—	—	(1,289)	—	—	—	—	(1,289)
Treasury stock shares purchased	—	—	—	—	—	2	(159)	—	(159)
Share-based compensation plans and other	—	—	47	—	—	(1)	93	—	140
Net income attributable to noncontrolling interests	—	—	—	—	—	—	—	5	5
Distributions attributable to noncontrolling interests	—	—	—	—	—	—	—	(3)	(3)
Balance at September 30, 2017	3,577	$ 1,788	$39,823	$43,701	$ (4,945)	851	$(42,119)	$ 251	$38,499
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
	—	—	—	—	(29)	—	—	—	(29)

Other comprehensive loss, net of taxes									
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

Notes to Condensed Consolidated Financial Statements (unaudited) (continued)

	Nine Months Ended September 30,								
($ and shares in millions)	Common Stock Shares	Common Stock Par Value	Other Paid-In Capital	Retained Earnings	Accumulated Other Comprehensive Loss	Treasury Stock Shares	Treasury Stock Cost	Non-Controlling Interests	Total
Balance at January 1, 2017	3,577	$ 1,788	$39,939	$44,133	$ (5,226)	828	$(40,546)	$ 220	$40,308
Net income attributable to Merck & Co., Inc.	—	—	—	3,440	—	—	—	—	3,440
Other comprehensive income, net of taxes	—	—	—	—	281	—	—	—	281
Cash dividends declared on common stock ($1.41 per share)	—	—	—	(3,872)	—	—	—	—	(3,872)
Treasury stock shares purchased	—	—	—	—	—	36	(2,312)	—	(2,312)
Share-based compensation plans and other	—	—	(116)	—	—	(13)	739	—	623
Acquisition of Vallée	—	—	—	—	—	—	—	25	25
Net income attributable to noncontrolling interests	—	—	—	—	—	—	—	16	16
Distributions attributable to noncontrolling interests	—	—	—	—	—	—	—	(10)	(10)
Balance at September 30, 2017	3,577	$ 1,788	$39,823	$43,701	$ (4,945)	851	$(42,119)	$ 251	$38,499
Balance at January 1, 2018	3,577	$ 1,788	$39,902	$41,350	$ (4,910)	880	$(43,794)	$ 233	$34,569
Adoption of new accounting standards (see Note 1)	—	—	—	322	(274)	—	—	—	48
Net income attributable to Merck & Co., Inc.	—	—	—	4,393	—	—	—	—	4,393
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

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,

	30,			
($ in millions)	2018	2017	2018	2017
Pretax share-based compensation expense	$91	$76	$261	$232
Income tax benefit	(14)	(23)	(42)	(70)
Total share-based compensation expense, net of taxes	$77	$53	$219	$162

During the first nine months of 2018 and 2017, the Company granted 7 million RSUs with a weighted-average grant date fair value of $58.19 per RSU and 5 million RSUs with a weighted-average grant date fair value of $63.96 per RSU, respectively. During the first nine months of 2018 and 2017, the Company granted 855 thousand PSUs with a weighted-average grant date fair value of $56.70 per PSU and 1 million PSUs with a weighted-average grant date fair value of $63.62 per PSU, respectively.

During the first nine months of 2018 and 2017, the Company granted 3 million stock options with a weighted-average exercise price of $57.72 per option and 4 million stock options with a weighted-average exercise price of $63.96 per option, respectively. The weighted-average fair value of options granted for the first nine months of 2018 and 2017 was $8.19 and $7.04 per option, respectively, and was determined using the following assumptions:

Notes to Condensed Consolidated Financial Statements (unaudited) (continued)

	Nine Months Ended September 30,	
	2018	2017
Expected dividend yield	3.4 %	3.6 %
Risk-free interest rate	2.8 %	2.0 %
Expected volatility	19.1%	17.8%
Expected life (years)	6.1	6.1

At September 30, 2018, there was $654 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 2.1 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,			
	2018		2017		2018		2017	
($ in millions)	U.S.	International	U.S.	International	U.S.	International	U.S.	International
Service cost	$77	$ 56	$80	$ 66	$245	$ 181	$234	$ 189
Interest cost	109	43	114	44	324	134	341	127
Expected return on plan assets	(209)	(106)	(210)	(101)	(634)	(326)	(646)	(292)
Amortization of unrecognized prior service credit	(12)	(3)	(13)	(3)	(37)	(10)	(40)	(8)
Net loss amortization	63	21	46	25	174	64	135	72
Termination benefits	1	—	3	1	18	—	11	2
Curtailments	3	—	4	(1)	7	(1)	8	(1)
Settlements	—	—	—	—	1	3	—	—
	$32	$ 11	$24	$ 31	$98	$ 45	$43	$ 89

The Company now anticipates contributing approximately $375 million to its U.S. pension plans in 2018, of which $325 million was contributed in the third quarter.

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)	2018	2017	2018	2017
Service cost	$15	$15	$43	$43
Interest cost	17	20	52	61
Expected return on plan assets	(21)	(20)	(63)	(59)
Amortization of unrecognized prior service credit	(21)	(24)	(63)	(74)
Net loss amortization	—	—	1	1
Termination benefits	—	—	2	1
Curtailments	(1)	(1)	(7)	(6)
	$(11)	$(10)	$(35)	$(33)

In connection with restructuring actions (see Note 5), 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.

Notes to Condensed Consolidated Financial Statements (unaudited) (continued)

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)	2018	2017	2018	2017
Interest income	$(92)	$(90)	$(257)	$(284)
Interest expense	190	189	569	564
Exchange losses (gains)	42	(6)	119	5
Equity income from affiliates	(81)	(18)	(93)	(11)
Net periodic defined benefit plan (credit) cost other than service cost	(119)	(121)	(384)	(381)
Other, net	(112)	(161)	(466)	(244)
	$(172)	$(207)	$(512)	$(351)

The increases in equity income from affiliates in the third quarter and first nine months of 2018 compared with the same periods of 2017 were driven primarily by higher equity income from certain research investment funds.

Other, net (as reflected in the table above) includes net gains on securities of $80 million and $202 million in the third quarter and first nine months of 2018, respectively, compared with $25 million and $74 million for the third quarter and first nine months of 2017, respectively. The increase in net gains on securities is attributable to the recognition of unrealized gains on equity securities pursuant to the prospective adoption of ASU 2016-01 on January 1, 2018 (see Note 1). Other, net in the first nine months of 2018 also includes a $115 million gain on the settlement of certain patent litigation (see Note 9). These gains were partially offset by lower income related to AstraZeneca's option exercise in 2014.

Interest paid for the nine months ended September 30, 2018 and 2017 was $535 million and $505 million, respectively.

14. Taxes on Income

The effective income tax rates of 26.5% and 125.5% for the third quarter of 2018 and 2017, respectively, and 27.6% and 25.5% for the first nine months of 2018 and 2017, respectively, reflect the impacts of acquisition and divestiture-related costs and restructuring costs, partially offset by the beneficial impact of foreign earnings. In addition, the effective income tax rates for the third quarter and first nine months of 2018 reflect the unfavorable impact of a $420 million aggregate pretax charge related to the termination of a collaboration agreement with Samsung for which no tax benefit was recognized. The effective income tax rate for the first nine months of 2018 also reflects the unfavorable impact of a $1.4 billion aggregate pretax charge recorded in connection with the formation of an oncology collaboration with Eisai for which no tax benefit was recognized. In addition, the effective income tax rates for the third quarter and first nine months of 2017 reflect the unfavorable impact of a $2.35 billion aggregate pretax charge recorded in connection with the formation of an oncology collaboration with AstraZeneca for which no tax benefit was recognized, partially offset by the favorable impact of a net tax benefit of $234 million related to the settlement of certain federal income tax issues (discussed below). The effective income tax rate for the first nine months of 2017 also reflects a benefit of $88 million related to the settlement of a state income tax issue.

In the third quarter of 2017, the Internal Revenue Service (IRS) concluded its examinations of Merck's 2006-2011 U.S. federal income tax returns. As a result, the Company was required to make a payment of approximately $2.8 billion. 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 net $234 million tax benefit in the third quarter of 2017. 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, as well as adjustments to reserves for unrecognized tax benefits relating to years which remain open to

examination that are affected by this settlement.

On December 22, 2017, new U.S. tax legislation known as the Tax Cuts and Jobs Act of 2017 (TCJA) was enacted. Among other provisions, the TCJA reduced the U.S. federal corporate statutory tax rate from 35% to 21% effective January 1, 2018, requires companies to pay a one-time transition tax on undistributed earnings of certain foreign subsidiaries, and creates new taxes on certain foreign sourced earnings. The Company reflected the impact of the TCJA in its 2017 financial statements as described below. However, application of certain provisions of the TCJA was and remains subject to further interpretation and in

Notes to Condensed Consolidated Financial Statements (unaudited) (continued)

these instances the Company made a reasonable estimate of the effects of the TCJA. Changes to these amounts in the first nine months of 2018 were immaterial.

The one-time transition tax is based on the Company's post-1986 undistributed earnings and profits (E&P). For a substantial portion of these undistributed E&P, the Company had not previously provided deferred taxes as these earnings were deemed by Merck to be retained indefinitely by subsidiary companies for reinvestment. The Company recorded a provisional amount for its one-time transition tax liability of $5.3 billion in 2017. Merck has not yet finalized its calculation of the total post-1986 undistributed E&P for these foreign subsidiaries. The transition tax is based in part on the amount of undistributed E&P held in cash and other specified assets; therefore, this amount may change when the Company finalizes its calculation of post-1986 undistributed foreign E&P and finalizes the amounts held in cash or other specified assets. This provisional amount was reduced by the reversal of $2.0 billion of deferred taxes that were previously recorded in connection with the merger of Schering-Plough Corporation in 2009 for certain undistributed foreign E&P. The Company anticipates that it will be able to utilize certain foreign tax credits to partially reduce the transition tax payment, resulting in a net transition tax payment of $5.1 billion.

The Company remeasured its deferred tax assets and liabilities at the new federal statutory tax rate of 21%, which resulted in a provisional deferred tax benefit of $779 million in 2017. The deferred tax benefit calculation remains subject to certain clarifications, particularly related to executive compensation and benefits.

Beginning in 2018, the TCJA includes a tax on "global intangible low-taxed income" (GILTI) as defined in the TCJA. The Company is allowed to make an accounting policy election to account for the tax effects of the GILTI tax either in the income tax provision in future periods as the tax arises, or as a component of deferred taxes on the related investments in foreign subsidiaries. The Company is currently evaluating the GILTI provisions of the TCJA and the implications on its tax provision and has not finalized the accounting policy election; therefore, the Company has not recorded deferred taxes for GILTI.

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)	2018	2017	2018	2017
Net income (loss) attributable to Merck & Co., Inc.	$1,950	$(56)	$4,393	$3,440
Average common shares outstanding	2,662	2,727	2,680	2,735
Common shares issuable [1]	16	—	14	19
Average common shares outstanding assuming dilution	2,678	2,727	2,694	2,754
Basic earnings (loss) per common share attributable to Merck & Co., Inc. common shareholders	$0.73	$(0.02)	$1.64	$1.26
Earnings (loss) per common share assuming dilution attributable to Merck & Co., Inc. common shareholders	$0.73	$(0.02)	$1.63	$1.25

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

For the three months ended September 30, 2018, 2 million, and for the first nine months of 2018 and 2017, 7 million and 4 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. The Company recorded a net loss for the three months ended September 30, 2017; therefore, no potential dilutive common shares were used in the computation of loss per common share assuming dilution because the effect would have been antidilutive.

Notes to Condensed Consolidated Financial Statements (unaudited) (continued)

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, 2017, net of taxes	$(37)	$ 75	$(3,133)	$(1,999)	$ (5,094)
Other comprehensive income (loss) before reclassification adjustments, pretax	(88)	170	2	23	107
Tax	31	(19)	(13)	44	43
Other comprehensive income (loss) before reclassification adjustments, net of taxes	(57)	151	(11)	67	150
Reclassification adjustments, pretax	(14)[1]	(24)[2]	31[3]	—	(7)
Tax	5	8	(7)	—	6
Reclassification adjustments, net of taxes	(9)	(16)	24	—	(1)
Other comprehensive income (loss), net of taxes	(66)	135	13	67	149
Balance September 30, 2017, net of taxes	$(103)	$ 210	$(3,120)	$(1,932)	$ (4,945)
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)

Notes to Condensed Consolidated Financial Statements (unaudited) (continued)

	Nine Months Ended September 30,				
($ in millions)	Derivatives	Investments	Employee Benefit Plans	Cumulative Translation Adjustment	Accumulated Other Comprehensive Income (Loss)
Balance January 1, 2017, net of taxes	$338	$ (3)	$ (3,206)	$ (2,355)	$ (5,226)
Other comprehensive income (loss) before reclassification adjustments, pretax	(520)	283	27	261	51
Tax	182	(23)	(7)	162	314
Other comprehensive income (loss) before reclassification adjustments, net of taxes	(338)	260	20	423	365
Reclassification adjustments, pretax	(159) [1]	(73) [2]	86 [3]	—	(146)
Tax	56	26	(20)	—	62
Reclassification adjustments, net of taxes	(103)	(47)	66	—	(84)
Other comprehensive income (loss), net of taxes	(441)	213	86	423	281
Balance September 30, 2017, net of taxes	$ (103)	$ 210	$ (3,120)	$ (1,932)	$ (4,945)
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 (see Note 1)	(23)	1	(344)	100	(266)
Adoption of ASU 2016-01 (see Note 1)	—	(8)	—	—	(8)
Balance September 30, 2018, net of taxes	$92	$ (124)	$ (3,025)	$ (2,094)	$ (5,151)

(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 investments that were reclassified from AOCI to Other (income) expense, net. In 2017, these amounts included both debt and equity investments; however, upon adoption of ASU 2016-01 in 2018 (see Note 1), these amounts relate only to available-for-sale debt investments.

(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 Animal Health segment met the criteria for separate reporting and became a reportable segment in the first quarter of 2018.

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. Vaccine products consist of preventive pediatric,

adolescent and adult vaccines, primarily administered at physician offices. The Company sells these human health vaccines primarily to physicians, wholesalers, physician distributors and government entities. A large component of pediatric and adolescent vaccine sales are made to the U.S. Centers for Disease Control and Prevention Vaccines for Children program, which is funded by the U.S. government. Additionally, the Company sells vaccines to the Federal government for placement into vaccine stockpiles.

The Animal Health segment discovers, develops, manufactures and markets animal health products, including vaccines, 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.

Notes to Condensed Consolidated Financial Statements (unaudited) (continued)

Sales of the Company's products were as follows:

	Three Months Ended September 30,						Nine Months Ended September 30,					
	2018			2017			2018			2017		
($ in millions)	U.S.	Int'l	Total	U.S.	Int'l	Total	U.S.	Int'l	Total	U.S.	Int'l	To
Pharmaceutical:												
Oncology												
Keytruda	$1,109	$780	$1,889	$604	$442	$1,047	$2,906	$2,114	$5,020	$1,522	$990	$2
Emend	71	52	123	88	49	137	239	157	396	257	156	41
Temodar	—	46	46	—	68	68	3	156	159	4	194	19
Alliance revenue - Lynparza	33	15	49	—	5	5	88	37	125	—	5	5
Alliance revenue - Lenvima	30	13	43	—	—	—	49	29	78	—	—	—
Vaccines												
Gardasil/Gardasil 9	740	308	1,048	484	191	675	1,422	894	2,317	1,195	481	1,
ProQuad/M-M-R II/Varivax	429	96	525	419	100	519	1,097	246	1,343	1,058	215	1,
Pneumovax 23	160	54	214	174	56	229	394	192	586	392	166	55
RotaTeq	134	57	191	127	52	179	384	156	540	377	148	52
Zostavax	(1)	56	54	139	94	234	16	147	163	356	191	54
Hospital Acute Care												
Bridion	96	120	217	63	122	185	272	389	661	162	333	49
Noxafil	89	99	188	78	83	162	257	294	551	220	237	45
Invanz	74	62	137	93	66	159	252	185	437	268	177	44
Cubicin	55	40	95	41	50	91	150	137	287	148	141	29
Cancidas	2	77	79	6	88	94	10	247	257	17	310	32
Primaxin	1	71	72	5	68	73	6	206	212	7	199	20
Immunology												
Simponi	—	210	210	—	219	219	—	673	673	—	602	60
Remicade	—	135	135	—	214	214	—	459	459	—	651	65
Neuroscience												
Belsomra	23	43	66	27	30	56	76	115	191	72	78	15
Virology												
Isentress/Isentress HD	123	151	275	143	167	310	383	477	860	422	474	89
Zepatier	18	86	104	228	241	468	8	339	347	683	680	1,
Cardiovascular												
Zetia	9	157	165	65	255	320	34	662	696	298	723	1,
Vytorin	—	92	92	(6)	148	142	11	402	414	114	451	56
Atozet	—	84	84	—	59	59	—	258	258	—	171	17
Adempas	—	94	94	—	70	70	—	238	238	—	221	22
Diabetes												
Januvia	498	429	927	598	414	1,012	1,466	1,291	2,756	1,646	1,153	2,
Janumet	225	339	563	197	316	513	625	1,067	1,693	640	933	1,
Women's Health												
NuvaRing	193	41	234	160	54	214	550	135	686	425	148	57
Implanon/Nexplanon	133	53	186	110	45	155	375	160	535	367	137	50
Diversified Brands												
Singulair	5	156	161	16	145	161	16	505	521	28	522	55
Cozaar/Hyzaar	4	99	103	9	119	128	18	330	348	15	345	36

Nasonex	7	64	71	(23)	65	42	8	266	274	16	250	26
Arcoxia	—	83	83	—	80	80	—	249	249	—	272	27
Follistim AQ	26	34	60	30	41	72	83	115	198	104	128	23
Fosamax	2	42	45	4	48	53	3	155	159	7	173	18
Dulera	44	6	50	52	7	59	128	21	149	191	19	21
Other pharmaceutical [1]	317	666	980	266	688	952	877	2,150	3,023	876	2,140	3,0
Total Pharmaceutical segment sales	4,649	5,010	9,658	4,197	4,959	9,156	12,206	15,653	27,859	11,887	14,214	26
Animal Health:												
Livestock	153	508	660	137	518	655	383	1,563	1,946	359	1,457	1,
Companion Animals	153	207	361	153	192	345	541	689	1,230	483	595	1,0
Total Animal Health segment sales	306	715	1,021	290	710	1,000	924	2,252	3,176	842	2,052	2,
Other segment sales [2]	55	—	55	100	—	100	194	1	195	294	—	29
Total segment sales	5,010	5,725	10,734	4,587	5,669	10,256	13,324	17,906	31,230	13,023	16,266	29
Other [3]	20	39	60	7	63	69	101	(35)	66	73	327	40
	$5,030	$5,764	$10,794	$4,594	$5,732	$10,325	$13,425	$17,871	$31,296	$13,096	$16,593	$2

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. Other in the first nine months of 2018 and 2017 also includes $81 million and $60 million, respectively, related to the sale of the marketing rights to certain products.

Notes to Condensed Consolidated Financial Statements (unaudited) (continued)

Consolidated revenues by geographic area where derived are as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
($ in millions)	2018	2017	2018	2017
United States	$5,030	$4,594	$13,425	$13,096
Europe, Middle East and Africa	2,884	2,941	9,218	8,374
Asia Pacific	1,178	1,112	3,766	3,164
Japan	761	775	2,353	2,320
Latin America	622	585	1,748	1,654
Other	319	318	786	1,081
	$10,794	$10,325	$31,296	$29,689

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
($ in millions)	2018	2017	2018	2017
Segment profits:				
Pharmaceutical segment	$6,479	$5,906	$18,109	$16,657
Animal Health segment	409	389	1,273	1,202
Other segments	5	93	94	234
Total segment profits	6,893	6,388	19,476	18,093
Other profits (losses)	55	(78)	(35)	107
Unallocated:				
Interest income	92	90	257	284
Interest expense	(190)	(189)	(569)	(564)
Equity income from affiliates	85	23	101	16
Depreciation and amortization	(324)	(334)	(1,006)	(1,036)
Research and development	(1,855)	(4,208)	(6,878)	(7,399)
Amortization of purchase accounting adjustments	(679)	(765)	(2,144)	(2,322)
Restructuring costs	(171)	(153)	(494)	(470)
Aggregate charge related to termination of collaboration agreement with Samsung	(420)	—	(420)	—
Other unallocated, net	(821)	(574)	(2,191)	(2,067)
	$2,665	$200	$6,097	$4,642

Pharmaceutical segment profits are comprised of segment sales less standard costs, as well as marketing and administrative expenses and research and development costs directly incurred by the segment. Animal Health segment profits are comprised of segment sales, less all materials and production costs, as well as marketing 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 materials and production costs not included in segment profits as described above, research and development expenses incurred in Merck Research Laboratories, the Company’s research and development division that focuses on human health-related activities, or general and administrative expenses, nor the cost of financing these activities. Separate divisions maintain responsibility for monitoring and managing these costs, including depreciation related to fixed assets utilized by these divisions and, therefore, they are not included in segment profits. In addition, costs related to restructuring activities, as well as the amortization of purchase accounting adjustments are not allocated to segments.

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

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

In the first quarter of 2018, the Company adopted a new accounting standard related to the classification of certain defined benefit plan costs (see Note 1), which resulted in a change to the measurement of segment profits. Net periodic benefit cost (credit) other than service cost is no longer included as a component of segment profits. Prior period amounts have been recast to conform to the new presentation.

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

Recent Developments

Dividend Increase and Share Repurchase Program

In October 2018, Merck announced that its Board of Directors approved a 15% increase to the Company's quarterly dividend, raising it to $0.55 per share from $0.48 per share of the Company's outstanding common stock. The Board also authorized an additional $10 billion of treasury stock purchases with no time limit for completion. The Company has entered into a $5 billion accelerated share repurchase program under its expanded authorization (see "Liquidity and Capital Resources" below).

Business Developments

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 Cavatak (V937, formerly CVA21), Viralytics's investigational oncolytic immunotherapy. Cavatak 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. Cavatak 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 (pembrolizumab), Merck's anti-PD-1 (programmed death receptor-1) therapy. Under a previous agreement between Merck and Viralytics, a study is investigating the use of the Keytruda and Cavatak combination in melanoma, prostate, lung and bladder cancers.

In March 2018, Merck and Eisai Co., Ltd. (Eisai) announced a strategic collaboration for the worldwide co-development and co-commercialization of Lenvima (lenvatinib mesylate), an orally available tyrosine kinase inhibitor discovered by Eisai. Under the agreement, Merck and Eisai will develop and commercialize Lenvima jointly, both as monotherapy and in combination with Keytruda. Eisai records Lenvima product sales globally 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. Under the agreement, Merck made upfront payments to Eisai of $750 million and will make payments of up to $650 million for certain option rights through 2021 ($325 million in January 2019 or earlier in certain circumstances, $200 million in January 2020 and $125 million in January 2021). The Company recorded an aggregate charge of $1.4 billion in Research and development expenses in the first nine months of 2018 related to the upfront payments and future option payments. In addition, the agreement provides for Eisai to receive up to $385 million associated with the achievement of certain clinical and regulatory milestones and up to $3.97 billion for the achievement of milestones associated with sales of Lenvima. Lenvima has since been approved for the treatment of patients with unresectable hepatocellular carcinoma in the United States, Europe, China and Japan.

Pricing

Global efforts toward health care cost containment continue to exert pressure on product pricing and market access worldwide. In the United States, pricing pressures continue 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, could result in further pricing pressures. In July 2018, the Company announced its commitment not to increase the average net price in the United States across its human health portfolio of products by more than inflation annually.

In several international markets, government-mandated pricing actions have reduced prices of generic and patented drugs. In addition, other austerity measures negatively affected the Company's revenue performance in the first nine months of 2018. The Company anticipates these pricing actions and other austerity measures will continue to negatively affect revenue performance for the remainder of 2018.

Cyber-attack

On June 27, 2017, the Company experienced a network cyber-attack that led to a disruption of its worldwide operations, including manufacturing, research and sales operations. Due to a residual backlog of orders for certain

products as a result of the cyber-attack, the Company was unable to fulfill orders for certain products in certain markets, which had an unfavorable effect on sales for the first nine months of 2018 of approximately $150 million, including an immaterial impact to sales in the third quarter of 2018. The Company expects an immaterial impact to sales for the remainder of 2018. Sales in the third quarter and first nine months of 2017 were unfavorably affected by $135 million due to the cyber-attack. In addition, the Company recorded manufacturing-related expenses, primarily unfavorable manufacturing variances, in Materials and production costs, as well as expenses related to remediation efforts in Marketing and administrative expenses and Research and development expenses, which aggregated approximately $175 million for the third quarter and first nine months of 2017. Costs in the first nine months of 2018 were immaterial.

The Company has insurance coverage insuring against costs resulting from cyber-attacks and has received insurance proceeds. However, there may be disputes with the insurers about the availability of the insurance coverage for claims related to this incident.

Operating Results

Sales

Worldwide sales were $10.8 billion for the third quarter of 2018, an increase of 5% compared with the third quarter of 2017 including a 1% unfavorable effect from foreign exchange. Global sales were $31.3 billion for the first nine months of 2018, an increase of 5% compared with the same period of 2017. Sales growth in both periods was driven primarily by higher sales in the oncology franchise reflecting strong growth of Keytruda, as well as alliance revenue related to Lynparza (olaparib) and Lenvima. Also contributing to revenue growth were higher sales in the hospital acute care franchise, largely attributable to Bridion (sugammadex) Injection and Noxafil (posaconazole). The sales increases in the third quarter and first nine months of 2018 also reflect higher sales of human papillomavirus (HPV) vaccine Gardasil (Human Papillomavirus Quadrivalent [Types 6, 11, 16 and 18] Vaccine, Recombinant)/Gardasil 9 (Human Papillomavirus 9-valent Vaccine, Recombinant), which were attributable in part to a reduction of Gardasil 9 sales due to a borrowing the Company made from the U.S. Centers for Disease Control and Prevention (CDC) Pediatric Vaccine Stockpile in the third quarter of 2017 as discussed below. Higher sales of animal health products also drove revenue growth in the third quarter and first nine months of 2018. Additionally, a lower impact from the June 2017 cyber-attack as discussed above also contributed to the sales increase in the third quarter and first months of 2018.

Revenue growth in the third quarter and first nine months of 2018 was partially offset by declines in the virology franchise driven primarily by lower sales of hepatitis C virus (HCV) treatment Zepatier (elbasvir and grazoprevir), as well as lower sales of shingles (herpes zoster) vaccine Zostavax (Zoster Vaccine Live). The ongoing effects of generic and biosimilar competition for cardiovascular products Zetia (ezetimibe), Vytorin (ezetimibe and simvastatin), and immunology product Remicade (infliximab), as well as lower sales of products within the diversified brands franchise also partially offset revenue growth in the quarter and year-to-date period. 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.

Sales of the Company's products were as follows:

	Three Months Ended September 30,						Nine Months Ended September 30,					
	2018			2017			2018			2017		
($ in millions)	U.S.	Int'l	Total	U.S.	Int'l	Total	U.S.	Int'l	Total	U.S.	Int'l	Tot
Pharmaceutical:												
Oncology												
Keytruda	$1,109	$780	$1,889	$604	$442	$1,047	$2,906	$2,114	$5,020	$1,522	$990	$2,5
Emend	71	52	123	88	49	137	239	157	396	257	156	413
Temodar	—	46	46	—	68	68	3	156	159	4	194	198
Alliance revenue - Lynparza	33	15	49	—	5	5	88	37	125	—	5	5
Alliance revenue - Lenvima	30	13	43	—	—	—	49	29	78	—	—	—
Vaccines												
Gardasil/Gardasil 9	740	308	1,048	484	191	675	1,422	894	2,317	1,195	481	1,67
ProQuad/M-M-R II/Varivax	429	96	525	419	100	519	1,097	246	1,343	1,058	215	1,27
Pneumovax 23	160	54	214	174	56	229	394	192	586	392	166	558
RotaTeq	134	57	191	127	52	179	384	156	540	377	148	525
Zostavax	(1)	56	54	139	94	234	16	147	163	356	191	547
Hospital Acute Care												
Bridion	96	120	217	63	122	185	272	389	661	162	333	495
Noxafil	89	99	188	78	83	162	257	294	551	220	237	458
Invanz	74	62	137	93	66	159	252	185	437	268	177	445
Cubicin	55	40	95	41	50	91	150	137	287	148	141	290
Cancidas	2	77	79	6	88	94	10	247	257	17	310	327
Primaxin	1	71	72	5	68	73	6	206	212	7	199	206
Immunology												
Simponi	—	210	210	—	219	219	—	673	673	—	602	602
Remicade	—	135	135	—	214	214	—	459	459	—	651	651
Neuroscience												
Belsomra	23	43	66	27	30	56	76	115	191	72	78	150
Virology												
Isentress/Isentress HD	123	151	275	143	167	310	383	477	860	422	474	896
Zepatier	18	86	104	228	241	468	8	339	347	683	680	1,36
Cardiovascular												
Zetia	9	157	165	65	255	320	34	662	696	298	723	1,02
Vytorin	—	92	92	(6)	148	142	11	402	414	114	451	565
Atozet	—	84	84	—	59	59	—	258	258	—	171	171
Adempas	—	94	94	—	70	70	—	238	238	—	221	221
Diabetes												
Januvia	498	429	927	598	414	1,012	1,466	1,291	2,756	1,646	1,153	2,79
Janumet	225	339	563	197	316	513	625	1,067	1,693	640	933	1,57
Women's Health												
NuvaRing	193	41	234	160	54	214	550	135	686	425	148	573
Implanon/Nexplanon	133	53	186	110	45	155	375	160	535	367	137	503
Diversified Brands												

Singulair	5	156	161	16	145	161	16	505	521	28	522	550
Cozaar/Hyzaar	4	99	103	9	119	128	18	330	348	15	345	360
Nasonex	7	64	71	(23)	65	42	8	266	274	16	250	266
Arcoxia	—	83	83	—	80	80	—	249	249	—	272	272
Follistim AQ	26	34	60	30	41	72	83	115	198	104	128	232
Fosamax	2	42	45	4	48	53	3	155	159	7	173	180
Dulera	44	6	50	52	7	59	128	21	149	191	19	210
Other pharmaceutical [1]	317	666	980	266	688	952	877	2,150	3,023	876	2,140	3,01
Total Pharmaceutical segment sales	4,649	5,010	9,658	4,197	4,959	9,156	12,206	15,653	27,859	11,887	14,214	26,1
Animal Health:												
Livestock	153	508	660	137	518	655	383	1,563	1,946	359	1,457	1,81
Companion Animals	153	207	361	153	192	345	541	689	1,230	483	595	1,07
Total Animal Health segment sales	306	715	1,021	290	710	1,000	924	2,252	3,176	842	2,052	2,89
Other segment sales [2]	55	—	55	100	—	100	194	1	195	294	—	294
Total segment sales	5,010	5,725	10,734	4,587	5,669	10,256	13,324	17,906	31,230	13,023	16,266	29,2
Other [3]	20	39	60	7	63	69	101	(35)	66	73	327	400
	$5,030	$5,764	$10,794	$4,594	$5,732	$10,325	$13,425	$17,871	$31,296	$13,096	$16,593	$29

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. Other in the first nine months of 2018 and 2017 also includes $81 million and $60 million, respectively, related to the sale of the marketing rights to certain products.

Product sales are recorded net of the provision for discounts, including chargebacks, which are customer discounts that occur when a contracted customer purchases through an intermediary wholesale purchaser, and rebates that are owed based upon definitive contractual agreements or legal requirements with private sector and public sector (Medicaid and Medicare Part D) benefit providers, after the final dispensing of the product by a pharmacy to a benefit plan participant. These discounts, in the aggregate, reduced U.S. sales by $2.6 billion and $2.9 billion for the three months ended September 30, 2018 and 2017, respectively, and by $7.7 billion and $8.2 billion for the nine months ended September 30, 2018 and 2017, respectively. Inventory levels at key U.S. wholesalers for each of the Company's major pharmaceutical products are generally less than one month.

Pharmaceutical Segment

Oncology

Keytruda, an anti-PD-1 therapy, is approved in the United States and in the European Union (EU) as monotherapy for the treatment of certain patients with non-small-cell lung cancer (NSCLC), melanoma, classical Hodgkin lymphoma (cHL), head and neck squamous cell carcinoma (HNSCC) and urothelial carcinoma, a type of bladder cancer, and in combination with pemetrexed and carboplatin for certain patients with nonsquamous NSCLC. Keytruda is also approved in the United States as monotherapy for the treatment of certain patients with gastric or gastroesophageal junction adenocarcinoma and microsatellite instability-high or mismatch repair deficient cancer. In addition, the U.S. Food and Drug Administration (FDA) recently approved Keytruda for the treatment of certain patients with cervical cancer, primary mediastinal large B-cell lymphoma (PMBCL), a type of non-Hodgkin lymphoma, and in combination with carboplatin and either paclitaxel or nab-paclitaxel for patients with squamous NSCLC (see below). Keytruda is approved in Japan for the treatment of certain patients with melanoma, NSCLC, cHL, and urothelial carcinoma. Additionally, in July 2018, Keytruda was approved in China for the treatment of adult patients with unresectable or metastatic melanoma following failure of one prior line of therapy. Keytruda is also approved in many other international markets. The Keytruda clinical development program includes studies across a broad range of cancer types (see "Research and Development" below).

In August 2018, the FDA approved an expanded label for Keytruda 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 results of the KEYNOTE-189 trial. Keytruda in combination with pemetrexed and carboplatin was first approved in 2017 under the FDA's accelerated approval process for the first-line treatment of patients with metastatic nonsquamous NSCLC, based on tumor response rates and PFS data from a Phase 2 study (KEYNOTE-021, Cohort G1). 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-189 and has resulted in the FDA converting the accelerated approval to full (regular) approval. Also, in September 2018, the EU approved Keytruda in combination with pemetrexed and platinum chemotherapy for the first-line treatment of metastatic nonsquamous NSCLC in adults whose tumors have no EGFR or ALK positive mutations. This is the first approval in Europe for an anti-PD-1 therapy in combination with chemotherapy.

In June 2018, the FDA approved Keytruda for the treatment of patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy whose tumors express PD-L1 as determined by an FDA-approved test. Also in June 2018, the FDA approved Keytruda for the treatment of adult and pediatric patients with refractory PMBCL, or who have relapsed after two or more prior lines of therapy. With this indication, Keytruda becomes the first anti-PD-1 therapy to be approved for the treatment of PMBCL. Both of these indications were approved under the FDA's accelerated approval regulations based on tumor response rate and durability of response.

Additionally, in September 2018, the EC approved Keytruda as monotherapy for the treatment of recurrent or metastatic HNSCC in adults whose tumors express PD-L1 with a tumor proportion score (TPS) of ≥50%, and who progressed on or after platinum-containing chemotherapy, based on data from the Phase 3 KEYNOTE-040 trial.

In October 2018, the FDA approved Keytruda, in combination with carboplatin and either paclitaxel or nab-paclitaxel, for the first-line treatment of patients with metastatic squamous NSCLC based on results from the KEYNOTE-407 trial. This approval marks the first time an anti-PD-1 regimen has been approved for the first-line treatment of squamous NSCLC regardless of tumor PD-L1 expression status. Keytruda is the first anti-PD-1 approved in the

first-line setting as both combination and monotherapy in certain patients with metastatic NSCLC.

Global sales of Keytruda were $1.9 billion in the third quarter of 2018 compared with $1.0 billion in the third quarter of 2017 and were $5.0 billion in the first nine months of 2018 compared with $2.5 billion for the same period of 2017. Sales growth in both periods was driven by volume growth in all markets 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 reflecting both the continued adoption of Keytruda in the first-line setting as monotherapy for patients with metastatic NSCLC whose tumors have high PD-L1 expression, as well as the uptake of Keytruda in combination with pemetrexed and carboplatin, a commonly used chemotherapy regimen, for the first-line treatment of metastatic nonsquamous NSCLC with or without PD-L1 expression. Other indications, including HNSCC, bladder, and microsatellite instability-high cancer, also contributed to Keytruda sales growth in the third quarter and first nine months of 2018. Sales growth in international

markets reflects continued uptake for the treatment of NSCLC, as the Company has secured reimbursement in most major markets, along with growth in the melanoma, HNSCC, and bladder cancer indications.

Lynparza, an oral poly (ADP-ribose) polymerase (PARP) inhibitor being developed as part of a collaboration with AstraZeneca PLC (AstraZeneca) (see Note 4 to the condensed consolidated financial statements), is currently approved for certain types of ovarian and breast cancer. Merck recorded alliance revenue of $49 million and $125 million in the third quarter and first nine months of 2018, respectively, related to Lynparza. In January 2018, the FDA approved Lynparza for use in patients with BRCA-mutated, human epidermal growth factor receptor 2 (HER2)-negative metastatic breast cancer who have been previously treated with chemotherapy, triggering a $70 million milestone payment from Merck to AstraZeneca. Lynparza was also approved in Japan in July 2018 for use in patients with unresectable or recurrent BRCA-mutated, HER2-negative breast cancer who have received prior chemotherapy. Lynparza was approved for use as a maintenance therapy in patients with platinum-sensitive relapsed ovarian cancer, regardless of BRCA mutation status in the EU in May 2018 and in Japan in January 2018.

Lenvima, an orally available tyrosine kinase inhibitor being developed as part of a collaboration with Eisai (see Note 4 to the condensed consolidated financial statements), is currently approved for certain types of thyroid cancer, hepatocellular carcinoma, and in combination for certain patients with renal cell cancer. Merck recorded alliance revenue of $43 million and $78 million in the third quarter and first nine months of 2018, respectively, related to Lenvima. Lenvima was approved for the treatment of certain patients with unresectable hepatocellular carcinoma in Japan in March 2018, in the United States and EU in August 2018, and in China in September 2018, triggering capitalized milestone payments of $25 million, $125 million, $50 million, and $25 million, respectively, to Eisai.

Vaccines

Worldwide sales of Gardasil/Gardasil 9, vaccines to help prevent certain cancers and diseases caused by certain types of HPV, were $1.0 billion in the third quarter of 2018, an increase of 55% compared with the third quarter of 2017 including a 1% unfavorable effect from foreign exchange. The increase was driven primarily by higher sales in the United States attributable to a borrowing from the CDC Pediatric Vaccine Stockpile in the third quarter of 2017 as discussed below. The increase in sales of Gardasil/Gardasil 9 during the third quarter of 2018 was also driven by higher demand in most international markets, particularly in China due to the ongoing launch and in Europe. Global sales of Gardasil/Gardasil 9 were $2.3 billion in the first nine months of 2018, an increase of 38% compared with the same period of 2017 including a 2% favorable effect from foreign exchange. The increase was driven in part by the 2017 CDC stockpile borrowing, as well as by higher demand in the Asia Pacific region, particularly in China, and in Europe. In April 2018, China’s Food and Drug Administration approved Gardasil 9 for use in girls and women ages 16 to 26. In October 2018, the FDA approved an expanded age indication for use in women and men ages 27 to 45 for the prevention of certain cancers and diseases caused by the nine HPV types covered by the vaccine.

During the third quarter of 2017, the Company made a request to borrow doses of Gardasil 9 from the CDC Pediatric Vaccine Stockpile, which the CDC granted. The Company’s decision to borrow the doses from the CDC was driven in part by the temporary shutdown resulting from the cyber-attack that occurred in June 2017, as well as by overall higher demand than expected. As a result of the borrowing, the Company reversed the sales related to the borrowed doses, which reduced revenues by approximately $240 million in the third quarter of 2017, and recognized a corresponding liability. The Company subsequently replenished a portion of the borrowed doses in the fourth quarter of 2017. The net effect of the borrowing and subsequent partial replenishment was a reduction in sales of $125 million for the full year of 2017. The Company anticipates it will replenish the remaining borrowed doses in the fourth quarter of 2018.

Global sales of ProQuad (Measles, Mumps, Rubella and Varicella Virus Vaccine Live), a pediatric combination vaccine to help protect against measles, mumps, rubella and varicella, were $186 million in the third quarter of 2018, an increase of 10% compared with $169 million in the third quarter of 2017. Worldwide sales of ProQuad were $455 million in the first nine months of 2018, an increase of 13% compared with $402 million in the first nine months of 2017. Foreign exchange unfavorably affected global sales performance by 1% in the third quarter of 2018. 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 (Measles, Mumps and Rubella Virus Vaccine Live), a vaccine to help protect against measles, mumps and rubella, were $121 million for the third quarter of 2018, a decline of 2% compared with $124 million for the third quarter of 2017. Global sales of M M R II were $310 million in the first nine months of 2018, an increase of 2% compared with $303 million in the first nine months of 2017. Foreign exchange favorably affected global sales performance by 1% in the third quarter of 2018.

Global sales of Varivax (Varicella Virus Vaccine Live), a vaccine to help prevent chickenpox (varicella), were $217 million for the third quarter of 2018, a decline of 4% compared with $226 million for the third quarter of 2017. The sales decrease primarily reflects volume declines in Turkey due to the loss of a government tender, partially offset by volume growth in Latin America. Worldwide sales of Varivax were $578 million in the first nine months of 2018, an increase of 2% compared with $568 million in the first nine months of 2017. Foreign exchange favorably affected global sales performance by 1% in the first nine

months of 2018. Sales growth in the year-to-date period was largely attributable to volume growth in most international markets, along with higher pricing in the United States, partially offset by volume declines in Turkey due to the loss of a government tender.

Global sales of Pneumovax 23 (pneumococcal vaccine polyvalent), a vaccine to help prevent pneumococcal disease, were $214 million in the third quarter of 2018, a decline of 7% compared with the third quarter of 2017, driven primarily by lower sales in the United States reflecting lower demand, partially offset by higher pricing. Worldwide sales of Pneumovax 23 were $586 million in the first nine months of 2018, an increase of 5% compared with the same period of 2017, driven primarily by volume growth in Europe. Sales in the United States were relatively flat in the first nine months of 2018 as higher pricing offset lower volumes. Foreign exchange unfavorably affected global sales performance by 1% in the third quarter of 2018 and favorably affected global sales performance by 1% in the first nine months of 2018.

Worldwide sales of RotaTeq (Rotavirus Vaccine, Live Oral, Pentavalent), a vaccine to help protect against rotavirus gastroenteritis in infants and children, were $191 million in the third quarter of 2018, an increase of 7% compared with the third quarter of 2017 including a 1% unfavorable effect from foreign exchange. Sales growth was driven primarily by the launch in China and higher volumes and pricing in the United States. Global sales of RotaTeq were $540 million in the first nine months of 2018, up 3% compared with the same period of 2017 including a 1% favorable effect from foreign exchange. Sales growth was driven primarily by the launch in China and higher pricing in the United States.

Worldwide sales of Zostavax, a vaccine to help prevent shingles (herpes zoster) in adults 50 years of age and older, were $54 million in the third quarter of 2018 and $163 million in the first nine months of 2018, declines of 77% and 70%, respectively, compared with the same periods of 2017. Foreign exchange favorably affected global sales performance by 1% in the first nine months of 2018. The sales declines were driven by lower volumes in most markets, particularly in the United States. Lower demand in the United States reflects the approval of a competitor’s vaccine that received a preferential recommendation from the CDC’s Advisory Committee on Immunization Practices in October 2017 for the prevention of shingles over Zostavax. The Company anticipates competition will continue to have a material adverse effect on sales of Zostavax in future periods.

Hospital Acute Care

Worldwide sales of Bridion, for the reversal of two types of neuromuscular blocking agents used during surgery, were $217 million in the third quarter of 2018, an increase of 17% compared with the third quarter of 2017 including a 3% unfavorable effect from foreign exchange. Global sales of Bridion were $661 million in the first nine months of 2018, an increase of 33% compared with the same period of 2017 including a 2% favorable effect from foreign exchange. Sales growth in both periods primarily reflects volume growth in the United States and certain European markets.

Worldwide sales of Noxafil, for the prevention of invasive fungal infections, were $188 million in the third quarter of 2018, an increase of 16% compared with the third quarter of 2017 including a 2% unfavorable effect from foreign exchange. Global sales of Noxafil were $551 million in the first nine months of 2018, an increase of 21% compared with the same period of 2017 including a 3% favorable effect from foreign exchange. Sales growth in both periods primarily reflects higher demand in the United States, as well as volume growth in certain European markets and in China.

Global sales of Invanz (ertapenem sodium), for the treatment of certain infections, were $137 million in the third quarter of 2018, a decline of 14% compared with the third quarter of 2017 including a 2% unfavorable effect from foreign exchange. Worldwide sales of Invanz were $437 million for the first nine months of 2018, a decrease of 2% compared with the same period of 2017. The sales declines were driven primarily by lower volumes in the United States. The patent that provided U.S. market exclusivity for Invanz expired in November 2017 and the Company is experiencing a decline in U.S. Invanz sales as a result of generic competition and expects the decline to continue.

Global sales of Cancidas (caspofungin acetate), an anti-fungal product sold primarily outside of the United States, were $79 million in the third quarter of 2018 and $257 million in the first nine months of 2018, declines of 16% and 22%, respectively, compared with the same periods of 2017. Foreign exchange unfavorably affected global sales performance by 2% in the third quarter of 2018 and favorably affected global sales performance by 3% in the first

nine months of 2018. The sales declines were driven by generic competition in certain European markets. The EU compound patent for Cancidas expired in April 2017. Accordingly, the Company is experiencing a significant decline in Cancidas sales in these European markets and expects the decline to continue.

In September 2018, Merck announced that the pivotal Phase 3 clinical study evaluating the Company's antibiotic Zerbaxa (ceftolozane and tazobactam) at an investigational dose for the treatment of adult patients with either ventilated hospital-acquired bacterial pneumonia or ventilator-associated bacterial pneumonia met the pre-specified primary endpoints, demonstrating non-inferiority to meropenem, the active comparator, in day 28 all-cause mortality and in clinical cure rate at the test-of-cure visit. Based on these results, Merck plans to submit supplemental new drug applications to the FDA and European Medicines Agency (EMA) seeking regulatory approval of Zerbaxa for these potential new indications. Zerbaxa is currently approved in the United States for the treatment of adult patients with complicated urinary tract infections caused by certain Gram-negative microorganisms

and in combination with metronidazole for the treatment of complicated intra-abdominal infections caused by certain Gram-negative and Gram-positive microorganisms.

Immunology

Sales of Simponi (golimumab), a once-monthly subcutaneous treatment for certain inflammatory diseases (marketed by the Company in Europe, Russia and Turkey), were $210 million in the third quarter of 2018, a decline of 4% compared with the third quarter of 2017 including a 1% unfavorable effect from foreign exchange. The sales decline reflects lower pricing, partially offset by higher volumes in Europe. Sales of Simponi were $673 million in the first nine months of 2018, growth of 12% compared with the same period of 2017 including a 7% favorable effect from foreign exchange. Sales growth was driven by volume growth in Europe.

Sales of Remicade, a treatment for inflammatory diseases (marketed by the Company in Europe, Russia and Turkey), were $135 million in the third quarter of 2018 and $459 million in the first nine months of 2018, declines of 37% and 29%, respectively, compared with the same periods of 2017. Foreign exchange unfavorably affected global sales performance by 2% in the third quarter of 2018 and favorably affected global sales performance by 4% in the first nine months of 2018. The Company lost market exclusivity for Remicade in major European markets in 2015 and no longer has market exclusivity in any of its marketing territories. The Company is experiencing pricing and volume declines in these markets as a result of biosimilar competition and expects the declines to continue.

Virology

Global sales of Isentress/Isentress HD (raltegravir), an HIV integrase inhibitor for use in combination with other antiretroviral agents for the treatment of HIV-1 infection, were $275 million in the third quarter of 2018, a decline of 11% compared with the third quarter of 2017 including a 2% unfavorable effect from foreign exchange. Worldwide sales of Isentress/Isentress HD were $860 million in the first nine months of 2018, a decline of 4% compared with the same period of 2017 including a 1% favorable effect from foreign exchange. The sales declines were driven primarily by lower demand in the United States and competitive pricing pressure and lower volumes in Europe.

In August 2018, the FDA approved two new HIV-1 medicines: Delstrigo, a once-daily fixed-dose combination tablet of doravirine, lamivudine and tenofovir disoproxil fumarate; and Pifeltro (doravirine), a new non-nucleoside reverse transcriptase inhibitor to be administered in combination with other antiretroviral medicines. Both Delstrigo and Pifeltro are indicated for the treatment of HIV-1 infection in adult patients with no prior antiretroviral treatment experience. In September 2018, the Committee for Medicinal Products for Human Use (CHMP) of the EMA adopted a positive opinion recommending granting of marketing authorization for Delstrigo and Pifeltro. These two recommendations will now be reviewed by the European Commission (EC) for marketing authorization in the EU.

Global sales of Zepatier, a treatment for adult patients with certain types of chronic HCV infection, were $104 million in the third quarter of 2018 and $347 million in the first nine months of 2018, declines of 78% and 75%, respectively, compared with the same periods of 2017. Foreign exchange unfavorably affected global sales performance by 1% in the third quarter of 2018 and favorably affected global sales performance by 1% in the first nine months of 2018. The sales declines were driven primarily by the unfavorable effects of increasing competition and declining patient volumes, particularly in the United States, Europe and Japan. The Company anticipates that sales of Zepatier in the future will continue to be materially adversely affected by competition and lower patient volumes.

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 $353 million in the third quarter of 2018, a decline of 34% compared with the third quarter of 2017 including a 1% unfavorable effect from foreign exchange. The sales decline in the third quarter was driven primarily by lower sales in Europe, as well as in the United States. The Company lost market exclusivity in major European markets for Ezetrol in April 2018 and has also lost market exclusivity in certain European markets for Inegy (see Note 9 to the condensed consolidated financial statements). Accordingly, the Company is experiencing sales declines in these markets as a result of generic competition and expects the declines to continue. In addition, Zetia and Vytorin lost market exclusivity in the United States in December 2016 and April 2017, respectively. Accordingly, the

Company experienced a rapid and substantial decline in U.S. Zetia and Vytorin sales as a result of generic competition and has lost nearly all U.S. sales of these products. Combined global sales of the ezetimibe family were $1.4 billion in the first nine months of 2018, a decline of 21% compared with the same period of 2017 including a 4% favorable effect from foreign exchange. The sales decline primarily reflects lower volumes and pricing of Zetia and Vytorin in the United States, as well as in certain European markets as a result of generic competition. These declines were partially offset by higher sales in Japan due in part to the launch of Atozet.

Pursuant to a collaboration with Bayer AG (Bayer) (see Note 4 to the condensed consolidated financial statements), Merck has lead commercial rights for Adempas (riociguat), a cardiovascular drug for the treatment of pulmonary arterial hypertension, in countries outside the Americas while Bayer has lead rights in the Americas, including the United States. The companies share profits equally under the collaboration. In 2016, Merck began promoting and distributing Adempas in Europe. Transition from Bayer in other Merck territories, including Japan, continued in 2017. Revenue from Adempas includes sales in Merck's marketing territories, as well as Merck's share of profits from the sale of Adempas in Bayer's marketing territories. Merck recorded sales related to Adempas of $94 million in the third quarter of 2018, an increase of 35% compared with the third quarter of 2017. Sales growth in the third quarter reflects higher sales in Merck's marketing territories and higher profit sharing from Bayer. Merck recorded sales related to Adempas of $238 million in the first nine months of 2018, growth of 7% compared with the same period of 2017 including a 3% favorable effect from foreign exchange. Sales growth in the first nine months of 2018 reflects higher sales in Merck's marketing territories, partially offset by lower profit sharing from Bayer, due in part to lower pricing in the United States.

Diabetes

Worldwide combined sales of Januvia (sitagliptin) and Janumet (sitagliptin/metformin HCl), medicines that help lower blood sugar levels in adults with type 2 diabetes, were $1.5 billion in the third quarter of 2018, a decline of 2% compared with the third quarter of 2017 including a 1% unfavorable effect from foreign exchange. Global combined sales of Januvia and Janumet were $4.4 billion in the first nine months of 2018, essentially flat compared with the same period of 2017 excluding a 2% favorable effect from foreign exchange. Sales performance in both periods reflects continued pricing pressure, particularly in the United States, partially offset by higher demand globally. The Company expects pricing pressure to continue.

Women's Health

Worldwide sales of NuvaRing (etonogestrel/ethinyl estradiol vaginal ring), a vaginal contraceptive product, were $234 million in the third quarter of 2018 and $686 million in the first nine months of 2018, increases of 9% and 20%, respectively, compared with the same periods of 2017. Foreign exchange unfavorably affected global sales performance by 1% in the third quarter of 2018 and favorably affected global sales performance by 1% in first nine months of 2018. Sales growth in both periods was driven primarily by higher pricing in the United States. 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

Animal Health includes pharmaceutical and vaccine products for the prevention, treatment and control of disease in all major farm and companion animal species. The Animal Health segment met the criteria for separate reporting and became a reportable segment in the first quarter of 2018. Animal Health sales are affected by competition and the frequent introduction of generic products. Global sales of Animal Health products totaled $1.0 billion for the third quarter of 2018, an increase of 2% compared with the third quarter of 2017 including a 4% unfavorable effect from foreign exchange. Worldwide sales of Animal Health products totaled $3.2 billion for the first nine months of 2018, an increase of 10% compared with the same period of 2017 including a 2% favorable effect from foreign exchange. Sales growth in both periods was driven by higher sales of companion animal products, primarily the Bravecto (fluralaner) line of products that kill fleas and ticks in dogs and cats for up to 12 weeks, due in part to the timing of customer purchases and a delayed flea and tick season, as well as higher sales of livestock products, including ruminant and poultry products.

Costs, Expenses and Other

Materials and Production

Materials and production costs were $3.6 billion for the third quarter of 2018, an increase of 9% compared with the third quarter of 2017 and were $10.2 billion for the first nine months of 2018, an increase of 8% compared with the same period of 2017. Costs in the third quarter and first nine months of 2018 include a $420 million aggregate charge related to the termination of a collaboration agreement with Samsung Bioepis Co., Ltd. (Samsung) (see Note 3 to the condensed consolidated financial statements). Additionally, costs in the third quarter of 2018 and 2017 include $679

million and $765 million, respectively, and for the first nine months of 2018 and 2017 include $2.1 billion and $2.3 billion, respectively, of expenses for the amortization of intangible assets recorded in connection with business acquisitions. Also, in the first nine months of 2018, the Company recorded $135 million of cumulative amortization expense for amounts capitalized in connection with the recognition of liabilities for potential future milestone payments related to collaborations (see Note 4 to the condensed consolidated financial statements). In addition, costs in the first nine months of 2017 include $123 million of intangible asset impairment charges, including $47 million related to a marketed product (see Note 8 to the condensed consolidated financial statements) and $76 million related to a licensing agreement. 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. Also included in materials and production costs are expenses associated with restructuring activities which amounted to $2 million and

$25 million in the third quarter of 2018 and 2017, respectively, and $11 million and $121 million for the first nine months of 2018 and 2017, 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 66.5% in the third quarter of 2018 compared with 68.0% in the third quarter of 2017 and was 67.3% for the first nine months of 2018 compared with 68.1% in the first nine months of 2017. The declines in gross margin primarily reflect an aggregate charge recorded in conjunction with the termination of a collaboration agreement with Samsung as noted above. The gross margin decline in the year-to-date period also reflects cumulative amortization expense for potential future milestone payments related to collaborations also as noted above. The gross margin declines were partially offset by the favorable effects of foreign exchange and the amortization of unfavorable manufacturing variances recorded in the third quarter of 2017, resulting in part from the June 2017 cyber-attack. The gross margin declines in both periods were also partially offset by lower net impacts from the amortization of intangible assets related to business acquisitions, intangible asset impairment charges and restructuring costs as noted above, which unfavorably affected gross margin by 6.3 percentage points in the third quarter of 2018 compared with 7.7 percentage points in the third quarter of 2017 and by 6.9 percentage points in the first nine months of 2018 compared with 8.7 percentage points in the first nine months of 2017.

Marketing and Administrative

Marketing and administrative (M&A) expenses were $2.4 billion in the third quarter of 2018, a decline of 1% compared with the third quarter of 2017, reflecting lower selling and promotional costs and the favorable effects of foreign exchange, partially offset by higher administrative costs. M&A expenses were $7.5 billion for the first nine months of 2018, up slightly compared with the same period of 2017. The increase primarily reflects higher administrative costs and the unfavorable effects of foreign exchange, offset by lower promotional and selling expenses.

Research and Development

Research and development (R&D) expenses were $2.1 billion for the third quarter of 2018, a decline of 53% compared with the third quarter of 2017. The decline primarily reflects an aggregate charge recorded in third quarter of 2017 related to the formation of an oncology collaboration with AstraZeneca and lower in-process research and development (IPR&D) impairment charges, partially offset by increased clinical development spending, in particular for oncology, higher licensing costs and investment in discovery and early drug development. R&D expenses were $7.5 billion for the first nine months of 2018, a decline of 6% compared with the same period of 2017. The decline primarily reflects an aggregate charge recorded in the first nine months of 2017 related to the formation of an oncology collaboration with AstraZeneca and lower IPR&D impairment charges, partially offset by an aggregate charge in the first nine months of 2018 related to the formation of an oncology collaboration with Eisai, a charge for the acquisition of Viralytics, as well as higher clinical development spending and investment in discovery 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 $1.3 billion and $1.1 billion in the third quarter of 2018 and 2017, respectively, and were $3.7 billion and $3.4 billion for the first nine months of 2018 and 2017, respectively. Also included in R&D expenses are costs incurred by other divisions in support of R&D activities, including depreciation, production and general and administrative, as well as licensing activity, and certain costs from operating segments, including the Pharmaceutical and Animal Health segments, which in the aggregate were approximately $775 million and $670 million for the third quarter of 2018 and 2017, respectively, and were $2.1 billion and $2.0 billion for the first nine months of 2018 and 2017, respectively. Additionally, R&D expenses in the first nine months of 2018 include a $1.4 billion aggregate charge related to the formation of an oncology collaboration with Eisai (see Note 4 to the condensed consolidated financial statements), as well as a $344 million charge for the acquisition of Viralytics (see Note 3 to the condensed consolidated financial statements). R&D expenses in the third quarter and first nine months of 2017 include a $2.35 billion aggregate charge related to the formation of an oncology collaboration with AstraZeneca (see Note 4 to the condensed consolidated

financial statements). R&D expenses also include IPR&D impairment charges of $245 million and $253 million for the third quarter and first nine months of 2017, respectively (see Note 8 to the condensed consolidated financial statements). The Company may recognize additional non-cash impairment charges in the future related to the cancellation or delay of other pipeline programs that were measured at fair value and capitalized in connection with business acquisitions and such charges could be material.

Restructuring Costs

In 2010 and 2013, the Company commenced actions under global restructuring programs designed to streamline its cost structure. The actions under these programs include the elimination of positions in sales, administrative and headquarters organizations, as well as the sale or closure of certain manufacturing and research and development sites and the consolidation of office facilities. The Company also continues to reduce its global real estate footprint and improve the efficiency of its manufacturing and supply network.

Restructuring costs, primarily representing separation and other related costs associated with these restructuring activities, were $171 million and $153 million for the third quarter of 2018 and 2017, respectively, and were $494 million and $470 million for the first nine months of 2018 and 2017, 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. Merck eliminated approximately 525 positions and 205 positions in the third quarter of 2018 and 2017, respectively, and 1,870 positions and 1,225 positions in the first nine months of 2018 and 2017, respectively, related to these restructuring activities. 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 Materials and production, Marketing and administrative and Research and development. The Company recorded aggregate pretax costs of $169 million and $180 million in the third quarter of 2018 and 2017, respectively, and $508 million and $605 million for the first nine months of 2018 and 2017, respectively, related to restructuring program activities (see Note 5 to the condensed consolidated financial statements). While the Company has substantially completed the actions under the programs, approximately $50 million of additional pretax costs are expected to be incurred in the fourth quarter of 2018 relating to anticipated employee separations and remaining asset-related costs.

Other (Income) Expense, Net

Other (income) expense, net was $172 million of income in the third quarter of 2018 compared with $207 million of income in the third quarter of 2017 and was $512 million of income for the first nine months of 2018 compared with $351 million of income for the first nine months of 2017. 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)	2018	2017	2018	2017
Pharmaceutical segment profits	$6,479	$5,906	$18,109	$16,657
Animal Health segment profits	409	389	1,273	1,202
Other non-reportable segment profits	5	93	94	234
Other	(4,228)	(6,188)	(13,379)	(13,451)
Income before taxes	$2,665	$200	$6,097	$4,642

Pharmaceutical segment profits are comprised of segment sales less standard costs, as well as marketing and administrative expenses and research and development costs directly incurred by the segment. Animal Health segment profits are comprised of segment sales, less all materials and production costs, as well as marketing 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 materials and production costs 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 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, restructuring costs, and a portion of equity income. 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. In the first quarter of 2018, the

Company adopted a new accounting standard related to the classification of certain defined benefit plan costs, which resulted in a change to the measurement of segment profits (see Note 17 to the condensed consolidated financial statements). Prior period amounts have been recast to conform to the new presentation.

Pharmaceutical segment profits grew 10% in the third quarter of 2018 and 9% in the first nine months of 2018 compared with the corresponding prior year periods driven primarily by higher sales and lower selling and promotional costs. Animal Health segment profits grew 5% in the third quarter of 2018 and 6% in the first nine months of 2018 compared to the corresponding prior year periods driven primarily by higher sales, partially offset by increased selling and promotional costs.

Taxes on Income

The effective income tax rates of 26.5% and 125.5% for the third quarter of 2018 and 2017, respectively, and 27.6% and 25.5% for the first nine months of 2018 and 2017, respectively, reflect the impacts of acquisition and divestiture-related costs and restructuring costs, partially offset by the beneficial impact of foreign earnings. In addition, the effective income tax rates for the third quarter and first nine months of 2018 reflect the unfavorable impact of a $420 million aggregate pretax charge related to the termination of a collaboration agreement with Samsung for which no tax benefit was recognized. The effective income tax rate for the first nine months of 2018 also reflects the unfavorable impact of a $1.4 billion aggregate pretax charge recorded in connection with the formation of an oncology collaboration with Eisai for which no tax benefit was recognized. In addition, the effective income tax rates for the third quarter and first nine months of 2017 reflect the unfavorable impact of a $2.35 billion aggregate pretax charge recorded in connection with the formation of an oncology collaboration with AstraZeneca for which no tax benefit was recognized, partially offset by the favorable impact of a net tax benefit of $234 million related to the settlement of certain federal income tax issues (discussed below). The effective income tax rate for the first nine months of 2017 also reflects a benefit of $88 million related to the settlement of a state income tax issue.

In the third quarter of 2017, the Internal Revenue Service (IRS) concluded its examinations of Merck's 2006-2011 U.S. federal income tax returns. As a result, the Company was required to make a payment of approximately $2.8 billion. 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 net $234 million tax benefit in the third quarter of 2017. 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, as well as adjustments to reserves for unrecognized tax benefits relating to years which remain open to examination that are affected by this settlement.

Net Income (Loss) and Earnings (Loss) per Common Share

Net income (loss) attributable to Merck & Co., Inc. was $2.0 billion for the third quarter of 2018 compared with $(56) million for the third quarter of 2017 and was $4.4 billion for the first nine months of 2018 compared with $3.4 billion for the first nine months of 2017. Earnings (loss) per common share assuming dilution attributable to Merck & Co., Inc. common shareholders (EPS) for the third quarter of 2018 were $0.73 compared with $(0.02) in the third quarter of 2017 and were $1.63 for the first nine months of 2018 compared with $1.25 for the first nine months of 2017.

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)	2018	2017	2018	2017
Income before taxes as reported under GAAP	$2,665	$200	$6,097	$4,642
Increase (decrease) for excluded items:				
Acquisition and divestiture-related costs	677	1,032	2,265	2,797
Restructuring costs	169	180	508	605
Other items:				
Aggregate charge related to the termination of a collaboration with Samsung	420	—	420	—
Aggregate charge related to the formation of a collaboration with Eisai	—	—	1,400	—
Charge for the acquisition of Viralytics	—	—	344	—
Aggregate charge related to the formation of a collaboration with AstraZeneca	—	2,350	—	2,350
Other	—	—	(54)	(9)
Non-GAAP income before taxes	3,931	3,762	10,980	10,385
Taxes on income as reported under GAAP	707	251	1,682	1,186
Estimated tax benefit on excluded items [1]	38	218	400	593
Net tax benefit related to the settlement of certain federal income tax issues	—	234	—	234
Tax benefit related to the settlement of state income tax issue	—	—	—	88
Non-GAAP taxes on income	745	703	2,082	2,101
Non-GAAP net income	3,186	3,059	8,898	8,284
Less: Net income attributable to noncontrolling interests	8	5	22	16
Non-GAAP net income attributable to Merck & Co., Inc.	$3,178	$3,054	$8,876	$8,268
EPS assuming dilution as reported under GAAP	$0.73	$(0.02)	$1.63	$1.25
EPS difference [2]	0.46	1.13	1.66	1.75
Non-GAAP EPS assuming dilution	$1.19	$1.11	$3.29	$3.00

[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 5 to the condensed consolidated financial statements). These amounts include employee separation costs and accelerated depreciation associated with facilities to be closed or divested. Accelerated depreciation costs represent the difference between the depreciation expense to be recognized over the revised useful life of the asset, based upon the anticipated date the site will be closed or divested or the equipment disposed of, and depreciation expense as determined utilizing the useful life prior to the restructuring actions. Restructuring costs also include asset abandonment, 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 2018 is an aggregate charge related to the termination of a collaboration agreement with Samsung for insulin glargine (see Note 3 to the condensed consolidated financial statements), a charge for the acquisition of Viralytics (see Note 3 to the condensed consolidated financial statements) and an aggregate charge related to the formation of a collaboration with Eisai (see Note 4 to the condensed consolidated financial statements). Excluded from non-GAAP income and non-GAAP EPS in 2017 is an aggregate charge related to the formation of a collaboration with AstraZeneca (see Note 4 to the condensed

consolidated financial statements), as well as a net tax benefit related to the settlement of certain federal income tax issues and a tax benefit related to the settlement of a state income tax issue (see Note 14 to the condensed consolidated financial statements).

Research and Development Update

Keytruda is an FDA-approved anti-PD-1 therapy in clinical development for expanded indications in different cancer types.

In October 2018, the FDA approved Keytruda in combination with carboplatin-paclitaxel or nab-paclitaxel as a first-line treatment for metastatic squamous NSCLC, regardless of PD-L1 expression. This approval was based on data from the Phase 3 KEYNOTE-407 trial, which were presented at the American Society of Clinical Oncology (ASCO) 2018 Annual Meeting. Keytruda is under review for this indication in the EU.

In September 2018, the FDA accepted and granted Priority Review for a supplemental Biologics License Application (sBLA) seeking approval for Keytruda as monotherapy for first-line treatment of locally advanced or metastatic nonsquamous or squamous NSCLC in patients whose tumors express PD-L1 (TPS ≥1%)
without EGFR or ALK genomic tumor aberrations. The application is based on data from the pivotal Phase 3 KEYNOTE-042 trial. Data from the trial were presented at the ASCO 2018 Annual Meeting. The FDA set a Prescription Drug User Fee Act (PDUFA) date of January 11, 2019.

Also in July 2018, the FDA accepted and granted Priority Review for an sBLA seeking approval for Keytruda for previously treated patients with advanced hepatocellular carcinoma. This sBLA, which is seeking accelerated approval for this new indication, is based on data from the Phase 2 KEYNOTE-224 trial, which were presented at the ASCO 2018 Annual Meeting and published simultaneously in The Lancet Oncology. The FDA set a PDUFA date of November 9, 2018.

Also, in September 2018, the FDA accepted and granted Priority Review for an sBLA seeking accelerated approval for Keytruda for the treatment of adult and pediatric patients with recurrent locally advanced or metastatic Merkel cell carcinoma, a rare form of skin cancer. This sBLA is based on data from the Phase 2 KEYNOTE-017 trial including overall response rate and duration of response; these data were presented at the ASCO 2018 Annual Meeting. The FDA set a PDUFA date of December 28, 2018.

In June 2018, the FDA accepted for standard review an sBLA for Keytruda as adjuvant therapy in the treatment of patients with resected, high-risk stage III melanoma and granted a PDUFA date of February 16, 2019. This sBLA is based on a significant benefit in recurrence-free survival demonstrated by Keytruda in the pivotal Phase 3 EORTC1325/KEYNOTE-054 trial, which was conducted in collaboration with the European Organisation for Research and Treatment of Cancer (EORTC). These data were presented at the American Association of Cancer Research 2018 Annual Meeting and published in The New England Journal of Medicine. In October 2018, the CHMP of the EMA adopted a positive opinion recommending approval of Keytruda as adjuvant therapy in the treatment of patients with melanoma with lymph node involvement who have undergone complete surgical resection based on data from the EORTC1325/KEYNOTE-054 trial. The CHMP's recommendation will now be reviewed by the EC for marketing authorization in EU. A final decision is expected in the fourth quarter of 2018.

In addition, Keytruda has received Breakthrough Therapy designation from the FDA in combination with axitnib as a first-line treatment for patients with advanced or metastatic renal cell carcinoma; and for the treatment of high-risk early-stage triple-negative breast cancer in combination with neoadjuvant chemotherapy. Also, the FDA granted Breakthrough Therapy designation for Keytruda in combination with Lenvima for the potential treatment of patients with advanced and/or metastatic renal cell carcinoma and for the potential treatment of certain patients with advanced and/or metastatic non-microsatellite instability high/proficient mismatch repair endometrial carcinoma. The Lenvima and Keytruda combination therapy is being jointly developed by Merck and Eisai. The FDA's Breakthrough Therapy designation is intended to expedite the development and review of a candidate that is planned for use, alone or in combination, to treat a serious or life-threatening disease or condition when preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints.

In October 2018, Merck announced the first presentation of interim data from the pivotal Phase 3 KEYNOTE-048 trial investigating Keytruda, as both monotherapy and in combination with chemotherapy, for the first-line treatment of recurrent or metastatic HNSCC. These interim results were presented at the ESMO 2018 Congress. Interim data from KEYNOTE-048 showed Keytruda monotherapy improved overall survival (OS), a primary endpoint of the study, by 39% in patients whose tumors expressed PD-L1 with Combined Positive Score (CPS) ≥20, and by 22% in patients with CPS≥1, compared to the EXTREME regimen (cetuximab with carboplatin or cisplatin plus 5-fluorouracil (5-FU), the current standard of care. In addition, Keytruda in combination with chemotherapy (carboplatin or cisplatin plus 5-FU) (Keytruda combination) demonstrated improved OS compared to the EXTREME regimen by 23%, regardless of PD-L1 expression. At the final analysis, superiority for OS will be evaluated for Keytruda monotherapy in the total population and Keytruda combination in patients whose tumors express PD-L1 at CPS≥20 and CPS≥1; at this interim analysis, based upon the prespecified testing algorithm, non-inferiority for Keytruda monotherapy in the total population was demonstrated and statistical significance was not achieved for the Keytruda combination in the subset of patients whose tumors expressed PD-L1 at CPS ≥20 or ≥1. Additionally, at this time point there was no difference in progression-

free survival (PFS), a dual primary endpoint of the study, in any of the groups studied. Merck plans to file an sBLA with the FDA for a first-line indication based on KEYNOTE-048 data and will include data from the Phase 3 KEYNOTE-040 trial as supportive data. Based on these results, Merck has withdrawn the sBLA for KEYNOTE-040 for Keytruda as a second-line treatment in patients with recurrent or metastatic HNSCC. The results from KEYNOTE-048 will also be submitted to regulatory authorities worldwide.

In October 2018, Merck announced that the pivotal Phase 3 KEYNOTE-426 trial investigating Keytruda in combination with Inlyta (axitinib), Pfizer's tyrosine kinase inhibitor, met both primary endpoints of OS and PFS in the first-line treatment of advanced or metastatic renal cell carcinoma (RCC), the most common type of kidney cancer. Based on the first interim analysis by the independent Data Monitoring Committee, the Keytruda plus Inlyta combination resulted in statistically significant and clinically meaningful improvements in OS and PFS, compared to sunitinib monotherapy. These results will be presented at an upcoming medical meeting and submitted to regulatory authorities worldwide.

In October 2018, Merck announced the first presentation of results from an interim analysis of KEYNOTE-057, a Phase 2 trial evaluating Keytruda for previously treated patients with high-risk non-muscle invasive bladder cancer. An interim analysis of the study's primary endpoint showed a complete response rate of nearly 40% at three months with Keytruda in patients whose disease was unresponsive to Bacillus Calmette-Guérin therapy, the current standard of care for this disease, and who were ineligible for or who refused to undergo radical cystectomy. These results, as well as other study findings, were presented at the ESMO 2018 Congress.

The Keytruda clinical development program consists of more than 850 clinical trials, including more than 500 trials that combine Keytruda with other cancer treatments. These studies encompass more than 30 cancer types including: bladder, colorectal, esophageal, gastric, HNSCC, hepatocellular, Hodgkin lymphoma, non-Hodgkin lymphoma, melanoma, mesothelioma, nasopharyngeal, NSCLC, ovarian, PMBCL, prostate, renal, small-cell lung cancer and triple-negative breast, many of which are currently in Phase 3 clinical development. Further trials are being planned for other cancers.

In April 2018, Merck and AstraZeneca announced that the EMA validated for review the Marketing Authorization Application for Lynparza for use in patients with deleterious or suspected deleterious BRCA-mutated, HER2-negative metastatic breast cancer who have been previously treated with chemotherapy in the neoadjuvant, adjuvant or metastatic setting. This is the first regulatory submission for a PARP inhibitor in breast cancer in Europe.

In October 2018, Merck and AstraZeneca announced results from the Phase 3 SOLO-1 trial testing Lynparza as a maintenance treatment for patients with newly-diagnosed advanced BRCA-mutated ovarian cancer who were in complete or partial response following first-line standard platinum-based chemotherapy. Results of the trial confirm the statistically-significant and clinically-meaningful improvement in PFS for Lynparza as compared to placebo, reducing the risk of disease progression or death by 70%. The data were presented at the ESMO 2018 Congress and published simultaneously online in The New England Journal of Medicine.

As noted above, in March 2018, Merck and Eisai announced a strategic collaboration for the worldwide co-development and co-commercialization of Lenvima (see Note 4 to the condensed consolidated financial statements). Under the agreement, Merck and Eisai will develop and commercialize Lenvima jointly, both as monotherapy and in combination with Keytruda. Per the agreement, the companies will jointly initiate clinical studies evaluating the Lenvima/Keytruda combination to support 11 potential indications in six types of cancer (endometrial cancer, NSCLC, hepatocellular carcinoma, head and neck cancer, bladder cancer and melanoma), as well as a basket trial targeting multiple cancer types.

In September 2018, the CHMP of the EMA adopted a positive opinion recommending granting of marketing authorization for MK-1439A, Delstrigo, a once-daily fixed-dose combination tablet of doravirine, lamivudine and tenofovir disoproxil fumarate; and MK-1439, Pifeltro (doravirine), a new non-nucleoside reverse transcriptase inhibitor to be administered in combination with other antiretroviral medicines. These two recommendations will now be reviewed by the EC for marketing authorization in the EU. Delstrigo and Pifeltro were approved by the FDA in August 2018.

In April 2018, Merck announced that a pivotal Phase 3 study of relebactam, the Company's investigational beta-lactamase inhibitor, in combination with imipenem/cilastatin (MK-7655A), demonstrated a favorable overall response in the treatment of certain imipenem-non-susceptible bacterial infections, the primary endpoint, with lower treatment-emergent nephrotoxicity (kidney toxicity), a secondary endpoint, compared to a Colistin (colistimethate sodium) plus imipenem regimen. Based on these results, the Company plans to submit a New Drug Application to the FDA seeking regulatory approval of a fixed-dose combination of imipenem/cilastatin and relebactam.

In June 2018, Merck began the first Phase 3 study of V114, its investigational polyvalent conjugate vaccine for the prevention of pneumococcal disease, which will evaluate the safety, tolerability and immunogenicity of V114 followed by Pneumococcal Vaccine Polyvalent one year later in healthy adult subjects 50 years of age or older. Two additional Phase 3 studies started in July 2018. One will evaluate the safety, tolerability and immunogenicity of V114 followed by Pneumococcal Vaccine Polyvalent administered eight weeks later in adults infected with HIV, and the other will evaluate the safety, tolerability, and

immunogenicity of V114 in adults ages 18 to 49 at increased risk for pneumococcal disease. In September 2018, two additional adult Phase 3 studies started. One will evaluate the safety, tolerability, and immunogenicity of V114 when administered concomitantly with influenza vaccine in healthy adults 50 years of age or older, and the other will evaluate the safety, tolerability, and immunogenicity of V114 in recipients of allogeneic hematopoietic stem cell transplant. In October 2018, Merck began the first Phase 3 study of V114 in healthy infants to evaluate the safety and tolerability of V114 and Prevnar 13.

V920 is an investigational rVSV-ZEBOV (Ebola) vaccine candidate being studied in large scale Phase 2/3 clinical trials. In November 2014, Merck and NewLink Genetics announced an exclusive licensing and collaboration agreement for the investigational Ebola vaccine. In December 2015, Merck announced that the application for Emergency Use Assessment and Listing (EUAL) for V920 was accepted for review by the World Health Organization (WHO). According to the WHO, the EUAL process is designed to expedite the availability of vaccines needed for public health emergencies such as another outbreak of Ebola. The WHO decision to grant V920 EUAL status will be based on data regarding quality, safety, and efficacy/effectiveness; as well as a risk/benefit analysis for emergency use. While EUAL designation allows for emergency use, the vaccine remains investigational and has not yet been licensed for commercial distribution. In July 2016, Merck announced that the FDA granted V920 Breakthrough Therapy designation, and that the EMA granted the vaccine candidate PRIME (PRIority MEdicines) status. The Company intends to file the V920 Ebola vaccine with the FDA and EMA in 2019.

The chart below reflects the Company's research pipeline as of November 1, 2018. 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 oncology) 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	Bacterial Infection	New Molecular Entities/Vaccines
MK-3475 Keytruda	MK-7655A	HIV-1 Infection
Advanced Solid	(relebactam+imipenem/cilastatin)	MK-1439 (doravirine) (EU)
Tumors	(October 2015)	MK-1439A (doravirine/lamivudine/tenofovir disoproxil
Cutaneous	Cancer	fumarate) (EU)
Squamous Cell	MK-3475 Keytruda	Pediatric Hexavalent Combination Vaccine
Carcinoma	Breast (October 2015)	V419 (U.S.)[1][5]
Ovarian	Colorectal (November 2015)	
Prostate	Esophageal (December 2015)	
MK-7902	Gastric (May 2015) (EU)	Certain Supplemental Filings
Lenvima[1]	Hepatocellular (May 2016) (EU)	Cancer
Biliary Tract	Mesothelioma (May 2018)	MK-3475 Keytruda
Non-Small-Cell	Nasopharyngeal (April 2016)	• First-Line Metastatic Squamous Non-Small-Cell Lung
Lung	Renal (October 2016)	Cancer KEYNOTE-407 (EU)
V937 Cavatak	Small-Cell Lung (May 2017)	• First-Line Metastatic Nonsquamous or Squamous Non-
Melanoma	MK-7339 Lynparza[1]	Small-Cell Lung Cancer KEYNOTE-042 (U.S.) (EU)
MK-7690[2]	Pancreatic (December 2014)	• Second-Line Hepatocellular Carcinoma
Colorectal	Prostate (April 2017)	KEYNOTE-224 (U.S.)
Cytomegalovirus	MK-7902 Lenvima[1]	• First-Line Merkel Cell Carcinoma KEYNOTE-017 (U.S.)
V160	Endometrial (June 2018)[2]	• Adjuvant Therapy in Advanced Melanoma
Diabetes Mellitus	Cough	KEYNOTE-054 (U.S.) (EU)
MK-8521[3]	MK-7264 (gefapixant) (March	
HIV-1 Infection	2018)	MK-7339 Lynparza[1]

MK-8591	Ebola Vaccine	• Second-Line Metastatic Breast Cancer (EU)
Pediatric	V920 (March 2015)	
Neurofibromatosis	Heart Failure	
Type 1	MK-1242 (vericiguat) (September	
MK-5618	2016)[1]	Footnotes:
(selumetinib)[1][4]	Herpes Zoster	[1] Being developed in a collaboration.
Schizophrenia	V212 (inactivated VZV vaccine)	[2] Being developed in combination with Keytruda.
MK-8189	(December 2010)[3]	[3] Development is currently on hold.
Respiratory	Pneumoconjugate Vaccine	[4] This is a registrational study.
Syncytial Virus	V114 (June 2018)	[5] V419 is an investigational pediatric hexavalent
MK-1654		combination vaccine, DTaP5-IPV-Hib-HepB, that is being developed and, if approved, will be commercialized through a partnership of Merck and Sanofi. In November 2015, the FDA issued a CRL with respect to V419. Merck and Sanofi provided a response to the CRL, which was deemed complete and acceptable for review.

Liquidity and Capital Resources

($ in millions)	September 30, 2018	December 31, 2017
Cash and investments	$17,891	$20,623
Working capital	8,250	6,152
Total debt to total liabilities and equity	27.7 %	27.8 %

Cash provided by operating activities was $7.3 billion in the first nine months of 2018 compared with $2.4 billion in the first nine months of 2017. Cash provided by operating activities in the first nine months of 2018 reflects $750 million of upfront payments made by the Company related to the formation of a collaboration with Eisai (see Note 4 to the condensed consolidated financial statements). Cash provided by operating activities in the first nine months of 2017 reflects a $2.8 billion payment related to the settlement of certain federal income tax issues (see Note 14 to the condensed consolidated financial statements), a $1.6 billion upfront payment made by the Company related to the formation of a collaboration with AstraZeneca (see Note 4 to the condensed consolidated financial statements), and a $625 million payment made by the Company related to the previously disclosed settlement of worldwide Keytruda patent litigation. Cash provided by operating activities continues to be the Company's primary source of funds to finance operating needs, capital expenditures, treasury stock purchases and dividends paid to shareholders.

Cash provided by investing activities was $2.1 billion in the first nine months of 2018 compared with $2.7 billion in the first nine months of 2017. The decline in cash provided by investing activities was driven primarily by lower proceeds from the sales of securities and other investments and higher capital expenditures, as well as a $350 million milestone payment in 2018 related to a collaboration with Bayer (see Note 4 to the condensed consolidated financial statements), partially offset by lower purchases of securities and other investments.

Cash used in financing activities was $7.6 billion in the first nine months of 2018 compared with $4.2 billion in the first nine months of 2017. The higher use of cash in financing activities was driven primarily by higher payments on debt, higher purchases of treasury stock and payment of contingent consideration related to a prior year business acquisition, partially offset by higher short-term borrowings.

Capital expenditures totaled $1.7 billion and $1.2 billion for the first nine months of 2018 and 2017, respectively. In October 2018, the Company announced it now plans to invest approximately $16 billion on new capital projects, up $4 billion from its prior five-year plan of $12 billion announced in February 2018. The focus of this investment will be to increase manufacturing capacity across Merck's key businesses.

Dividends paid to stockholders were $3.9 billion for both the first nine months of 2018 and 2017. In May 2018, the Board of Directors declared a quarterly dividend of $0.48 per share on the Company's common stock for the third quarter that was paid in July 2018. In July 2018, the Board of Directors declared a quarterly dividend of $0.48 per share on the Company's common stock for the fourth quarter that was paid in October 2018. In October 2018, Merck announced that its Board of Directors approved a 15% increase to the Company's quarterly dividend, raising it to $0.55 per share from $0.48 per share on the Company's outstanding common stock. Payment will be made in January 2019.

In November 2017, Merck's Board of Directors authorized purchases of up to $10 billion of Merck's common stock for its treasury. The treasury stock purchase 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 2018, the Company purchased $3.2 billion (53 million shares) for its treasury under this and a previously authorized share repurchase program. As of September 30, 2018, the Company's remaining share repurchase authorization was $7.9 billion. In October 2018, Merck's Board of Directors authorized an additional $10 billion of treasury stock purchases with no time limit for completion. The Company entered into a $5 billion accelerated share repurchase (ASR) program under its expanded authorization as discussed below.

On October 25, 2018, the Company entered into an ASR agreement with Goldman Sachs & Co. and JP Morgan Chase (Dealers). Under the ASR, 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 current market price, made by the Dealers to Merck, and payment of $5 billion made by Merck to the Dealers on October 29, 2018, which was funded with existing cash and investments, as well as short-term borrowings. The payment to the Dealers will be recorded as a reduction to

shareholders' equity, consisting of a $4 billion increase in treasury stock, which reflects the value of the initial 56.7 million shares received upon execution, and a $1 billion decrease in other-paid-in capital, which reflects the value of the stock held back by the Dealers pending final settlement. The final number of shares of Merck's common stock that Merck may receive, or may be required to remit, upon settlement under the ASR will be based upon the average daily volume weighted-average price of Merck's common stock during the term of the ASR program. Final settlement of the transaction under the ASR agreement is expected to occur in the first half of 2019, and may occur earlier at the option of the Dealers, or later under certain circumstances. The terms of the transaction under the ASR agreement are subject to adjustment if Merck were to enter into or announce certain types of transactions. If Merck is obligated to make an

adjustment payment to the Dealers under the ASR, Merck may elect to satisfy such obligation in cash or in shares of Merck's common stock.

In January 2018, $1.0 billion of 1.10% notes matured in accordance with their terms and were repaid. In May 2018, $1.0 billion of 1.30% notes and $1.0 billion of floating-rate notes matured in accordance with their terms and were repaid.

The Company has a $6.0 billion credit facility that matures in June 2023. The facility provides backup liquidity for the Company's commercial paper borrowing facility and is to be used for general corporate purposes. The Company has not drawn funding from this facility.

In March 2018, the Company filed a securities registration statement with the U.S. Securities and Exchange Commission (SEC) under the automatic shelf registration process available to "well-known seasoned issuers" which is effective for three years.

The economy of Argentina was recently determined to be hyperinflationary; consequently, in accordance with U.S. GAAP, the Company began remeasuring its monetary assets and liabilities for those operations in earnings beginning in the third quarter of 2018. The impact to the Company's results was immaterial.

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, 2017 included in Merck's Form 10 K filed on February 27, 2018. 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, 2017. See Note 1 to the condensed consolidated financial statements for information on the adoption of new accounting standards during 2018.

Recently Issued Accounting Standards

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

Item 4. Controls and Procedures

Management of the Company, with the participation of its Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of the Company's disclosure controls and procedures over financial reporting for the period covered by this Form 10–Q. Based on this assessment, the Company's Chief Executive Officer and Chief Financial Officer have concluded that as of September 30, 2018, the Company's disclosure controls and procedures are effective. For the period covered by this report, there have been no changes in internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

CAUTIONARY FACTORS THAT MAY AFFECT FUTURE RESULTS

This report and other written reports and oral statements made from time to time by the Company may contain so-called "forward-looking statements," all of which are based on management's current expectations and are subject to risks and uncertainties which may cause results to differ materially from those set forth in the statements. One can identify these forward-looking statements by their use of words such as "anticipates," "expects," "plans," "will," "estimates," "forecasts," "projects" and other words of similar meaning, or negative variations of any of the foregoing. One can also identify them by the fact that they do not relate strictly to historical or current facts. These statements are likely to address the Company's growth strategy, financial results, product development, product approvals, product potential and development programs. One must carefully consider any such statement and should understand that many factors could cause actual results to differ materially from the Company's forward-looking statements. These factors include inaccurate assumptions and a broad variety of other risks and uncertainties, including some that are known and some that are not. No forward-looking statement can be guaranteed and actual future results may vary materially.

The Company does not assume the obligation to update any forward-looking statement. One should carefully evaluate such statements in light of factors, including risk factors, described in the Company's filings with the Securities and Exchange Commission, especially on Forms 10-K, 10-Q and 8-K. In Item 1A. "Risk Factors" of the Company's Annual Report on Form 10 K for the year ended December 31, 2017, as filed on February 27, 2018, 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, 2018 were as follows:

ISSUER PURCHASES OF EQUITY SECURITIES

Period	Total Number of Shares Purchased[1]	Average Price Paid Per Share	($ in millions) Approximate Dollar Value of Shares That May Yet Be Purchased Under the Plans or Programs[1]
July 1 - July 31	11,274,234	$62.31	$8,176
August 1 - August 31	2,386,135	$67.30	$8,016
September 1 - September 30	1,901,599	$69.79	$7,883
Total	15,561,968	$63.99	$7,883

(1) Shares purchased during the period were made as part of a plan approved by the Board of Directors in March 2015 to purchase up to $10 billion of Merck's common stock for its treasury. In October 2018, the Board of Directors authorized an additional $10 billion of treasury stock purchases with no time limit for completion. The Company entered into a $5 billion accelerated share repurchase program under its expanded authorization.

Item 6. Exhibits

Number	Description
3.1	Restated Certificate of Incorporation of Merck & Co., Inc. (November 3, 2009) – Incorporated by reference to Current Report on Form 8-K filed on November 4, 2009 (No. 1-6571)
3.2	By-Laws of Merck & Co., Inc. (effective July 22, 2015) – Incorporated by reference to Current Report on Form 8-K filed on July 28, 2015 (No. 1-6571)
31.1	Rule 13a – 14(a)/15d – 14(a) Certification of Chief Executive Officer
31.2	Rule 13a – 14(a)/15d – 14(a) Certification of Chief Financial Officer
32.1	Section 1350 Certification of Chief Executive Officer
32.2	Section 1350 Certification of Chief Financial Officer
101	The following materials from Merck & Co., Inc.'s Quarterly Report on Form 10-Q for the quarter ended September 30, 2018, formatted in XBRL (Extensible Business Reporting Language): (i) the Condensed Consolidated Statement of Income, (ii) the Condensed Consolidated Statement of Comprehensive Income, (iii) the Condensed Consolidated Balance Sheet, (iv) the Condensed Consolidated Statement of Cash Flows, and (v) Notes to the Condensed Consolidated Financial Statements.

Signatures

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

MERCK & CO., INC.

Date: November 6, 2018 /s/ Jennifer Zachary
JENNIFER ZACHARY
Executive Vice President and General Counsel

Date: November 6, 2018 /s/ Rita A. Karachun
RITA A. KARACHUN
Senior Vice President Finance - Global Controller

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	The following materials from Merck & Co., Inc.'s Quarterly Report on Form 10-Q for the quarter ended September 30, 2018, formatted in XBRL (Extensible Business Reporting Language): (i) the Condensed Consolidated Statement of Income, (ii) the Condensed Consolidated Statement of Comprehensive Income, (iii) the Condensed Consolidated Balance Sheet, (iv) the Condensed Consolidated Statement of Cash Flows, and (v) Notes to the Condensed Consolidated Financial Statements.